IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS, AMERICAN COLLEGE OF PHYSICIANS, INC., AMERICAN PUBLIC HEALTH ASSOCIATION, INFECTIOUS DISEASES SOCIETY OF AMERICA, MASSACHUSETTS PUBLIC HEALTH ASSOCIATION D/B/A MASSACHUSETTS PUBLIC HEALTH ALLIANCE, SOCIETY FOR MATERNAL-FETAL MEDICINE, THE MASSACHUSETTS CHAPTER OF THE AMERICAN ACADEMY OF PEDIATRICS, JANE DOE 1, JANE DOE 2, and JANE DOE 3, *Plaintiffs,* vs. ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the Department of Health and Human Services; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; JIM O'NEILL, in his official capacity as Acting Director of Centers for Disease Control and Prevention; CENTERS FOR DISEASE CONTROL AND PREVENTION; and DOES 1–50, inclusive, *Defendants.*	Case No. 1:25-cv-11916-BEM

PLAINTIFFS' MOTION FOR LEAVE TO FILE A FOURTH AMENDED COMPLAINT

Plaintiffs move for leave to file a Fourth Amended Complaint pursuant to Fed. R. Civ. P. 15(a)(2) to address new final agency actions and related conduct taken by Defendants since Plaintiffs' filing of the Third Amended Complaint. On January 5, 2026, two weeks to the day of this request, Defendants arbitrarily—and illegally—revised the existing childhood and adolescent immunization schedule through a "Decision Memorandum" to downgrade six different vaccines

without following the evidentiary-driven, and legally required processes for issuing recommended vaccine schedules in the United States. This drastic overhaul of the childhood vaccine schedule is but one in a series of arbitrary and harmful actions taken by the Defendants since Plaintiffs filed the Third Amended Complaint alleging Defendants violated the Administrative Procedures Act through a series of unlawful agency actions. Recent developments necessitate further amendment to allegations in the Third Amended Complaint.

The Court should exercise its discretion to permit Plaintiffs to file the Fourth Amended Complaint attached as Exhibit 1.

Background

On July 7, 2025, Plaintiffs filed the instant action challenging Defendants' unlawful administrative actions (ECF No. 1). As described below, Defendants' harmful and unlawful conduct upending both the process and recommended childhood and adolescent vaccine schedules in the United States has continued uninterrupted by Plaintiffs' filing this action on July 7, 2025. As they have in this motion, Plaintiffs have thrice amended their claims to incorporate new allegations capturing Defendants' latest violative actions, which have consistently and directly harmed Plaintiffs and the public health and welfare at large.

On May 27, 2025, the Secretary posted a video on the social media platform X in which he ordered the CDC to remove the recommendation of the Covid-19 vaccine for pregnant women and "healthy" children from CDC schedules. That same day, the Secretary released a one-page "SECRETARIAL DIRECTIVE ON PEDIATRIC COVID-19 VACCINES FOR CHILDREN LESS THAN 18 YEARS OF AGE AND PREGNANT WOMEN," backdated May 19, 2025 (the "Directive") repeating the instruction to the CDC that he gave in the video. On June 9, 2025, the Secretary fired all seventeen members of the ACIP for pretextual reasons. Two days after the terminations, on June 11, 2025, the Secretary announced the appointment of eight new members

to the ACIP. The first ACIP meeting with the new members was held on June 25–26, 2025. On July 7, 2025, Plaintiffs filed this lawsuit challenging the Directive and reconstitution of the ACIP (ECF No. 1) and later amended this Complaint as a matter of course under FED. R. CIV. P. 15(a)(1), on July 23, 2025 (ECF No. 63).

On July 31, 2025, an email from acip.cdc.gov was sent to members of ACIP Liaison organizations, which included members of Plaintiffs AAP and ACP, informing them that Liaison organizations were terminated from participating in ACIP workgroups, including the Covid-19 Work Group. On August 20, 2025, Plaintiffs filed a Motion for Leave to File a Second Amended Complaint to reflect the July changes to the ACIP workgroup membership (ECF No. 94). This Motion was allowed on September 3, 2025 (ECF No. 96), and Plaintiffs' Second Amended Complaint was filed that same day (ECF No. 99). Also on September 3, 2025, Defendants filed their Motion to Dismiss for Lack of Jurisdiction (ECF No. 103).

On September 11, 2025, the Secretary announced four more appointments to the ACIP, citing pretextual reasons for the appointments. On September 18–19, 2025, an ACIP meeting was held, and the improperly reconstituted ACIP voted to change the Covid-19 vaccine recommendation for adults from routine to SCDM without applying GRADE criteria or following the EtR framework. This vote codified the May 19 Secretarial Directive without following the standard ACIP policy. Plaintiffs filed their Opposition to Defendants' Motion to Dismiss on September 24, 2025 (ECF No. 118) and the hearing on the Motion to Dismiss was scheduled for October 8, 2025 (ECF No. 113).

On September 30, 2025, the eve of the government shut down, the Court cancelled the hearing on the Motion to Dismiss and the Bench Trial scheduled for October 14, 2025, with the intention of rescheduling them at a later date (ECF No. 119). Defendants filed a Motion for a Stay

on October 1, 2025 (ECF No. 121). Considering the government shut down, Plaintiffs agreed not to oppose the stay. On October 20, 2025, twenty days after Plaintiffs agreed to stay this Matter, the government was still shut down with no indication of when services would resume. With the flu season beginning and Covid-19 cases rising, Plaintiffs filed a Motion to Continue this Case (ECF No. 127). On October 22, this Case was assigned to Your Honor (ECF No. 129). Defendants filed their opposition to Plaintiffs' Motion to Continue on October 29, 2025 (ECF No. 133), and a hearing was held on October 30, 2025 (ECF No. 134).

At the October 30 hearing, the Court ordered the stay lifted in this case and for litigation to continue (ECF No. 134). The Court granted Plaintiffs leave to amend the Second Amended Complaint to include all harms occurring since that Complaint was filed August 2025. Plaintiffs and Defendants agreed on a schedule going forward, requiring the Motion to Dismiss and associated hearing to occur in short order (ECF No. 134).

On November 5, 2025, Plaintiffs filed the Third Amended Complaint with this Court, addressing the harms arising out of the September ACIP appointments and the Covid-19 recommendation change adopted at the September ACIP meeting. On November 19, 2025, Defendants filed their Motion to Dismiss the Third Amended Complaint for Lack of Jurisdiction and Failure to State a Claim (ECF No. 144). Plaintiffs filed their opposition to this motion on December 3, 2025 (ECF No. 146).

On December 4–5, 2025, an ACIP meeting was held, at which the committee voted to change the schedule of the Hepatitis B vaccine and presented the idea of aligning the U.S. Child and Adolescent Immunization Schedule (the "Childhood Schedule") with Denmark's childhood vaccine schedule. The hearing on the Motion to Dismiss was held on December 17, 2025 (ECF No. 164). The Court took the matter under advisement (ECF No. 164). The following day, on

December 18, 2025, CDC experts presented a slide deck on how the Childhood Schedule compares to other developed countries and indicated that an announcement on children's vaccine health would come after January 1, 2026.

On January 5, 2026, the Department of Health and Human Services issued a press release titled "CDC Acts on Presidential Memorandum to Update Childhood Immunization Schedule," which announced that the Childhood Schedule was changing to align with Denmark's childhood vaccine schedule, effective immediately. One day later, on January 6, 2026, Your Honor denied Defendants' Motion to Dismiss (ECF No. 168). On January 13, 2026, HHS and CDC announced the appointment of two more members to the ACIP.

The actions of the Defendants taken throughout this litigation have caused an abundance of harm and created a moving target. The enumerated actions above are escalations of the allegations already pleaded by Plaintiffs in the operative complaints not yet known or come to fruition at the time of Plaintiffs' earlier amendments.

Plaintiffs have been transparent with Defendants and the Court of their intentions to challenge Defendants' recent conduct. Just two days after the CDC issued the January 5 Decision Memo, Plaintiffs' counsel informed counsel for Defendants that Plaintiffs intended to seek leave to file a Fourth Amended Complaint (and injunctive relief) to address the January 5 Decision Memo and preceding actions of Defendants, including the dissemination of inaccurate information at the December 4–5, 2025 ACIP meeting. Through the parties' Joint Status Report (ECF No. 175) and at the status conference held on January 12, 2026, Plaintiffs previewed for the Court their plan to move for leave to amend and presented an agreed-upon briefing schedule to specifically accommodate Plaintiffs' motion for leave and motions for injunctive relief. The Court entered an Order adopting the parties' proposed schedule and set a deadline of January 19, 2026, for this

motion for leave (ECF No. 176).[1] On January 18, 2026, counsel for Plaintiffs sent a draft of the Fourth Amended Complaint to counsel for Defendants for their review. Defendants oppose the filing of a Fourth Amended Complaint.

Argument

Leave to amend is appropriate in this instance. Rule 15(a) embraces a "liberal amendment policy" under which "[t]he court should freely give leave when justice so requires." FED. R. CIV. P. 15(a)(2). District Courts have "significant latitude in deciding whether to grant leave to amend." *U.S. ex rel. Gagne v. City of Worcester*, 565 F.3d 40, 48 (1st Cir. 2009). Indeed, "[l]eave should be freely given absent an apparent or declared reason, such as undue delay, bad faith or dilatory motive on the part of the movant". *Lukas v. United States*, 133 F.Supp.3d 284, 286 (D. Mass. 2015) (citation modified). The analysis whether to grant leave to amend, even for complaints that have already been amended, is case specific. *See Gusakovs v. Johnson & Johnson*, No. 17-cv-11502-DJC, 2023 WL 4053059, at *5 (D. Mass. June 16, 2023) ("There is no delay that is *per se* undue and a district court mulling a motion to amend in a particular case must consider any alleged delay with that case's specific history in mind." (citation modified)).

Far from futile, Plaintiffs move to amend and incorporate recent agency actions, such as the January 5 Decision Memo, which drastically expand the scope of injuries and harm to Plaintiffs of downgrading the childhood and adolescent recommendations for one vaccine (Covid-19) to the consequences of downgrading ***six different*** vaccines.[2] Plaintiffs' amendments also include other recent public actions and statements by the Defendants taken in conjunction with this upending of

[1] On January 12, 2026, the Court ordered Plaintiffs file a motion for leave to file the Fourth Amended Complaint by January 19, 2026; Plaintiffs' motion(s) for preliminary junctive relief by January 26, 2026; and, Defendants' response to that motion and any subsequently filed motions, due by February 9, 2026.

[2] This Court held that Plaintiffs have standing to pursue to the claims set forth in the Third Amended Complaint, which allege Defendants violated the APA. ECF No. 168.

the vaccine schedule and spreading misinformation about vaccine efficacy and safety, including through the December 4–5, 2025 ACIP meeting and other forums. Plaintiffs respectfully submit that justice requires that they can challenge this conduct and litigate these evolving issues in good faith.

Plaintiffs' request is timely. Plaintiffs bring this motion at their earliest opportunity, providing notice to the Defendants of the intention to seek leave just two days after the most recent—and egregious—of the challenged action. Defendants issued the January 5 Decision Memo just two weeks ago. *See Amyndas Pharms, S.A. v. Zealand Pharma A/S*, 48 F.4th 18, 37 (1st Cir. 2022) (explaining that "[a]scertaining whether a delay is 'undue' is not simply a matter of counting days but, rather, depends on the totality of the circumstances in the particular case" (citation modified)). Unlike Defendants, Plaintiffs were unaware of these actions prior to the public announcement. Plaintiffs learned of the statements made in support of the now-implemented, sweeping changes proposed to the Childhood Schedule along with the general public, in December 2025. Those misstatements and sham meetings have now culminated in the January 5 December Memo. The fact that Plaintiffs have thrice amended their complaint only illustrates that the Defendants harm-inducing actions have continued unabated. Plaintiffs have met their burden of showing a valid reason to amend at this juncture in spades. *See Hagerty ex rel United States v. Cyberonics*, 844 F.3d 26, 34 (1st Cit. 2016) (explaining that "[i]n assessing whether a movant has carried this burden, courts must take into account what the plaintiff knew or should have known and what he did or should have done." (citation modified)).

Importantly, granting leave will not unduly prejudice Defendants. Plaintiffs bring this motion promptly after the final agency actions they seek to incorporate and challenge. Amending the complaint allows Plaintiffs to respond to Defendants' latest in its longstanding pattern of

unlawful agency actions and provides a basis to seek immediate injunctive relief. Defendants have long been on notice of Plaintiffs' allegations challenging the Defendants' failure to comply with the APA, including well-before Defendants ratified the January 5 Decision Memo, once again side-stepping the required administrative procedures for issuing vaccine recommendations. Presumably, then, Defendants were aware of the basis for this amendment well before Plaintiffs learned of events. *See Meador v. United States*, No. 22-cv-40024-DJC, 2024 WL 583687 (D. Mass. Feb. 13, 2024) (finding no undue prejudice where defendants had notice of claims at or before the time plaintiffs became aware of them).

Finally, the impact of the January 5 Decision Memo to Plaintiffs and the public at large cannot be overstated. Where this action arises out of the same factual allegations already pleaded in the Third Amended Complaint, Plaintiffs seek leave to amend the operative complaint to move efficiently and expeditiously to adjudicate their claims. While Plaintiffs could in the alternative file a new complaint as a related case, this Circuit favors granting leave to amend to promote judicial economy. *See United States v. Medtronic, Inc.*, 189 F.Supp.3d 259, 266–67 (D. Mass. 2016) (noting judicial economy is an important factor in the balance of pertinent considerations when deciding whether to allow an amended complaint).

Dated: January 19, 2026

Respectfully submitted,

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Attorneys for Plaintiffs

LOCAL RULE 7.1 CERTIFICATE REGARDING PLAINTIFFS' MOTION FOR LEAVE TO FILE THEIR FOURTH AMENDED COMPLAINT

Per Local Rule 7.1, counsel for Plaintiffs state that they conferred with counsel for Defendants via e-mail on January 19, 2026. In that conversation, counsel for Defendants stated that Defendants oppose Plaintiffs' Motion for Leave to File a Fourth Amended Complaint.

/s/ James J. Oh
James J. Oh

CERTIFICATE OF SERVICE

I hereby certify that this document was filed and served through the ECF system upon the following parties on this 19th day of January 2026:

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

Jim O'Neill, in his official capacity as Acting Director of the Centers for Disease Control and Prevention

c/o Issac Belfer
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/s/ James J. Oh
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EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS, AMERICAN COLLEGE OF PHYSICIANS, INC., AMERICAN PUBLIC HEALTH ASSOCIATION, INFECTIOUS DISEASES SOCIETY OF AMERICA, MASSACHUSETTS PUBLIC HEALTH ASSOCIATION D/B/A MASSACHUSETTS PUBLIC HEALTH ALLIANCE, SOCIETY FOR MATERNAL-FETAL MEDICINE, THE MASSACHUSETTS CHAPTER OF THE AMERICAN ACADEMY OF PEDIATRICS, JANE DOE 1, JANE DOE 2, and JANE DOE 3,

Plaintiffs,

vs.

ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the Department of Health and Human Services; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; JIM O'NEILL, in his official capacity as Acting Director of Centers for Disease Control and Prevention; CENTERS FOR DISEASE CONTROL AND PREVENTION; and DOES 1–50, inclusive,

Defendants.

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

FOURTH AMENDED COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

District Judge: Hon. Brian E. Murphy
Magistrate Judge: Hon. M. Page Kelley

INTRODUCTION

1. In this Fourth Amended Complaint, Plaintiffs now challenge four final agency actions, all related to vaccines, that Defendants, Robert F. Kennedy, Jr., Secretary of the United States Department of Health and Human Services (the "Secretary"), and Jim O'Neill, Acting Director of the Centers for Disease Control and Prevention ("O'Neill"), have taken during the Secretary's ten months in office. When taking these four actions, Defendants failed to "examine the relevant data and articulate a satisfactory explanation for [their] action[s]." *Motor Vehicle Mfrs. Ass'n v. State Farm*, 463 U.S. 29, 43 (1983). Accordingly, the Court should hold unlawful and set aside all final agency actions challenged in this action under the Administrative Procedure Act, 5 U.S.C. § 706(2)(A) ("APA"), declare that each final agency action is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" in contravention of the APA, and grant Plaintiffs' requested injunctive relief.

2. The most expansive and far-reaching, and thus the most egregious, reckless, and dangerous of the actions Defendants have taken to date, is the one announced in a "Decision Memo" dated January 5, 2026 (the "January 5 Action") that ordered the alignment of the Centers for Disease Control and Prevention's ("CDC") Recommended Immunization Schedule for Child and Adolescent Ages 18 Years or Younger (the "Childhood Schedule") with that of Denmark's. This action should be set aside, enjoined, and declared unlawful because Defendants failed to consider important factors such as whether the changes to the Childhood Schedule would lead to increases in serious illness and death due to vaccine-preventable illnesses, or increased burden on the American healthcare system, or increased financial burden on American families.

3. The Court should set aside and declare unlawful the Secretary's appointments to the Advisory Committee on Immunization Practices ("ACIP") and enjoin the ACIP as currently

constituted from meeting. Most immediately, Plaintiffs seek to enjoin the next public meeting of the ACIP scheduled for February 25-26, 2026, because of the overabundance of false and misleading misinformation disseminated at the three prior public meetings of the ACIP in June, September, and December, 2025, with December being the worst. The ACIP that conducted those meetings consists entirely of members appointed by the Secretary after he fired *en masse* the 17 prior members of the ACIP on June 9, 2025, for pretextual reasons. The current composition of the ACIP violates the Federal Advisory Committee Act, 5 U.S.C. § 1004(b)(2) ("FACA"), which requires federal advisory committees to be "fairly balanced" and not be "inappropriately influenced."[1] The public meetings of this ACIP have served as a megaphone for spreading misinformation about immunization and infectious diseases that is directly harming the Plaintiffs and the American public. Further, this ACIP should be enjoined from conducting further public meetings.

4. The current ACIP has cast three votes, approved by the CDC, that should be set aside: (a) the December 5, 2025, vote to remove the recommendation that babies receive the hepatitis B vaccine within 24 hours of birth (the "hepatitis B birth dose"); (b) the September 19, 2025, vote to classify the Covid vaccine as "Shared Clinical Decision Making" ("SCDM") for anyone under 65; and (c) the June 26 vote that manufacturers discontinue use of thimerosal as a

[1] Just a few days ago, on January 13, 2026, the Secretary announced the appointment of two new members to the ACIP, both of whom are obstetrician-gynecologists ("OB-GYN"), who have made public statements that align with the Secretary's well-known anti-vaccine views. One of the appointees, an OB-GYN in St. Petersburg, Florida, has publicly stated that: "I was not anti-vaccine. I am now." The other, an OB-GYN in the Boston area, has publicly stated that the "science is not 'long-settled' regarding vaccines" and that there are "too many vaccines." These most recent additions only add to the imbalance of the current ACIP. *See* Lena H. Sun, *New RFK Jr. pick for vaccine panel: 'I was not anti-vaccine. I am now.'*, THE WASH. POST (Jan. 13, 2026), https://www.washingtonpost.com/health/2026/01/13/rfk-jr-acip-appointments-vaccine-criticism/; *see also* Adam Urato, MD (@AdamUrato1), X (June 26, 2025, 3:45 PM), https://x.com/AdamUrato1/status/1938322690185544005?s=20.

preservative in influenza vaccines.

5. The other two final agency actions challenged in this Fourth Amended Complaint (previously asserted in the Third Amended Complaint) are (a) the ACIP's vote at its September 18-19, 2025 public meeting to no longer classify the Covid-19 vaccine for anyone under 65 as routinely recommended, but instead to classify the Covid-19 vaccine as "Shared Clinical Decision Making" ("SCDM") for those under 65; and (b) the Secretarial Directive dated May 19, 2025, and announced in a video posted on X on May 27 (the "May 19 Directive"), in which the Secretary instructed the CDC to remove the routine recommendation that children and pregnant women receive the Covid-19 vaccine from the CDC's immunization schedules.[2] These actions, too, should be set aside and declared unlawful under the APA, and the Court should enjoin Defendants from implementing or effectuating them in any way.

6. Moreover, the final agency actions challenged in this case, taken together, demonstrate that Defendants have engaged in a pattern and practice of changing U.S. vaccine policy without consideration of the relevant factors or providing any reasoned explanation. Accordingly, all of these actions violate the APA and, therefore, must be set aside, declared unlawful, and enjoined.

JURISDICTION AND VENUE

7. The Court has jurisdiction under 28 U.S.C. §§ 1331 and 1346. This Court has further remedial authority under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202 e*t seq*. Pursuant to 5 U.S.C. § 702, sovereign immunity is waived for the United States.

8. Pursuant to 28 U.S.C. § 1391(c) and (e), venue properly lies within the District of Massachusetts.

[2] Plaintiffs initially filed this action on July 7, 2025, to challenge the May 19 Directive.

PARTIES

A. PLAINTIFFS

9. Plaintiff, the American Academy of Pediatrics ("AAP"), is the nation's premier professional organization for pediatric medicine and serves as an independent forum for addressing children's health. The AAP's membership includes 67,000 pediatricians, with members in every state in the country, many of whom are currently providing direct care to infants, children, adolescents, and young adults in both hospital and outpatient settings.

10. Plaintiff, the American College of Physicians, Inc. ("ACP"), is a professional organization comprised of 161,000 internal medicine specialists in every state in the country, related subspecialists, and medical students who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults worldwide. The ACP's mission is to enhance the quality and effectiveness of health care by fostering excellence and professionalism in the practice of medicine.

11. Plaintiff, the American Public Health Association ("APHA"), has promoted the health of all U.S. residents since its founding in 1872. APHA members include more than 23,000 individual public health professional members, state and local health departments, organizations interested in health, and health-related businesses. APHA members work in every discipline of public health, in every state, and in countries across the globe.

12. Plaintiff, the Infectious Diseases Society of America ("IDSA"), is a professional nonprofit society comprised of over 13,000 members in every state in the country, including practicing clinicians, scientists and researchers in the academic setting, public health officials, hospital epidemiologists, and infectious disease specialists working in a variety of settings nationwide. Many IDSA members are currently providing direct care to infants, children, and

pregnant women, in both hospital and outpatient settings. IDSA's mission is to bring together the curiosity, compassion, and knowledge of its members and strengthen the field of infectious diseases, advance science, and advocate for health equity.

13. Plaintiff, the Massachusetts Public Health Association d/b/a Massachusetts Public Health Alliance ("MPHA"), is a nonprofit organization dedicated to advocating for health equity and strong public health systems across the Commonwealth of Massachusetts. MPHA's membership is comprised of both individual and organizational public health leaders, including members of local public health departments, physicians, nurses, community health center leaders, academic public health professionals, nonprofit executives, and other frontline practitioners.

14. Plaintiff, the Society for Maternal-Fetal Medicine ("SMFM"), is a professional organization with members in every state dedicated to advancing optimal and equitable perinatal outcomes for all people who desire or experience pregnancy. SMFM represents the interests of over 6,500 members comprised primarily of maternal-fetal medicine subspecialists, as well as physicians in related disciplines, scientists, nurses, genetic counselors, and ultrasound technicians. At its core, SMFM is committed to leading the evidence-based practice of high-risk pregnancy care to optimize maternal and fetal outcomes and assure medically appropriate treatment options are available to all patients.

15. Plaintiff, the Massachusetts Chapter of the American Academy of Pediatrics ("MCAAP"), is a member organization of over 1,600 pediatricians in Massachusetts who are committed to the attainment of optimal physical, mental, and social health for all Massachusetts infants, children, adolescents, and their families, and to supporting the medical professionals who care for them. The MCAAP is the leading voice for child health advocacy and high-value equitable care for all youth in the Commonwealth of Massachusetts.

16. Plaintiff, Jane Doe 1, is a physician working in a hospital where she puts herself at risk of infectious diseases every day to care for patients and save lives. Jane Doe 1 is also a new mother, having given birth to her first child Baby Doe 1 in October 2025. Although Jane Doe 1 was vaccinated against Covid-19 before becoming pregnant, early in her pregnancy, her doctors advised her to get another dose of the vaccine later in pregnancy to better protect herself and her developing baby from contracting this deadly disease. Pregnancy increases the risk of severe illness and complications from infectious disease, including preterm birth and stillbirth. However, the Directive created barriers to access to the vaccine, which led her obstetrician to advise her to consider getting an older version of the Covid-19 vaccine earlier in her pregnancy in addition to the 2025–2026 Covid-19 vaccine upon reaching 34 weeks gestation. Accordingly, Jane Doe 1 was forced to decide whether to risk getting an old Covid-19 vaccine early, possibly jeopardizing her access to a 2025–2026 vaccine at the optimal timing in her pregnancy, in order to ensure she could pass at least some immunity to Baby Doe 1 during the pregnancy. This decision weighed on Jane Doe 1, causing her headaches, sleep disturbances, and fatigue which negatively impacted her productivity at work.

17. Plaintiff, Jane Doe 2, is also a new mother, having given birth to her first child Baby Doe 2 in October 2025. Jane Doe 2, who lives in Massachusetts, tried to get the Covid-19 vaccine multiple times after the Secretary's announcement on X, but was refused. Even though Jane Doe 2 had a prescription from her obstetrician after the Directive was issued, a pharmacist refused to give her the vaccine because the pharmacist feared losing her license by giving a vaccine contrary to the CDC immunization schedules. A nurse at her obstetrician's office told her that their office's policy was not to give the vaccine with the change federal guidance regarding pregnant women. Jane Doe 2 subsequently tried at another location to get the Covid-19 vaccine but again was refused

because of the Directive. Finally, a chain pharmacy location advised Jane Doe 2 that she could only receive the vaccine if she scheduled an appointment with the pharmacy's "flexible" pharmacist, who would be willing to risk their license to vaccinate her. Even then, the pharmacy required Jane Doe 2 to sign an attestation stating: "If I am receiving a COVID-19 vaccine dose, I attest I am eligible for that dose according to current recommendations from the CDC." When she asked the pharmacist what this meant, he informed her that the CDC's guidelines are unclear, but he "personally chooses to follow the recommendations of OB and pediatric groups." Although Jane Doe 2 was ultimately successful in obtaining a Covid-19 vaccine during her pregnancy, she and Baby Doe 2 were exposed to Covid-19 over the Fourth of July before she could get vaccinated. The difficulty she faced in getting the Covid-19 vaccine while pregnant and her exposure to Covid-19 exacerbated Jane Doe 2's underlying anxiety and depression, causing her physical injuries including sleep disturbances, and tooth grinding that required a dental intervention. Jane Doe 2 still suffers with the physical manifestations of stress as a result of the uncertainty of being able to get the Covid-19 vaccine while pregnant.

18. Plaintiff, Jane Doe 3 and her two teenage boys live in the Seattle, Washington area. Jane Doe 3 has a Masters in Public Health with a focus on Epidemiology and is immunocompromised. Both of her children are neurodivergent and wanted to get the Covid-19 vaccine before they started school at the end of August, so she made an online appointment for both of them at a nearby location of a national pharmacy. She entered both of her sons' birthdates into the online appointment system and was able to make an appointment for both of them on August 14, 2025. Timmy Doe, who has attention deficit hyperactivity disorder ("ADHD"), anxiety, and a severe needle phobia, had a panic attack the night before his vaccine appointment. When she took her sons to the pharmacy for their vaccine appointments, Timmy Doe had another

bout of anxiety. The pharmacist first tried to dissuade her from giving her sons the Covid-19 vaccine because a new Covid-19 vaccine was allegedly coming out in September, to which Jane Doe 3 replied that she did not know that. The pharmacist then asked her why did her sons need the vaccine, and Jane Doe 3 replied that she wanted her children to be protected before school started, and because it takes up to two weeks to obtain the full effect of the Covid-19 vaccine, she wanted them to receive the vaccine now. The pharmacist then took out her phone and started scrolling through something on her screen. The pharmacist then looked up from her phone and told her that she could not give her sons the Covid-19 vaccine because they were not in the eligible age group. When Jane Doe 3 asked what the eligible age group is, the pharmacist replied either over 60 or 65 is the eligible age group. She was not sure whether it was 60 or over or 65 or over. The pharmacist then ended the conversation by stating that she would not vaccinate her sons because they are not in the eligible age group. Both of her sons were upset that they could not get the Covid-19 vaccine. They were fearful of catching the new Covid-19 strain's "razor-blade throat" themselves and were even more fearful of infecting Jane Doe 3 given her compromised immune system. Jane Doe 3 further demonstrates the harm that the Directive caused. Jane Doe 3 scheduled another appointment for Jimmy Doe and Timmy Doe to be vaccinated on September 12, 2025. Timmy Doe had another panic attack the night before that appointment, which he would not have had but for the first appointment being unsuccessful. The Directive has caused confusion amongst pharmacists; it has prevented those who want to get the Covid-19 vaccine from getting vaccinated, thereby increasing the risk that they and their family members, especially those who are immunocompromised, will get sick with Covid-19; and it has caused fear and anxiety in those who cannot get the vaccine.

B. DEFENDANTS

19. Defendant Robert F. Kennedy, Jr. is the Secretary of the United States Department

of Health and Human Services and that agency's highest ranking official. He is charged with the supervision and management of all decisions and actions of that agency. 42 U.S.C. § 300u. He is sued in his official capacity.

20. Defendant the United States Department of Health and Human Services ("HHS") is an agency of the United States.

21. Defendant Jim O'Neill is Acting Director of the CDC. He is sued in his official capacity.

22. Defendant CDC is an agency that is housed within HHS.

23. The names and capacities of defendants sued herein as Does 1 through 50, inclusive, are presently not known to Plaintiffs, who therefore sue these Defendants by such fictitious names. Plaintiffs will seek to amend this Complaint and include these Doe Defendants' names and capacities when they are ascertained. Each of the fictitiously named Defendants is responsible in some manner for the conduct alleged here and for the injuries suffered by Plaintiffs.

FACTUAL ALLEGATIONS AND LEGAL BACKGROUND

A. THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES AND THE VACCINATION RECOMMENDATION PROCESS IN THE UNITED STATES

24. For more than 25 years before the ACIP came into existence, the main body that made recommendations on vaccine use in the United States was the AAP's Committee on Infectious Diseases ("COID")—called the Committee on Immunization Procedures at the time of its inception.[3]

25. "By the early 1960s, with the licensure of additional new vaccines (monovalent oral poliovirus vaccine, 1961; trivalent oral poliovirus vaccine, 1963; and measles vaccine, 1963) and

[3] L. Reed Walton, et al., *The History of the United States Advisory Committee on Immunization Practices (ACIP)*, 33 VACCINE 405 (Jan. 2015), https://pubmed.ncbi.nlm.nih.gov/25446820/.

increased federal investment of resources in vaccines and immunization programs, it was evident that decision making on use of vaccines required a greater degree of continuity of expert technical advice rather than formation of ad hoc committees to address national immunization policy." Therefore, the Surgeon General established ACIP in March 1964. The committee was "charged with the responsibility of advising the Surgeon General regarding the most effective application in public health practice of specific preventive agents which may be applied in communicable disease control." That mission has remained essentially unchanged since the ACIP's inception.[4]

26. In 1972, the ACIP was designated a federal advisory committee under the Federal Advisory Committee Act, 5 U.S.C. § 1001, *et. seq*, which sets forth legal requirements for operations of federal advisory committees such as the ACIP.

27. HHS oversees the process by which vaccines are approved and recommended. To harmonize this process, it has entrusted the FDA and the CDC to support aspects of vaccine review and recommendation relevant to their respective areas of expertise. Since their inception, vaccines have undergone a rigorous and continued safety and efficacy review in the United States. Initially, the FDA reviews Biologics License Applications ("BLA") submitted by manufacturers for authorization to market new vaccines for use in the United States. 42 U.S.C. § 262(2). A BLA is a comprehensive submission that is submitted to the FDA. It includes preclinical and clinical data and information, as well as details of the manufacturing process and facilities. Before a vaccine manufacturer even submits a BLA to the FDA, the manufacturer will have conducted trials, including placebo-controlled randomized trials, of the vaccine on human subjects. The data from these trials is submitted with the BLA.

[4] Jean Clare Smith, et al., *History and Evolution of the Advisory Committee on Immunization Practices – United States, 1964-2014*, 63 MORBIDITY & MORTALITY WKLY. REP. 955, 955 (Oct. 24, 2014), https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6342a5.htm.

28. While the BLA is under review at the FDA, which can take several years, an ACIP Work Group also thoroughly reviews all available scientific information about the vaccine, including the data submitted with the BLA, so that the Work Group will be prepared to present information to the ACIP about the vaccine as soon as it is licensed. At this point, the vaccine already has undergone several phases of testing for safety and efficacy with thousands of volunteers.[5] The ACIP is required by the 21st Century Cures Act to take up consideration of a newly-FDA-approved vaccine at the next public ACIP meeting after FDA authorization is announced.[6]

29. The ACIP is responsible for examining the evidence and recommending how the vaccine will be used to control disease in the United States. In 2010, the ACIP adopted a best practice call the "GRADE" framework—Grading of Recommendations, Assessment, Development, and Evaluation— for assessing the quality of evidence and developing evidence-based recommendations.[7] The GRADE approach provides a framework for assessing the certainty (*i.e.*, quality or confidence) of the evidence and moving from evidence to decision making (*i.e.*, recommendations).[8]

30. In 2018, the ACIP by unanimous vote adopted another best practice, the Evidence to Recommendation ("EtR") framework. As explained in the ACIP Evidence to Recommendation User's Guide, the "ACIP has continued to follow and build upon the methodological advances in the GRADE approach and, as a result, has developed a modified Evidence to Recommendation

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[5] *Role of the Advisory Committee on Immunization Practices in CDC's Vaccine Recommendations*, (Sept. 17, 2024). https://restoredcdc.org/www.cdc.gov/acip/about/role-in-vaccine-recommendations.html.

[6] 21 U.S.C. § 360bbb-4 note ("Upon the licensure of any vaccine or any new indication for a vaccine, the Advisory Committee on Immunization Practices (in this section referred to as the 'Advisory Committee') shall, as appropriate, consider the use of the vaccine at its next regularly scheduled meeting").

[7] CDC, *Introduction* in ACIP GRADE HANDBOOK (2024) https://www.cdc.gov/acip-grade-handbook/hcp/chapter-1-introduction/index.html.

[8] *Id.*

(EtR) framework tailored to the needs of ACIP (Appendix 1). The purpose of the EtR framework is to help panels making recommendations move from evidence to decisions, and to provide transparency around the impact of additional factors on deliberations when considering a recommendation."[9]

31. The engines that power the ACIP recommendation process are the Work Groups. As stated in the Work Groups Standard Operating Procedures manual:

> The role of the Advisory Committee on Immunization Practices (ACIP) is to assist the Centers for Disease Control and Prevention (CDC) and the Department of Health and Human Services (HHS) in development of public policy related to immunization of the civilian population in the United States. ACIP utilizes subgroups of the Committee, known as work groups (WGs), to review relevant published and unpublished data and develop recommendation options for presentation to the ACIP. ACIP WGs are intended to augment the effectiveness of ACIP. …
>
> ACIP WGs are responsible for collection, analysis, and preparation of information for presentation, discussion, deliberation, and vote by the ACIP in an open public forum. WGs review specific topics in detail and elucidate issues in a manner that facilitates informed and efficient decision making by ACIP voting members.[10]

32. Each Work Group puts in hours of study and analysis of the evidence using the GRADE approach and EtR framework before a vaccine is presented for a vote at a public meeting of the ACIP. For example, the COVID-19 Vaccines Work Group, created in mid-2020:

> would have weekly, robust discussions regarding scientific data about the developing COVID-19 vaccines. I attended and participated in each of the COVID-19 Vaccines Work Group. These discussions included the creation of the vaccines, how the vaccines were manufactured, and how clinical trials were conducted. We also discussed the triage plan, the distribution plan, and how this critical resource should be allocated. The COVID-19 Vaccines Work Group thoroughly reviewed published works

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[9] CDC, ACIP EVIDENCE TO RECOMMENDATION USER'S GUIDE 1, 3 (2020), https://www.cdc.gov/acip/media/pdfs/2024/09/acip-etr-users-guide_october-1-2020.pdf.

[10] ACIP PRACTICES SECRETARIAT & CDC, ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES WORK GROUPS STANDARD OPERATING PROCEDURES 1, 2 (2018), https://www.cdc.gov/acip/downloads/Work-Group-Guidance-508.pdf.

> from all over the world, including independent research from various institutions and data from other countries.
>
> Each week, the COVID-19 Vaccines Work Group would have an agenda. We would build upon and adapt our discussions as more data were gathered. As it got closer to each ACIP meeting, each work group, including the COVID-19 Work Group, would use the Evidence-to-Recommendation (EtR) framework to craft our recommendations to the ACIP. The EtR looks at benefits and harms, feasibility, acceptability, health equity, and other similar domains. Each expert in the work group would be polled on each of the domains to reach a recommendation.
>
> Once the COVID-19 Vaccines Work Group came to a consensus on a proposed recommendation to the ACIP, we would put together a presentation that detailed the benefits and harms, feasibility, acceptability, comparators, and other domains to analyze each anticipated question from ACIP.
>
> Next, the COVID-19 Vaccines Work Group would come up with a specific set of recommendation language to present to the ACIP committee. This proposed recommendation, along with our analyses from the evidence gathered, would be presented to the full ACIP committee summarizing this discussion and data. …
>
> At the April 15-16, 2025 ACIP meeting, which I attended in my capacity as a Liaison for ACP, the COVID-19 Vaccines Work Group members presented five different presentations regarding the COVID-19 vaccines and ended with the Work Group's considerations for use of the 2025-2026 COVID-19 vaccines. *See* Ex. A; Ex. B, *Use of 2025-2026 COVID-19 Vaccines: Work Group Considerations*, CDC ACIP Meeting (April 15, 2025). …
>
> There was no vote scheduled at the April 15-16, 2025 ACIP meeting regarding COVID-19 vaccine recommendations, meaning that ACIP committee members did not vote on changing the COVID-19 vaccine schedule for pregnant persons or children at that meeting. In[stead], the vote on the 2025-2026 COVID-19 vaccine recommendations was slated for the June 25-26, 2025 ACIP meeting. *See* Ex. C, CDC ACIP Meeting Agenda, April 15-16, 2025; Ex. B at 3.[11]

33. Once the ACIP votes on a recommended use of the vaccine, the CDC Director has the authority to adopt ACIP recommendations, and, once approved, the CDC publishes all ACIP

[11] Decl. of Jason M. Goldman, ECF No. 75-18 at ¶ 16.

recommendations on its website and in the Morbidity and Mortality Weekly Report ("MMWR"), finalizing the agency action.

34. 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.[12]

35. In a podcast released on January 13, 2026, the Secretary talked about "resetting the vaccine schedule. … there was not good science behind the vaccine schedule. … we know very little about the risk profile of those products because vaccines are the only medical … intervention or pharmaceutical product that's exempted from pre-licensing safety trials. So none of the vaccines on the schedule with the exception of the COVID vaccine, ***none of them had ever been safety tested in a placebo controlled trial pre-licensure***." [13] Later in the interview, the Secretary elaborated on this false statement, stating: "we have no idea what the risk profile is of these products."[14]

36. The truth, however, is that "[c]linical trials for vaccines, including Phase I, II, and III, typically span 5 – 10 years with thousands to tens of thousands of participants ***before FDA approval***."[15]

37. The FDA website has a tutorial on "How Vaccines are Developed and Approved

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[12] *See supra* ¶ 88.
[13] The Katie Miller Podcast, *RFK Jr. on Dietary Guidelines, Vaccines & Trump*, at 5:04─6:03 (Jan. 13, 2026) (emphasis added), https://www.youtube.com/watch?v=w_fzlwxJZAA&t=843s.
[14] *Id.* at 8:57 – 9:01.
[15] Marisa Donnelly, Annicka Evans, David Higgins, Katelyn Jetelina, Elisabeth Marnik, Edward Nirenberg, Emily Smith, Jessica Steir, *Summary Of 2025 ACIP Meetings*, THE EVIDENCE COLLECTIVE (Jan. 2026) (emphasis added) https://static1.squarespace.com/static/68435457c33bc03421c23ff7/t/696beaa8cb9b640a609a510f/1768680104162/2025+ACIP+Falsehoods+Recap_Highlights.pdf.

for Use."[16] The section titled "Testing the vaccine" states:

Testing the vaccine

Next, the vaccine enters a clinical development stage, which is also called a clinical trial. To do this, researchers submit an Investigational New Drug (IND) application to FDA, which includes data from animal studies, information on manufacturing technology, and the quality of the vaccine. Vaccine quality is important because it affects how well it will work to provide long- and short-term protection against disease.

The clinical development stage is a three-phase process, which may include a fourth phase if the vaccine is approved by FDA.

Phase 1

Small groups of people (20 to 100) receive the trial vaccine. During this phase, researchers gather information on how safe the vaccine is in people. This includes learning about and identifying side effects, and studying how well the vaccine works to cause an immune response.

Phase 2

The clinical trial expands to hundreds (100-300) of trial participants who have characteristics (such as age and physical health) similar to the intended recipients for the vaccine. They can also include groups of people from diverse backgrounds to ensure representation across different populations.

This phase provides additional safety information on side effects and risks, and more information on how well the vaccine works to cause an immune response.

Phase 3

The clinical trial expands to thousands (1,000–3,000) of people. In this phase, researchers confirm how well the vaccine works, monitor common and less common side effects, and collect information to support safe use in people.

Phase 4 (after FDA approval)

After FDA approves (also known as "licenses") a vaccine for use in the general population, it might advance to an additional clinical trial phase

[16] *How Vaccines are Developed and Approved for Use*, CDC (Aug. 10, 2024), https://www.cdc.gov/vaccines/basics/how-developed-approved.html#cdc_generic_section_4-testing-the-vaccine.

> with thousands of participants. Phase 4 is a formal, ongoing study to evaluate the new vaccine's safety and effectiveness over a longer period of time.[17]

B. THE JANUARY 5 ACTION

38. The events in the public record leading up to the January 5 Action demonstrate an orchestrated plan to unilaterally change the U.S. Childhood Schedule without examining the relevant data or providing a reasonable explanation.

39. On Monday, November 17, 2025, the Secretary stated the following at a public meeting at George Washington University: "I know how to change things, and I'm not scared to disrupt things and these agencies need to be disrupted. They need to change their direction."

40. The ACIP met on December 4-5, 2025. On December 4, two outside presenters spoke on the Hepatitis B vaccine. The first, Cynthia Nevison, a climate scientist, presented on the "Burden of Disease." The second, Mark Blaxill, who has an MBA and no medical background, presented on the safety of the Hepatitis B vaccine.

41. The next day, December 5, Aaron Siri, a prominent anti-vaccine lawyer who has been identified as the Secretary's personal attorney and continues to be a key legal adviser to the Secretary, presented on the "Childhood/Adolescent Immunization Schedule," where he compared the U.S. Childhood Schedule to "other Developed Countries."[18]

42. A lunch break was taken after Siri presented. Three voting members of the ACIP attended the December 4-5 meeting remotely by Zoom: Chair Kirk Milhoan and voting members Cody Meissner and Joseph Hibbeln. Dr. Jason Goldman, current president of the American College of Physicians, serves as the ACP's liaison representative to the ACIP and attended both

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[17] *Id.*

[18] CDC, *Meeting of the Advisory Committee on Immunization Practices (ACIP) Agenda*, https://www.cdc.gov/acip/downloads/agendas/final-posted-2025-12-04-508.pdf (last visited Jan. 19, 2026).

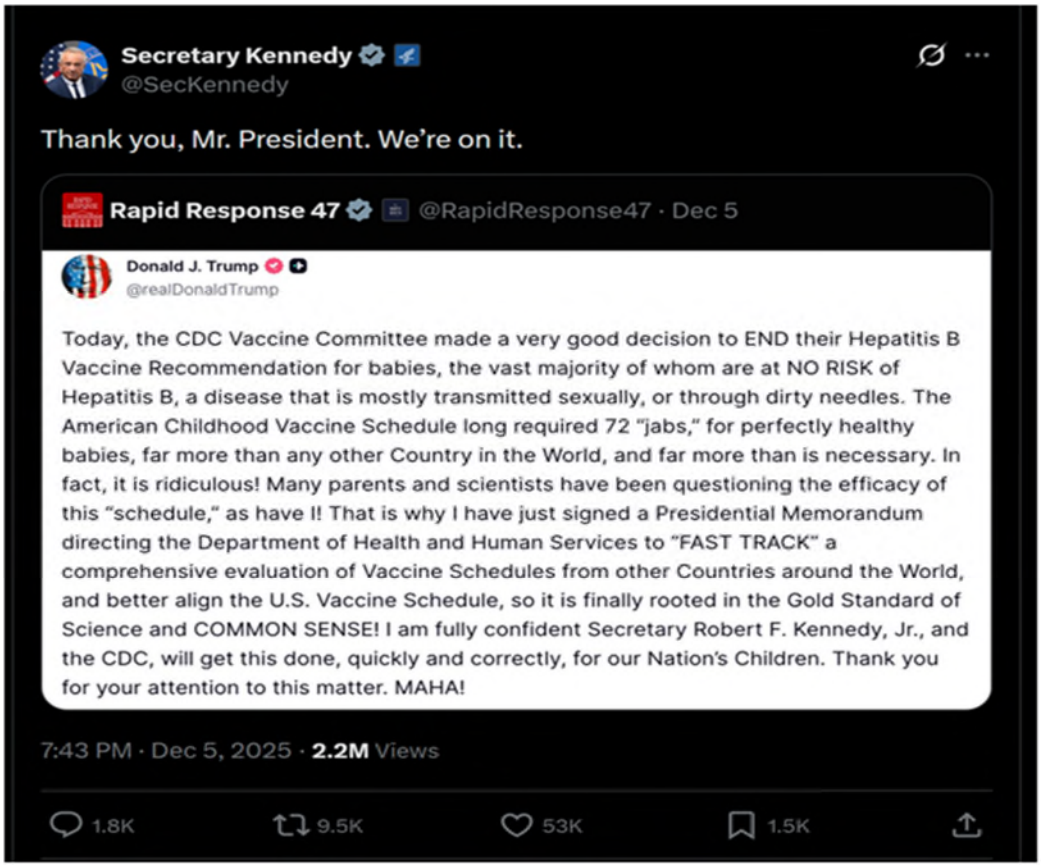
days by Zoom. At the beginning of the morning and afternoon sessions, an announcement was made on Zoom that the meeting was being recorded. Goldman has been participating in ACIP meetings as an ACIP Covid-19 Work Group member and ACP liaison representative for over five years. Whenever he participates in an ACIP meeting by Zoom and the announcement is made that the meeting is being recorded, he turns on the Zoom close-captioning and transcription functions and prints out the transcript to make sure he does not miss anything. At the end of the lunch break on December 5, the Zoom link was reactivated for the voting members and liaison representatives who were appearing remotely. Before the in-person meeting resumed, Milhoan and Meissner began conversing with each other over Zoom after the Zoom link had been reactivated. Goldman and others who were appearing by Zoom could hear what they said to each other. At one point in their conversation, Milhoan said: "You know, I feel like, you know, it's sort of like we feel like a puppet on a string as opposed to really being [an] independent advisory panel.[19]

43. The only presenter in the afternoon of December 5 was Tracy Beth Høeg ("Høeg"), whose medical degree is in sports medicine, who presented a comparison between the U.S. Childhood Schedule and the Danish Vaccine Schedule.

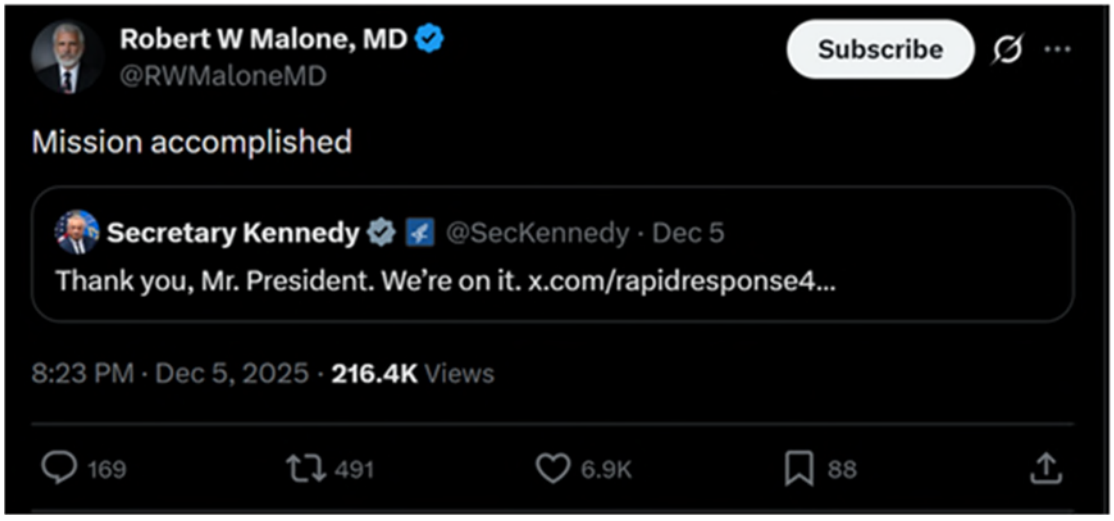
44. A few hours after the conclusion of the meeting on December 5, President Trump posted on X that he had "just signed a Presidential Memorandum directing the Department of Health and Human Services to 'FAST TRACK' a comprehensive evaluation of Vaccine Schedules from other Countries around the World, and better align the U.S. Vaccine Schedule, so it is finally rooted in the Gold Standard of Science and COMMON SENSE! I am fully confident Secretary Robert F. Kennedy, Jr., and the CDC, will get this done, quickly and correctly for our Nation's Children." The Secretary responded to the President's post with: "Thank you, Mr. President.

[19] Supp. Decl. of Jason Goldman, ECF No. 162 at ¶ 8.

We're on it."



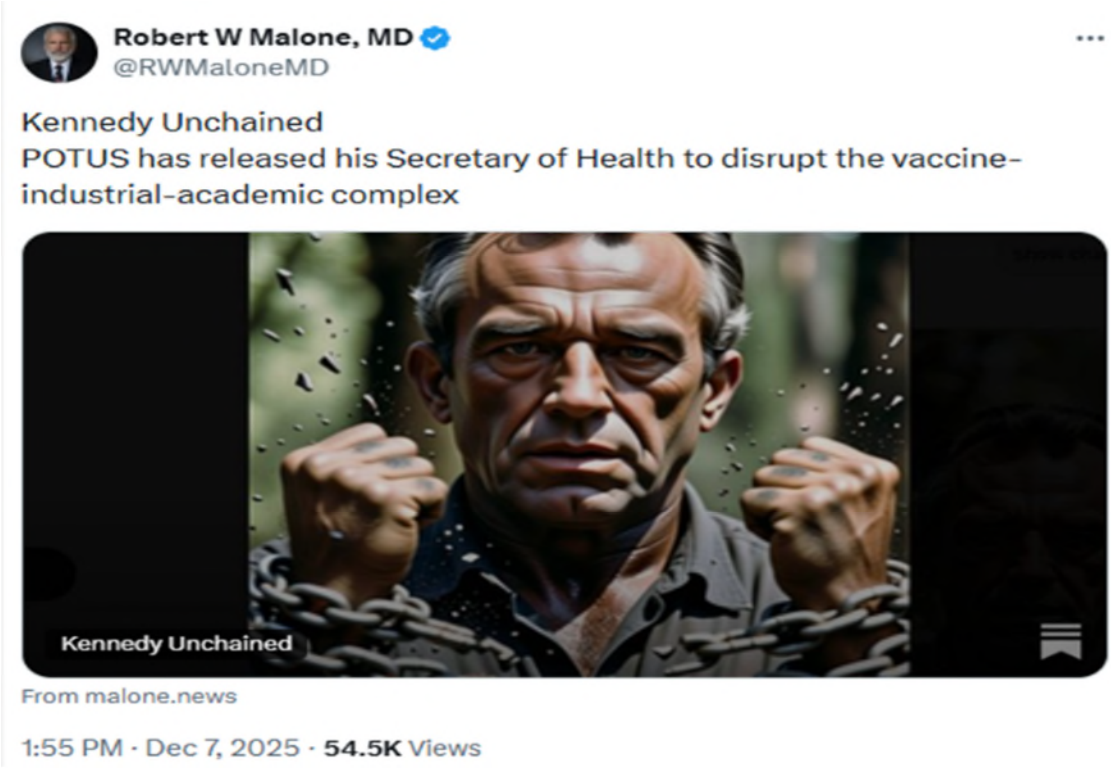
45. Vice-Chair of the ACIP, Robert Malone, who ran the ACIP meeting in-person on December 4-5, replied that evening to the Secretary's "We're on it" post with the following two-word post: "Mission accomplished."



46. The December 5 Presidential Memoranda instructed the Defendants as follows:

> I hereby direct the Secretary of Health and Human Services and the Director of the Centers for Disease Control and Prevention to review best practices from peer, developed countries for core childhood vaccination recommendations – vaccines recommended for children – and the scientific evidence that informs those best practices, and, if they determine that those best practices are superior to current domestic recommendations, update the United States core childhood vaccine schedule to align with such scientific evidence and best practices from peer, developed countries while preserving access to vaccines currently available to Americans.

47. Two days later, on December 7, Malone posted the following:



48. On the morning of December 18, 2025, the HHS press office issued the following Media Advisory:

MEDIA ADVISORY—FOR PLANNING PURPOSES ONLY

HHS, CDC to Make Announcement on Children's Health

WASHINGTON—DECEMBER 18, 2025—The U.S. Department of Health and Human Services (HHS) and Centers for Disease Control and Prevention (CDC) will make an announcement regarding children's health.

WHEN: Friday, December 19 at 4 PM ET

WHERE:
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

LIVESTREAM: The event will be livestreamed on HHS.gov, X, and YouTube.

WHO:

- U.S. Department of Health and Human Services **Secretary Robert F. Kennedy Jr.**
- U.S. Department of Health and Human Services **Deputy Secretary Jim O'Neill**
- Centers for Medicare & Medicaid Services **Administrator Mehmet Oz, M.D.**
- Food and Drug Administration **Commissioner Marty Makary, M.D., M.P.H.**
- National Institutes of Health **Director Jay Bhattacharya, M.D., Ph.D.**
- Acting Food and Drug Administration **Acting CDER Director Tracy Beth Høeg, M.D., Ph.D.**

49. On December 18, CDC experts briefed HHS officials, including O'Neill, with a 31-page slide presentation on how the U.S. Childhood Schedule compares to other developed countries, including Denmark's.[20]

50. In the evening of December 18, HHS announced that "[d]ue to a Presidential announcement tomorrow afternoon, we are postponing our children's health announcement to after the first of the new year."[21]

51. A news article on what the Friday, December 19, announcement was going to be stated:

[20] Lena H. Sun, *CDC staff 'blindsided' as child vaccine schedule unilaterally overhauled*, THE WASH. POST (Jan. 7, 2026), https://www.washingtonpost.com/health/2026/01/07/cdc-vaccine-recommendations-schedule-revisions/.
[21] Press Release, U.S. Dep't of Health & Human Servs., *POSTPONED: HHS, CDC Announcement on Children's Health* (Dec. 18, 2025).

> Health Secretary Robert F. Kennedy Jr. came within hours of publicly promoting Denmark's childhood vaccine schedule as an option for American parents — before legal and political concerns got in the way.
> A senior HHS official told POLITICO that a press conference set for Friday was canceled at the last minute after the HHS Office of the General Counsel said it would invite a lawsuit the administration could lose.
>
> A second senior official at the Department of Health and Human Services confirmed the press conference, which HHS had publicly announced, was to be about the Danish schedule. The second official said it was canceled because it was deemed politically risky.[22]

52. In the morning of January 5, 2026, the Secretary, O'Neill, and others, held an off-the-record press conference in which they informed the reporters that HHS would be releasing an announcement at 2 p.m. ET that afternoon about the U.S. Childhood Schedule. The Secretary himself answered questions during that press conference.

53. At 2 p.m. ET that afternoon, the HHS Press Office issued a press release titled "CDC Acts on Presidential Memorandum to Updated Childhood Immunization Schedule," that stated:

> **WASHINGTON, D.C. — JANUARY 5, 2026 —** Deputy Secretary of Health and Human Services Jim O'Neill, in his role as Acting Director of the Centers for Disease Control and Prevention (CDC), today signed a decision memorandum* [PDF, 894 KB] </sites/default/files/decision-memo-adopting-revised-childhood-adolescent-immunization-schedule.pdf> accepting recommendations from a comprehensive scientific assessment [PDF, 1.05 MB] </sites/default/files/assessment-of-the-us-childhood-and-adolescent-immunization-schedule-compared-to-other-countries.pdf> of U.S. childhood immunization practices, following a directive from President Trump to review international best practices from peer, developed countries.
> On December 5, 2025, via a Presidential Memorandum <https://www.whitehouse.gov/presidential-actions/2025/12/aligning-united-states-core-childhood-vaccine-recommendations-with-best-practices-from-peer-developed-countries/>, President Trump directed the Secretary of HHS and the Acting Director of CDC to examine how peer, developed nations structure their childhood vaccination schedules and to

[22] Tim Rohn, *RFK Jr. wanted to endorse the Danish vaccine schedule. He was forced to pull back,* POLITICO (Dec. 20, 2025), https://www.politico.com/news/2025/12/20/rfk-kennedy-danish-vaccine-schedule-denmark-00701999.

> evaluate the scientific evidence underlying those practices. He instructed them to update the U.S. childhood vaccine schedule if superior approaches exist abroad while preserving access to vaccine currently available to Americans.
>
> After consulting with health ministries of peer nations, considering the assessment's findings, and reviewing the decision memo presented by National Institutes of Health Director **Dr. Jay Bhattacharya**, Food and Drug Commissioner **Dr. Marty Makary**, and CMS Administrator **Dr. Mehmet Oz**, Acting Director O'Neill formally accepted the recommendations and directed the CDC to move forward with implementation.
>
> 'President Trump directed us to examine how other developed nations protect their children and to take action if they are doing better," **Secretary Robert F. Kennedy Jr. said.** "After an exhaustive review of the evidence, we are aligning the U.S. childhood vaccine schedule with international consensus while strengthening transparency and informed consent. This decision protects children, respects families, and rebuilds trust in public health.' …
>
> The scientific assessment compared U.S. childhood immunization recommendations with those of peer nations, analyzed vaccine uptake and public trust, evaluated clinical and epidemiological evidence and knowledge gaps, examined vaccine mandates, and identified next steps.
> The assessment reviewed 20 peer, developed nations and found that the U.S. is a global outlier among developed nations in both the number of diseases addressed in its routine childhood vaccination schedule and the total number of recommended doses but does not have higher vaccination rates than such countries. In fact, many peer nations that recommend fewer routine vaccines achieve strong child health outcomes and maintain high vaccination rates through public trust and education rather than mandates. For example, in 2024, the U.S. recommended more childhood vaccines than any peer nation, and more than twice as many doses as some European nations. At the lower end is Denmark, which immunizes children against 10 diseases compared to a total number of 18 diseases for which protection was provided in 2024 in the U.S.

54. The Decision Memo linked in the press release begins as follows:

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control and Prevention (CDC)
Atlanta GA 30329-4027

Decision Memo

DATE: January 5, 2026

TO: Jim O'Neill, Acting Director, Centers for Disease Control and Prevention (CDC)

FROM: Jay Bhattacharya, MD, PhD, Director, National Institutes of Health
Mehmet Oz, MD, MBA, Administrator, Centers for Medicare and Medicaid Services
Marty Makary, MD, MPH, Commissioner of Food and Drugs

SUBJECT: DECISION REQUESTED – Adopting Revised Childhood and Adolescent Immunization Schedule

PURPOSE

This memorandum proposes a revised childhood and adolescent immunization schedule for your review and approval.

RECOMMENDATION AND ACTION REQUESTED

After considering the data and recommendations contained in TAB 1, "Assessment of the U.S. Childhood and Adolescent Immunization Schedule Compared to Other Countries," and your discussions with relevant health officials, you should approve the revised immunization schedule.

55. Neither the Director of the National Institutes of Health, the Administrator of the Centers for Medicare and Medicaid Services, nor the Commissioner of the Food and Drug Administration have responsibility for or jurisdiction over revising CDC immunization schedules.

56. The Decision Memo announced a new U.S. Childhood Schedule that reduced the number of routinely recommended childhood vaccinations from 17 to 11 "to reflect[] the Danish schedule except that this revised schedule adds the varicella vaccine, which is not currently on the Danish schedule."

57. The Decision Memo states that the RSV, Hepatitis A, Hepatitis B, and Meningococcal ACWY, and Meningococcal B immunizations are now recommended only for high-risk groups. The immunizations for Rotavirus, Covid-19, Influenza, Hepatitis A, Hepatitis B,

and Meningococcal disease are classified as SCDM.

C. DEFENDANTS' EXPLANATIONS FOR THE JANUARY 5 ACTION

58. The Decision Memo states that O'Neill relied on three things in deciding to approve the recommendation to revise the Childhood Schedule: (a) discussions with health officials from Japan, Germany, and Denmark; (b) discussions "with CDC and Food and Drug Administration (FDA) officials with duties and responsibilities related to vaccine safety and efficacy;" and (c) "the data and recommendations contained in TAB 1, 'Assessment of the U.S. Childhood and Adolescent Immunization Schedule Compared to Other Countries,'" a document authored by Høeg and Kulldorff, which argues that the U.S. is an outlier with respect to how many immunizations children receive.

Explanation # 1:
Discussions with Health Officials from Denmark, Germany, and Japan

59. The Decision Memo fails to state what officials from Japan, Germany, and Denmark discussed with O'Neill. The Decision Memo fails to state whether officials from these countries agreed, disagreed, or had no opinion with aligning the U.S. Childhood Schedule with peer countries' childhood schedules.

60. The December 5 Presidential Memoranda directs the Defendants to "review best practices from peer, developed countries for core childhood vaccination recommendations – vaccines recommended for children – and the scientific evidence that informs those best practices." Neither the Decision Memo nor the Assessment discuss what other country's best practices are or the scientific evidence that informs those best practices.

61. A National Immunization Technical Advisory Group ("NITAG") is a multidisciplinary body of experts that provides evidence-based immunization recommendations to policymakers in their respective countries. NITAGs systematically evaluate evidence together with

the local epidemiological and social context to inform decision-making on vaccine use at the national level.[23] The ACIP is a NITAG. While the Secretary asserted in the January 5 press release that Defendants had done an "exhaustive review" of the best practices of peer countries, neither the Decision Memo nor Assessment mention that they consulted with the NITAG of Denmark, Germany, Japan, or any other so-called "peer" country.

62. After news of Defendants aligning the U.S. Childhood Schedule with that of Denmark's broke, a Danish health official, Dr. Anders Hviid, who leads research on vaccine safety at Denmark's equivalent of the CDC, commented: "'It's not at all fair to say look at Denmark unless you can match the other characteristics of Denmark.'"[24] He stated further that, in the United States, "'it turns out to get crazier and crazier in public health from month to month. It is surreal, and it is difficult, from a Danish perspective, to understand what's going on,'"[25] and "[y]ou cannot adopt the public health policies of another country unless the population, health care system and prevalence of infectious diseases match."[26]

63. Denmark's health care system purchases vaccines for its citizens and omits shots from some diseases from the childhood schedule because they do not pose enough of a problem there to make the vaccines cost-effective, not because of concerns about safety.[27]

64. Dr. Reinhard Berner, a pediatric infectious diseases expert in Germany and chair of STIKO, the independent committee that recommends vaccines for Germans, said the decisions in his country on not including certain vaccines on Germany's schedules were not based on safety

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[23] *National Immunization Technical Advisory Groups (NITAGs)*, WHO (2026) https://www.who.int/europe/groups/national-immunization-technical-advisory-groups-(nitags).
[24] Apoorva Mandavilli, *RFK Jr. Likely to Swap U.S. Childhood Vaccine Schedule for Denmark's*, THE N.Y. TIMES (Dec. 19, 2025), https://www.nytimes.com/2025/12/19/health/kennedy-childhood-vaccine-schedule-denmark.html?searchResultPosition=1.
[25] *Id.*
[26] Helen Branswell, *When it comes to vaccines schedules, the U.S. is now the outlier*, STAT (Jan. 9, 2026), https://www.statnews.com/2026/01/09/childhood-vaccination-fact-check-denmark-not-america-is-the-outlier/.
[27] *Id.*

concerns about the vaccines, but on the prevalence of diseases there.[28] German's NITAG does "not have any concerns about the content of aluminum, and we do not have any concerns about the application of different vaccines at the same time."[29]

Explanation # 2:
Discussions with CDC and FDA Officials

65. The Decision Memo fails to state what CDC and Food and Drug Administration officials discussed with O'Neill and whether they agreed or disagreed with aligning the US Childhood Schedule with the Danish schedule.

66. In fact, vaccine experts at the CDC were blindsided by the release of the Decision Memo.[30] The decision to change the U.S. Childhood Schedule "contradicted guidance from career scientists who prepared a presentation outlining how the U.S. vaccine policy is not an international outlier, according to a copy of the presentation obtained by The Washington Post. Five career scientists and researchers, who spoke on the condition of anonymity for fear of retaliation, said that they are angered by the bypassing of expertise in Monday's decision. That process to alter vaccine recommendations, they and several former health officials said, did not include extensive consultation with the agency's subject matter experts or the CDC's vaccine advisory panel that is usually done."[31]

Explanation # 3:
The Assessment

67. While the Assessment purports to be a "scientific, evidence-based, data-driven" assessment, neither the Assessment nor the Decision Memo indicate that Defendants considered

[28] Apoorva Mandavilli, *RFK Jr. Likely to Swap U.S. Childhood Vaccine Schedule for Denmark's*, THE N.Y. TIMES (Dec. 19, 2025), https://www.nytimes.com/2025/12/19/health/kennedy-childhood-vaccine-schedule-denmark.html?searchResultPosition=1.
[29] *Id.*
[30] Lena H. Sun, *CDC staff 'blindsided' as child vaccine schedule unilaterally overhauled*, THE WASH. POST (Jan. 7, 2026), https://www.washingtonpost.com/health/2026/01/07/cdc-vaccine-recommendations-schedule-revisions/.
[31] *Id.*

evidence on the following factors:[32]

(a) the impact that the schedule changes would have on illnesses, hospitalizations, deaths, and disabilities;

(b) input from the public;

(c) input from independent experts;

(d) the financial impact on families, such as paying a co-pay each time that an appointment with a doctor is made to engage in SCDM about a vaccination; missing work and school because the patient now must consult with a doctor each time s/he is considering a vaccination;

(e) the ability that the 27 million uninsured in this country have to engage in SCDM if they have no doctor;

(f) the impact on clinicians, such as higher stress levels, more fatigue and burnout, more doctors leaving the practice of medicine, all while reducing patient access with less available time to manage other clinically significant issues of their patient population;

(g) the burden on hospitals, *e.g.*, more uninsured patients showing up in the emergency room because they could not engage in SCDM with a doctor to get vaccinated and became seriously ill with a vaccine-preventable disease; more patients being hospitalized from vaccine-preventable diseases and the concomitant burden on staff and capacity;

(h) the differences between Denmark (or any other so-called "peer" country) and the U.S., including Denmark's universal healthcare system, better disease screening, paid

[32] *See* Marisa Donnelly, PhD; David Higgins, MD, MPH; Katelyn Jetelina, MPH, PhD; Christina M. Madison, PharmD, FCCP, AAHIVP; Elisabeth Marnik, PhD; Edward Nirenberg; Jessica Steier, DrPH, *In Response: Routine Childhood Vaccination Schedule Change*, p.1, THE EVIDENCE COLLECTIVE (Jan. 5, 2026), https://static1.squarespace.com/static/68435457c33bc03421c23ff7/t/6967fdeff24a3a6a4d791fb2/1768422895176/Childhood+vaccine+change.pdf.

parental leave, national coverage monitoring, near-universal prenatal screening, centralized medical records from birth to death, and a more homogeneous population.

68. The Assessment concludes that the "U.S. is a global outlier among peer nations in the number of target diseases included in its childhood vaccination schedule and in the total number of recommended vaccine doses" and recommends that the U.S. Childhood Schedule be brought "in line with the consensus of peer nations." However, Denmark is the actual outlier, with the fewest number of vaccines, as compared to Canada, Australia, Ireland, New Zealand, France, Italy, and Spain, who all have routine childhood vaccination schedules similar to the U.S.'s.[33]

69. The comparison of the U.S. schedule to so-called peer nations is a false, unreasonable, irrational comparison.[34]

70. The Assessment discusses no new evidence or data on the safety or efficacy of any of the vaccines on the Childhood Schedule.

D. CURRENT ACIP MEMBERS

Qualifications for ACIP Membership

71. While 42 U.S.C. § 217a gives the Secretary the authority to "appoint such advisory councils or committees (in addition to those authorized to be established under other provisions of law), for such periods of time, as he deems desirable … for the purpose of advising him in connection with any of his functions," he does not have unbridled discretion in doing so. First, by law, the Secretary is forbidden from considering political affiliation in making appointments to advisory committees. 42 U.S.C. § 217a–1. ("Advisory committees; prohibition of consideration of

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[33] *Id.*

[34] *See, e.g.*, Martin Kulldorff, *Study Designs for the Safety Evaluation of Different Childhood Immunization Schedules*, *in* INST. OF MED. & THE NAT'L ACAD. OF MED. THE CHILDHOOD IMMUNIZATION SCHEDULE AND SAFETY: STAKEHOLDER CONCERNS, SCIENTIFIC EVIDENCE, AND FUTURE STUDIES, app. at 161 (2013)(comparing different countries' vaccine schedules "is very difficult to do well and generally not recommended") https://www.ncbi.nlm.nih.gov/books/NBK206948/pdf/Bookshelf_NBK206948.pdf.

political affiliations. All appointments to advisory committees established to assist in implementing the Public Health Service Act [42 U.S.C. 201 et seq.] … *shall be made without regard to political affiliation*.").[35] Second, the ACIP Charter provides that "[m]embers shall be selected from authorities who are knowledgeable in the fields of immunization practices and public health, have expertise in the use of vaccines and other immunobiologic agents in clinical practice or preventive medicine, have expertise with clinical or laboratory vaccine research, or have expertise in assessment of vaccine efficacy and safety.[36] Third, by virtue of Congress incorporating ACIP recommendations within at least 13 federal statutes, and the adoption of nearly 600 statutes and regulations across 49 states, three territories, and Washington D.C., policy makers at all levels of government and healthcare providers, among others, have developed a very strong, deep reliance interest in the selection of ACIP members being done in good faith, without regard to political affiliation, based on qualifications and experience set forth in the ACIP Charter and regulation.[37]

The Secretary Fires The ACIP on June 9, 2025

72. During his confirmation process, the Secretary promised Congress that he would "maintain the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices without changes."[38]

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[35] This statute was passed because "[a]t a time when public confidence in Government is at an all time low, and the need for high performance by the Government is at an all time high, the area of science and health should not be brought into pork barrel politics." 121 CONG. REC. 39987 (1975).

[36] *ACIP Charter*, CDC, at 4 (Apr. 1, 2024), https://www.cdc the traditional American values of hard work, excellence, and individual achievement .gov/acip/about/acip-charter.html.

[37] *Id.* (requiring that members "be knowledgeable in the fields of immunization practices and public health, have expertise in the use of vaccines and other immunobiologic agents in clinical practice or preventive medicine, have expertise with clinical or laboratory vaccine research, or have expertise in assessment of vaccine efficacy and safety."); *see also* 41 CFR § 102-3.60(b)(3)(i) ("Advisory committees requiring technical expertise should include persons with demonstrated professional or personal qualifications and experience relevant to the functions and tasks to be performed by the committee.").

[38] KFF Health News, *Sen. Cassidy Says RFK Jr. Promised Key Vaccine Safety Commitments*, at 2:02. YOUTUBE (Feb. 4, 2025), https://www.youtube.com/watch?v=QrJcBtkfwvo.

73. It did not take long for the Secretary to break his promise. On June 9, 2025, at exactly 4 p.m. Eastern Time, an Opinion Commentary written by the Secretary appeared in the online version of the *Wall Street Journal*. In the column, the Secretary announced he was "totally reconstituting the Advisory Committee for Immunization Practices (ACIP)" and "retiring the 17 current members of the committee."[39]

74. The 17 members of the ACIP first learned of their terminations from a *Wall Street Journal* column. A few hours after the column appeared online, each of the 17 members received an email that stated:

> Per the June 9, 2025 directive from the Secretary of the U.S. Department of Health and Human Services, this email serves as formal notice of your immediate termination as a member of the Advisory Committee on Immunization Practices (ACIP).
>
> We appreciate your prior service and commitment.

75. The Secretary's June 9, 2025 column made a host of false accusations against the 17 ACIP members, including that they had "been plagued with persistent conflicts of interest," had "become little more than a rubber stamp for any vaccine," were corrupt," and were "directly work[ing] for the vaccine industry." These justifications were pretextual, as the following demonstrates:

(a) The Secretary justified the terminations by referencing reports from 1997, 2000, and 2009 on ACIP conflicts of interest, years in which none of the 17 terminated members were on the ACIP.

(b) Research from the USC Schaeffer Center for Health Policy & Economics finds that "reported conflicts on that Centers for Disease Control and Prevention panel had been *at historic*

[39] Robert F. Kennedy, Jr., *HHS Moves to Restore Public Trust in Vaccines*, WALL STREET JOURNAL (June 9, 2025, 4:00 PM), https://www.wsj.com/opinion/rfk-jr-hhs-moves-to-restore-public-trust-in-vaccines-45495112.

lows for years before Kennedy's abrupt dismissal. Furthermore, *the type of conflict typically considered the most concerning—income from vaccine makers—had been virtually eliminated among members of the CDC panel, known as the Advisory Committee on Immunization Practices* (ACIP)."[40] "Since 2016, an average of 6.2% of ACIP members and 1.9% of VRBAC members have reported a financial conflict of interest at any given meeting. During that time, *less than 1% of reported conflicts on both committees were related to personal income from vaccine makers*, which includes consulting fees, stock, royalties or ownership."[41]

(c) The Secretary has failed to fulfill his promise to release both the Confidential Financial Disclosure Report (for Special Government Employees) and the OGE Form 450s[42] for those he has appointed to the ACIP. Shortly before the Secretary's new ACIP met in June of this year, an HHS spokesperson stated: "[b]efore starting work on ACIP, the new members' ethics agreements *will be made public*. Every ACIP member will be vetted in accordance with their ethics agreement before they are permitted to participate in each meeting agenda item," and further, that "both the ethics agreement and the OGE 450s will be disclosed."[43] Nothing has been disclosed, even though new ACIP member Robert W. Malone, MD, posted on X on June 12, 2025, that "i [sic] have already completed three months of ethics vetting and COI training by the appropriate

[40] *Conflicts of Interest on CDC Vaccine Panel Were at Historic Lows Before RFK Jr. Dismissal*, UNIV. OF SOUTHERN CAL. SCHAEFFER CTR. (Aug. 18, 2025), https://schaeffer.usc.edu/research/cdc-acip-vaccine-conflicts-rfk-jr/.
[41] *Id*. (emphasis added).
[42] *See* 5 CFR. § 2634.901 Policies of confidential financial disclosure reporting ("High-level officials in the executive branch are required to report certain financial interests publicly to ensure that every citizen can have confidence in the integrity of the Federal Government. It is equally important in order to guarantee the efficient and honest operation of the Government that other, less senior, executive branch employees, whose Government duties involve the exercise of significant discretion in certain sensitive areas, report their financial interests and outside business activities to their employing agencies, to facilitate the review of possible conflicts of interest.").
[43] Isabella Cueto, *HHS backtracks on pledge to disclose new vaccine advisers' conflict of interest*, STAT (July 9, 2025), https://www.statnews.com/2025/07/09/kennedy-conflict-of-interest-radical-transparency-acip-vaccine-experts/#:~:text=WASHINGTON%20%E2%80%94%20The%20Department%20of%20Health,make%20key%20disclosure%20documents%20public.

HHS officials."

(d) The Secretary has not followed the Advisory Committee on Immunization Practices Policies and Procedures manual that provides: '[u]pon appointment, each voting member is required to file an Office of Government Ethics 450 form … and a Confidential Financial Disclosure Report."[44]

(e) The Secretary, contrary to law, and upon information and belief, required candidates for membership on the ACIP to be a registered Republican or Independent and could not have previously made public criticisms of the President or the Secretary.

The Secretary's Appointments To The ACIP

76. On June 11, 2025, two days after he fired the previous ACIP members, the Secretary announced the appointment of eight new members to the ACIP. When announcing his picks, the Secretary asserted that his selections were "highly credentialed scientists, leading public-health experts, and some of America's most accomplished physicians… committed to evidence-based medicine, gold-standard science, and common sense.[45] On or about September 11, 2025, the Secretary announced four more appointments to the ACIP. On January 13, 2026, the Secretary announced two more appointments to the ACIP.

77. With one exception, the Secretary's appointments to the ACIP do not possess the requisite expertise, background, and credentials to sit on the federal advisory committee that votes on how vaccines are listed on the CDC's immunization schedules:

(a) **Kimberly Biss**, MD, an OB-GYN in St. Petersburg, Florida, is a Fellow of the Independent Medical Alliance, a physician group aligned with the Secretary, who has publicly

[44] *Advisory Committee on Immunization Practices Policies and Procedures*, CDC, at 14-15 (June 2022), https://www.cdc.gov/acip/downloads/policies-procedures-508.pdf.
[45] Robert F. Kennedy, Jr. (@SecKennedy), X (June 11, 2025, 4:36 PM), https://x.com/SecKennedy/status/1932899858920120692.

stated: "I was not anti-vaccine. I am now," and "My grandchildren will not get any shots if I can help it. The vaccine industry is disgusting."

(b) **Adam Urato**, MD, an OB-GYN in Boston, who has stated: "The science is not 'long-settled' regarding vaccines," and "My patients often ask: 'How do we know that all these vaccines won't have adverse effects on my baby and me?' The answer is 'we don't.'"

(c) **Hillary Blackburn**, who holds a PharmD from the University of Mississippi and was the Director of Medication Access and Affordability at AscensionRx when appointed to the ACIP. Upon information and belief, she has not published any articles or participated in any studies or performed any research on vaccines, immunizations, or infectious diseases. At the September 2025 ACIP meeting she speculated that the Covid-19 vaccine could be connected to her mother's lung cancer diagnosis.[46]

(d) **Evelyn Griffin**, whom the CDC's website lists as being an Obstetrician and Gynecologist at Baton Rouge General Hospital and states that she is "board-certified in obstetrics and gynecology, lifestyle medicine, and functional medicine.[47] With 15 years of clinical practice, she was among the first robotic-assisted gynecologic surgeons in the U.S. and has led efforts to reduce maternal morbidity and mortality."[48] The Baton Rouge General Hospital lists an **Ewelina Griffin**, MD, Obstetrics & Gynecology, Gynecology, Hospitalist, but provides no information on where she went to medical school or college. Upon information and belief, Evelyn or Ewelina Griffin, assuming that they are the same person, has not engaged in any vaccine-related research, vaccine administration, or worked in a relevant public health policy position. Dr. Griffin spoke at

[46] CDC, *Meeting of the Advisory Committee on Immunization Practices (ACIP) September 18-19, 2025 Meeting Summary*, at 78 https://www.cdc.gov/acip/downloads/minutes/summary-2025-9-18-19-508.pdf (last visited Jan. 19, 2026).
[47] *ACIP Membership Roster*, CDC (Jan. 14, 2026), https://www.cdc.gov/acip/membership/roster.html#cdc_generic_section_5-evelyn-griffin-m-d.
[48] *Id.*

a 2024 Louisiana "Health Freedom Day" event promoting efforts to repeal vaccine mandates, where she was introduced as being harassed for her coronavirus opinions and having lost her job with a health care system for refusing to get a coronavirus vaccine. In her speech, she said physicians "blindly believed" in the coronavirus vaccines because they were taught in medical school that vaccines were harmless. 'When you are faced with this vaccination schedule, you are just taught, "Just memorize it at this point. Trust us, it's safe,"' she said, also adding that 'Big Pharma' influences medical school curriculums."[49]

(e) **Joseph Hibbeln, MD**. The CDC's website describes Hibbeln as a Psychiatrist, Neuroscientist, and former Chief of Section on Nutritional Neurosciences, National Institutes of Health where he led "research on immune regulation, neurodevelopment, and mental health. His work has informed U.S. public health guidelines, particularly in maternal and child health." Upon information and belief, Dr. Hibbeln has not studied, researched, or published on vaccines, immunizations, infectious disease, or epidemiology. He has, however, been vocal at ACIP meetings about how the ACIP meetings that he has attended have been conducted.

(f) **Martin Kulldorff, PhD**, was appointed chair of the ACIP shortly after the Secretary fired the previous ACIP. Kulldorff "previously served as a professor of medicine at Harvard University" according to the CDC's website but lost his position at Harvard (and at Brigham and Women's Hospital) when he refused to get vaccinated with the Covid-19 vaccine. He also is a co-author of "The Great Barrington Declaration" (dated October 4, 2020, after Operation Warp Speed began but before Covid-19 vaccines were authorized for use in the United States) that promoted "natural immunity" over public health measures and opposed vaccination in children against Covid-19, masking, lockdowns, and vaccine mandates. On December 1, 2025,

[49] Lena H. Sun & Lauren Weber, *RFK Jr. weighs adding critics of coronavirus shots to key vaccine panel*, THE WASH. POST (Sept. 8, 2025), https://www.washingtonpost.com/health/2025/09/08/rfk-jr-new-vaccine-advisers/.

only a few days before the ACIP public meeting on December 4, 2025, HHS announced Kulldorff's appointment as chief science officer for the Office of the Assistant Secretary for Planning and Evaluation.[50]

(g) **Retsef Levi**, has a PhD in Operations Research from Cornell University and, according to his bio on the Massachusetts Institute of Technology website, has an impressive background in *operations management*. Noticeably absent from his MIT bio, however, is any mention of *vaccines*.[51] The CDC's website, however, states that Dr. Levi is "a leading expert in healthcare analytics, supply chain and manufacturing analytics, risk management, and biologics and *vaccine safety*" and that he has "co-authored studies examining the association between mRNA COVID-19 vaccines and risks of cardiovascular disease, mortality, and adverse pregnancy outcomes.[52] Upon information and belief, Dr. Levi has co-authored only two articles on the association between mRNA COVID-19 vaccines and adverse health outcomes, neither were peer reviewed, and both were published in 2025.[53] Before he co-authored these articles, Levi is on record stating that: "The evidence is mounting and indisputable that mRNA vaccines cause serious harm including death, especially among young people. We have to stop giving them

[50] *Renowned Epidemiologist and Biostatistician Martin Kulldorff Appointed to Senior HHS Role*, HHS (Dec. 1, 2025), https://www.hhs.gov/press-room/renowned-epidemiologist-and-biostatistician-martin-kulldorff-appointed-to-senior-hhs-role.html.

[51] Levi's bio notes that he is "the J. Spencer Standish (1945) Professor of Operations Management at the MIT Sloan School of Management. He is a member of the Operations Management Group at MIT Sloan and affiliated with the MIT Operations Research Center. Levi also serves as the faculty leader for Food Chain Supply Analytics. … *Levi's current research is focused on the design of analytical data-driven decision support models and tools addressing complex business and system design decisions under uncertainty in areas such as health and healthcare management, supply chain, procurement and inventory management, revenue management, pricing optimization and logistics*. He is interested in the theory underlying these models and algorithms, as well as their computational and organizational applicability in practical settings." *Retsef Levi*, MASS. INST. OF TECH., https://mitsloan.mit.edu/faculty/directory/retsef-levi (last visited Nov. 2, 2025).

[52] *ACIP Membership Roster*, CDC (Sept. 16, 2025), https://www.cdc.gov/acip/membership/roster.html#cdc_generic_section_5-evelyn-griffin-m-d (emphasis added).

[53] Retsef Levi, et al., *Twelve-Month All-Cause Mortality after Initial COVID-19 Vaccination with Pfizer-BioNTech or mRNA-1273 among Adults Living in Florida*, MEDRXIV (Apr. 29, 2025), https://www.medrxiv.org/content/10.1101/2025.04.25.25326460v1; Josh Guetzkow, et al., *Observed-to-Expected Fetal Losses Following mRNA COVID-19 Vaccination in Early Pregnancy*, MEDRXIV (June 20, 2025), https://www.medrxiv.org/content/10.1101/2025.06.18.25329352v1.full-text.

immediately!"[54] Both of Levi's studies were published online by medRxiv, which warns that: "This article is a preprint and has not been peer reviewed. It reports new medical research that has yet to be evaluated and so should *not* be used to guide clinical practice." The publisher further warns that "authors use the medRxiv service to make their manuscripts available as 'preprints' before certification by peer review, allowing other scientists to see, discuss, and comment on the findings immediately. Readers should therefore be aware that articles on medRxiv have not been finalized by authors, *might contain errors, and report information that has not yet been accepted or endorsed in any way by the scientific or medical community*. We also urge journalists and other individuals who report on medical research to the general public to consider this when discussing work that appears on medRxiv preprints and *emphasize it has yet to be evaluated by the medical community and the information presented may be erroneous."*[55] A co-author of one of these articles was Dr. Joseph Lapado, the current Surgeon General of the State of Florida, who has vowed to eliminate all vaccine mandates in the State of Florida and has compared vaccine mandates to slavery.[56] On the other article, a co-author was Tracy Beth Høeg, a surprise hire as a "special assistant" at the FDA in April 2025, who is a former sports medicine doctor who has promoted incorrect information and misinterpreted data about vaccines. [57,58]

(h) **Robert W. Malone** has an MS in Biology from UC San Diego, an MD from Northwestern University, did one year of post-doctoral work at Harvard University, and was involved in early research on mRNA technology in the 1980s and 1990s. Malone claimed to be

[54] Retsef Levi (@RetsefL), X (Jan. 30, 2025, 1:28 AM), https://x.com/RetsefL/status/1619945525670981632.
[55] *Frequently Asked Questions (FAQ)*, MEDRXIV, https://www.medrxiv.org/about/FAQ#unrefereed (last visited Nov. 4, 2025) (emphasis added).
[56] Kayla Epstein, *The Florida surgeon general who likens vaccine mandates to slavery*, BBC NEWS (Sept. 4, 2025) https://www.bbc.com/news/articles/c62q41qm9pvo.
[57] Sarah Karlin-Smith, *'Highly Problematic': Acting FDA Commissioner Paused Planned OK Of Novavax Shot*, CITELINE (Apr. 4, 2025), https://insights.citeline.com/pink-sheet/agency-leadership/us-fda/highly-problematic-acting-fda-commissioner-paused-planned-ok-of-novavax-shot-GUT6LR4X6ZALRMMZAEXYZHY36Y/.
[58] *Id.*

the inventor of mRNA vaccines, but "[w]hile he was involved in some early research into the technology, his role in its creation was minimal at best", according to half a dozen Covid experts and researchers, including three who worked closely with Dr. Malone.[59] Malone spread so much misinformation and disinformation about the COVID-19 vaccine that he was permanently suspended from Twitter for repeated violations of Twitter's COVID-19 misinformation policy.[60] Malone claimed on The Joe Rogan Experience podcast in late 2021 that "mass formation psychosis" was developing in American society in its reaction to COVID-19 just as during the rise of Nazi Germany[61] and has spoken at anti-vaccine rallies.[62]

(i) **Cody Meissner** is "a Professor of Pediatrics at the Geisel School of Medicine at Dartmouth and a nationally recognized expert in pediatric infectious disease epidemiology, vaccine development, and immunization safety. He previously served as Chief of the Division of Pediatric Infectious Disease at Tufts-New England Medical Center and on the CDC's Advisory Committee on Immunization Practices and the FDA's Vaccine and Related Biologic Products Advisory Committee."[63]

(j) **Kirk Milhoan** has an MD from Jefferson Medical College and a Ph.D. in the mechanisms of myocardial inflammation from University of California, San Diego. He is a Senior Fellow at the Independent Medical Alliance, which advocates for mRNA-based Covid-19

[59] Davey Alba, *The Latest Covid Misinformation Star Says He Invited the Vaccines*, NEW YORK TIMES (Apr. 3, 2022), https://www.nytimes.com/2022/04/03/technology/robert-malone-covid.html.
[60] Sophie Mellor, *Science Vs podcast takes on the Joe Rogan Experience and others, vowing to fact-check what Spotify won't*, FORTUNE (Feb. 1, 2022), https://fortune.com/2022/02/01/science-vs-podcast-drops-show-focus-fact-checking-joe-rogan-experience-spotify-slap-in-the-face/.
[61] Timothy Bella, *A vaccine scientist's discredited claims have bolstered a movement of misinformation*, THE WASH. POST (Jan. 24, 2022), https://www.washingtonpost.com/health/2022/01/24/robert-malone-vaccine-misinformation-rogan-mandates/.
[62] *Id.*
[63] *ACIP Membership Roster*, CDC (Sept. 16, 2025), https://www.cdc.gov/acip/membership/roster.html.

vaccines to be withdrawn from the market.[64] The Secretary appointed Milhoan Chair of the ACIP upon Kulldorff's transfer to another office inside HHS.[65]

(k) **James Pagano**, according to the CDC's website, "is a board-certified emergency medicine physician with more than 40 years of clinical experience. He has worked in diverse emergency settings, from Level 1 trauma centers to small community hospitals, caring for patients across all age groups including infants, pregnant women, and the elderly. Dr. Pagano has served on multiple hospital committees, including utilization review, critical care, and medical executive boards."[66] He has no discernable expertise in vaccines or immunology.

(l) **Vicky Pebsworth**, who has a Ph.D in Health Services Organization and Policy from University of Michigan, is currently the Director of Research & Patient Safety at the National Vaccine Information Center, a known anti-vaccine organization and has "'probably been anti-vax longer than RFK has.'"[67]

(m) **Catherine Stein**, who has a Ph.D. in Epidemiology and Biostatistics from Case Western Reserve University, is a "COVID-19 truther" who claimed that Covid-19 was "not the scary killer the media and government portray it to be," and claimed that Ohio's Department of Health was misconstruing the data.[68] Stein has ties to Health Freedom Ohio, which is linked to Children's Health Defense, the anti-vaccine organization founded by the Secretary.[69] Dr. Stein has testified in support of different versions of legislation written to allow lawmakers to vote down

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[64] Stephanie Armour, *mRNA Vaccines, Once a Trump Boast, Now Face Attacks from Some in GOP*, KFF HEALTH NEWS (Mar. 10, 2025), https://kffhealthnews.org/news/article/mrna-vaccines-trump-boast-under-gop-attacks-legislation/

[65] *See supra* text accompanying note 50.

[66] *ACIP Membership Roster*, CDC (Sept. 16, 2025), https://www.cdc.gov/acip/membership/roster.html.

[67] *Nurse on new CDC Vaccine Panel said to have been 'anti-vax longer than RFK,'* The Guardian (July 5, 2025) https://www.theguardian.com/us-news/2025/jul/05/vicky-pebsworth-vaccine-experts-rfk-jr

[68] Jake Zuckerman, *She's a public health professor by day; a COVID-19 truther by night*, THE OHIO CAPITAL JOURNAL (Feb. 22, 2021), https://ohiocapitaljournal.com/2021/02/22/shes-a-public-health-professor-by-day-a-covid-19-truther-by-night/.

[69] Sara Moniuszko, *New CDC advisory panel members include more COVID vaccine critics*, CBS NEWS (Sept. 16, 2025), https://www.cbsnews.com/news/new-cdc-acip-members-covid-vaccine-critics/.

public health orders. She has spoken in support of the bills alongside affiliates of Health Freedom Ohio and the Ohio Advocates for Medical Freedom, another anti-vaccine group. Dr. Stein also testified in support of a "Truth in Covid Statistics" bill, which essentially would force the Ohio Department of Health to publish certain data points about Covid-19 — most of which the department already publishes. She also has spread misinformation equating Covid-19 disease severity with influenza.

(n) **Raymond Pollack** is the Chief of Liver Transplantation and Director of Multiorgan Transplant Programs at the University of Illinois and has held leadership roles with the United Network for Organ Sharing and the American Society of Transplant Surgeons. He lacks expertise regarding vaccines and infectious disease.

78. With the recent appointments of two more anti-vaxxers, ten out of the 14 current ACIP members have publicly stated views on vaccines that align with the Secretary's. Seven lack the relevant expertise and credentials required by the ACIP Charter. Only one (Cody Meissner) has legitimate credentials and expertise comparable to those whom the Secretary fired from the ACIP.

79. None of the new ACIP members were required to follow the rigorous application process to become an ACIP member.[70] Historically, the application process to become a voting ACIP member has taken up to two years.

80. The Secretary's appointments of non-experts to the ACIP reflect his well-documented distrust of experts. In an interview with Tucker Carlson on June 30, 2025, he stated:

> You know, my opinion, I always tell people is irrelevant. Um, we, you know, people, ***we need to stop trusting the experts, right***? We were told at the beginning of Covid don't look at any data yourself. Don't do any

[70] *Id.*; *Apply for ACIP Membership*, CDC (Dec. 20, 2024), https://www.cdc.gov/acip/apply-for-membership/; Edwin J. Asturias, MD, et al., *Advisory Committee on Immunization Practices at a Crossroads*, 334 JAMA NETWORK (2025), https://jamanetwork.com/journals/jama/article-abstract/2835626.

> investigation yourself. Just trust the experts. And trusting the experts is not a feature of science. It's not a feature of democracy. It's a feature of religion and it's a feature of totalitarianism. In democracies, we have the obligation, and it's one of the burdens of citizenship, to do our own research and make our own determinations about things.[71]

81. In a recent appearance on a podcast, the Secretary repeated his distrust of experts, when asked the question "what would you currently recommend that I give my child upon birth?" His response was:

> We've made our recommendations and as an agency, I don't give medical advice to individuals because I'm not a doctor and I'm not competent to do that. And but what I would say to people is do your own research that, you know, um ***this idea that you should trust the experts. A good mother doesn't do that. Good, good mother***.[72]

82. On July 31, 2025, an email from acip@cdc.gov was sent to members of ACIP Liaison organizations, which include members of Plaintiffs AAP and ACP, informing them that Liaison organizations were terminated from participating in ACIP workgroups like the Covid-19 Work Group. The pretextual reason given in the email was that "[l]iaison organizations are special interest groups and therefore are expected to have a 'bias' based on their constituency and/or population they represent. It is important that the ACIP Workgroup activities remain free of influence from any special interest groups so ACIP workgroups will no longer include Liaison organizations." While Liaison members do not vote at ACIP public meetings on vaccine recommendations, they have "historically done important work undertaking detailed evidence reviews of the safety and effectiveness of vaccines that helps to inform the group's votes."[73]

83. The ACIP Charter, however, states that: "There also ***shall*** be non-voting liaison representatives from … American Academy of Pediatrics; … the American College of Physicians;

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[71] The Katie Miller Podcast, *RFK Jr. on Dietary Guidelines, Vaccines & Trump*, at 13:52─14:35 (Jan. 13, 2026) (emphasis added), https://www.youtube.com/watch?v=w_fzlwxJZAA&t=843s.
[72] *Id.* at 16:52─17:17.
[73] Brenda Goodman, *HHS further constrains certain vaccine advisors to the CDC, limiting their input in evidence reviews,* CNN (Aug. 1, 2025), https://www.cnn.com/2025/08/01/health/hhs-liaison-acip-vaccine-advisers-cdc.

… Infectious Diseases Society of America; …" The Secretary's termination of liaison representatives from participation in ACIP work groups violates the ACIP Charter.

E. THE THREE MEETINGS OF THIS ACIP

The December 4-5, 2025 Meeting

84. This ACIP held three public meetings in 2025: June 25-26, September 18-19, and December 4-5. At each meeting of this ACIP, current ACIP members and invited speakers made claims "that were inaccurate, misleading, or not supported by the best available evidence."[74]

85. At the December 4-5 ACIP meeting, voting members and presenters made numerous false or misleading statements, including the following:

Claim	Statements	Correction
Pre-licensure trials for hepatitis B vaccines had no control groups and only days of safety follow-up.	Aaron Siri, Dec. 5, at 3:17:13 ("the two current standalone hepatitis B vaccines, Engerix B and Recombivax HB... were licensed for children based on an uncontrolled trial. So there was no control group.")[75] Mark Blaxill, Dec. 4, at 1:12:24 ("there were basically no randomized or placebo-controlled trials … the cited trials had very short follow-up periods").[76]	There have been more than 15 studies of Hep B vaccines, including randomized control studies and extensive US "real-world" analyses (VSD, VAERS). Follow-up periods ranged from 21 days to 24 months. Four studies directly compared birth dose to delayed first dose and found no increased risk of any short- or long-term adverse events.[78]

[74] Marisa Donnelly, *et al*., Summary Of 2025 ACIP Meetings, THE EVIDENCE COLLECTIVE (Jan. 2026) (emphasis added) https://static1.squarespace.com/static/68435457c33bc03421c23ff7/t/696beaa8cb9b640a609a510f/1768680104162/2025+ACIP+Falsehoods+Recap_Highlights.pdf.

[75] *Advisory Committee on Immunization Practices (ACIP) – December 5, 2025 – Day 2 of 2*, CDC, at 3:17:13 (Dec. 5, 2025) https://www.youtube.com/live/kUgXRUpKal4.

[76] *Advisory Committee on Immunization Practices (ACIP) – December 4, 2025 – Day 1 of 2*, CDC, at 1:12:24 (Dec. 4, 2025) https://www.youtube.com/watch?v=LpthhPBFAgI.

[78] Marisa Donnelly, *et al*., Summary Of 2025 ACIP Meetings, THE EVIDENCE COLLECTIVE (Jan. 2026) (emphasis added) https://static1.squarespace.com/static/68435457c33bc03421c23ff7/t/696beaa8cb9b640a609a510f/1768680104162/2025+ACIP+Falsehoods+Recap_Highlights.pdf.

Claim	Statements	Correction
	Evelyn Griffin, Dec. 4, at 2:38:08 ("These two products for birth dose were set for four and five days of testing, and without a placebo trial.").[77]	
Hepatitis B vaccine is associated with Sudden Infant Death Syndrome ("SIDS")	Mark Blaxill, Day 1, 1:25:02 ("There were eight cases of SIDS and that was the single largest cause of death in the vaccinated group … There were zero cases of SIDS in the unvaccinated group. That was a potential signal that the authors discounted."[79]	Multiple studies have found no association between vaccines and SIDS, including at least one focused explicitly on the Hepatitis B vaccine. The study referred to "did not withstand statistical scrutiny … The total number of unexpected infant deaths from any cause was not statistically different between the vaccinated and unvaccinated groups. The unvaccinated group had zero SIDS deaths but higher rates of other causes of death, suggesting infants in this group were more medically fragile, making them a poor comparison group for this study. When the authors calculated SIDS rates using the full population, 240,717 vaccinated infants (8 SIDS deaths, 3.3 per 100,000) and 120,979 unvaccinated infants (4 SIDS deaths, also 3.3 per 100,000), the rates were identical. The apparent imbalance found in this single study reflects confounding, not a real signal. The study found no causal or temporal link

[77] *Advisory Committee on Immunization Practices (ACIP) – December 4, 2025 – Day 1 of 2*, CDC, at 2:38:08 (Dec. 4, 2025) https://www.youtube.com/watch?v=LpthhPBFAgI.
[79] *Id.* at 1:25:02.

Claim	Statements	Correction
		between vaccination and death."[80]
"Targeted measures" have been more effective than universal vaccination for Hepatitis B disease.	Cynthia Nevison, Dec. 4, at 39:01 ("it's the more targeted measures that have had the biggest effect in bringing down cases of Hepatitis B"); and 41:12 ("selective vaccination of persons with identified risk factors has not lowered the incidence of Hepatitis B, but that is not true according to this graphs because the cases were already down 33 percent by 1991").[81]	"A targeted strategy that focused on vaccinating only infants with HepB-positive mothers was implemented throughout the 1980s and was unsuccessful at decreasing rates of disease. A 1991 CDC MMWR that recommended switching to universal vaccination explicitly stated: 'Over one-third of patients with acute hepatitis B do not have readily identifiable risk factors.' This makes targeted approaches ineffective. Similarly, 35–65% of HBsAg-positive mothers had no identifiable risk factors and would never have been flagged under targeted screening. The 1991 switch to universal vaccination reduced pediatric hepatitis B cases by 99% (from 16,000 to fewer than 20 annually). The pre-1991 declines in hepatitis B cases that Nevison cited were in adult populations due to blood screening. This cannot be used as evidence for targeted infant vaccination."[82]

[80] Marisa Donnelly, *et al.*, Summary Of 2025 ACIP Meetings, THE EVIDENCE COLLECTIVE (Jan. 2026) (emphasis added) https://static1.squarespace.com/static/68435457c33bc03421c23ff7/t/696beaa8cb9b640a609a510f/1768680104162/2025+ACIP+Falsehoods+Recap_Highlights.pdf.

[81] *Advisory Committee on Immunization Practices (ACIP) – December 4, 2025 – Day 1 of 2*, CDC, at 39:01, 41:12 (Dec. 4, 2025) https://www.youtube.com/watch?v=LpthhPBFAgI.

[82] Marisa Donnelly *et al.*, *Summary Of 2025 ACIP Meetings*, THE EVIDENCE COLLECTIVE (Jan. 2026) (emphasis added) https://static1.squarespace.com/static/68435457c33bc03421c23ff7/t/696beaa8cb9b640a609a510f/1768680104162/2025+ACIP+Falsehoods+Recap_Highlights.pdf.

86. **The hepatitis B vote**: at the December 5, 2025, meeting, the ACIP voted "8 to 3 to recommend individual-based decision-making for parents deciding whether to give the hepatitis B vaccine, including the birth dose, to infants born to women who test negative for the virus."[83] The new recommendation is that parents discuss with their doctors whether to give the hepatitis B vaccine at birth, or at all, and that those who choose to do so should wait to begin the vaccine series until their baby is at least two months old.

(a) Since 1991, the United States has recommended that all babies receive a dose of hepatitis B vaccine within 24 hours of birth, including mothers who test negative for the hepatitis B surface antigen (HBsAg-negative).[84] The second dose is given at 1 to 2 months and a third dose at 6 to 18 months.

(b) The presenters on the hepatitis B vaccine the morning of the December 4, 2025 ACIP meeting (Pebsworth, Nevison, Blaxill) presented no fresh safety concerns or effectiveness issues that would prompt reconsideration of the hepatitis B vaccine birth dose. Instead, "panelists said the review was prompted by parents concerned about the shot, the fact that most European countries give the immunization a few months after birth, and the length of time since ACIP last reviewed the topic."[85]

(c) Before the 1991 universal birth dose recommendation, the United States had tried a targeted approach like the one the ACIP voted to recommend on December 5. "A targeted

[83] *ACIP Recommends Individual Based Decision-Making for Hepatitis B Vaccine for Infants Born to Women Who Test Negative for the Virus*, CDC (Dec. 5, 2025), https://www.cdc.gov/media/releases/2025/2025-acip-recommends-individual-based-decision-making-for-hepatitis-b-vaccine-for-infants-born-to-women.html.
[84] Aliza Rosen, *Hepatitis B Vaccination is an Essential Safety Net for Newborns*, JOHNS HOPKINS BLOOMBERG SCHOOL OF PUBLIC HEALTH (Sept. 24, 2025) https://publichealth.jhu.edu/2025/why-hepatitis-b-vaccination-begins-at-birth; *see also Hepatitis B Perinatal Vaccine Information*, CDC (Aug. 27, 2025), https://www.cdc.gov/hepatitis-b/hcp/perinatal-provider-overview/vaccine-administration.html#:~:text=Birth%20dose,a%20parent%20with%20HBV%20infection.
[85] Helen Braswell, *CDC panel recommends delaying birth dose of hepatitis B vaccine*, STAT (Dec. 5, 2025), https://www.statnews.com/2025/12/05/cdc-hepatitis-b-vaccination-acip-panel-overturns-30-year-policy/.

strategy that focused on vaccinating only infants with HepB-positive mothers was implemented throughout the 1980s and was unsuccessful at decreasing rates of disease. A 1991 CDC MMWR that recommended switching to universal vaccination explicitly stated: 'Over one-third of patients with acute hepatitis B do not have readily identifiable risk factors.' This makes targeted approaches ineffective. Similarly, 35–65%_of HBsAg-positive mothers had no identifiable risk factors and would never have been flagged under targeted screening. The 1991 switch to universal vaccination ***reduced pediatric hepatitis B cases by 99% (from 16,000 to fewer than 20 annually)***."[86]

(d) Before he joined the Senate, Senator Bill Cassidy (R-La.) was a liver doctor. He posted the following on social media after the December 5 vote: "As a liver doctor who has treated patients with hepatitis B for decades, this change to the vaccine schedule is a mistake. This makes America sicker."[87]

(e) A modeling study on the impact of removing the universal birth dose of hepatitis B was posted online shortly before the December 4-5 ACIP meeting.[88] The results of the study were:

> **Results** All delayed vaccination scenarios resulted in more infections, worse health outcomes, and higher costs than the current universal birth dose recommendation. Under perfect adherence, delaying HepB vaccination by 2 months for infants of HBsAg-negative parents led to an additional 90 acute infections, 75 chronic infections, 29 HBV-related deaths, with $16.4 million in added costs for infants born during one year. Delaying to 12 years resulted in an additional 190 acute infections, 50 deaths, and nearly $30 million in added costs. Delaying HepB vaccination to 12 years for infants of both HBsAg-negative and HBsAg-unknown parents resulted in an additional 2,351 acute infections, 744 deaths, and

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[86] Marisa Donnelly, *et al*., *Summary Of 2025 ACIP Meetings*, THE EVIDENCE COLLECTIVE (Jan. 2026) (emphasis added) https://static1.squarespace.com/static/68435457c33bc03421c23ff7/t/696beaa8cb9b640a609a510f/1768680104162/2025+ACIP+Falsehoods+Recap_Highlights.pdf.

[87] Helen Braswell, *CDC panel recommends delaying birth dose of hepatitis B vaccine*, STAT (Dec. 5, 2025), https://www.statnews.com/2025/12/05/cdc-hepatitis-b-vaccination-acip-panel-overturns-30-year-policy/.

[88] Eric W. Hall, *et al.*, *Economic evaluation of delaying the infant hepatitis B vaccination schedule*, MEDRxiv (Nov. 25, 2025) (Preprint), https://www.medrxiv.org/content/10.1101/2025.11.24.25340907v1.full.pdf.

> $368 million in excess costs. Imperfect adherence to the vaccination schedule amplified all negative outcomes substantially. Incorporating pre-vaccination serologic screening for delayed schedules markedly increased total costs.
>
> **Conclusions** Even brief delays in HepB vaccine initiation substantially increase HBV infections, adverse health outcomes, and health system costs. Our results quantify and demonstrate the importance of the universal HepB birth dose in preventing perinatal and early childhood HBV transmission in the United States.

(f) On December 16, the CDC adopted the ACIP's December 5 vote on the hepatitis B immunization, thus making it a final agency action.[89]

September 18-19, 2025 Meeting

87. At the September 18-19 ACIP meeting, voting members and presenters made numerous false or misleading statements, including the following:

Claim	Statements	Correction
Hep B vaccines are unsafe	Malone, September 19, at 25:22: "We have an IOM report indicating that they could not conclude statistically whether or not those [case reports] had merit. That does not mean that it is safe, which was the assertion."[90]	The Institute of Medicine found insufficient evidence to establish causation for extremely rare events (except anaphylaxis). Insufficient evidence "means there was not enough evidence to suggest that vaccines were causing these rare events. It does not mean that harm was found. Rare, coincidental events occur when vaccinating millions; causation requires large studies. It should also be noted that, because these events are so rare, our main source of evidence for them is case reports, which actually underscores that the vaccines

[89] *CDC Adopts Individual-Based Decision-Maing for Hepatitis B Immunization for Infants Born to Women Who Test Negative for the Hepatitis B Virus*, CDC (Dec. 16, 2025), https://www.hhs.gov/press-room/cdc-adopts-individual-based-decision-making-for-hepatitis-b-immunization-for-infants-born-to-women-who-test-negative-for-the-hepatitis-b-virus.html.

[90] *Advisory Committee on Immunization Practices (ACIP) – September 19, 2025 – Day 2 of 2*, CDC, at 25:22 (Sept. 19, 2025) https://www.youtube.com/watch?v=_9ChY9SpPlY.

Claim	Statements	Correction
		in question are safe for the vast majority of people."[91,92]
Covid-19 vaccines contain dangerous levels of DNA contamination exceeding regulatory limits.	El-Deiry and Kuperwasser, September 19, at 2:12:06: "DNA impurities, both the Pfizer and Moderna vaccines have been found to contain DNA that exceeds the FDA limits. Importantly, the DNA impurity limits do not take into account lipid nanoparticles, which carry DNA into cells and nuclei. There are concerns due to known DNA integration and gene activation disruption by SV40 promoter/enhancer sequences."[93]	"Manufacturing impurities, including DNA, are carefully monitored because the FDA requires that residual DNA in vaccines below 10 ng per dose. The presence of DNA fragments used in the manufacturing process is expected, found at acceptable levels, and is accounted for in safety standards. Multiple independent analyses have confirmed that mRNA vaccines meet these stringent requirements. Claims of dangerous DNA contamination typically arise from studies that use inappropriate detection methods or misinterpret the significance of trace amounts that are orders of magnitude below safety thresholds. Moreover, the work that initially flagged the concern used inappropriate methods. Despite this, they found that vaccine lots with DNA levels above regulatory limits had fewer VAERS reports than those below the limits. SV40 (simian virus 40) is a virus originally found in a monkey kidney cell line that was used in the production of polio vaccines. Some data

[91] Marisa Donnelly, *et al*., *Summary Of 2025 ACIP Meetings*, THE EVIDENCE COLLECTIVE (Jan. 2026) (emphasis added) https://static1.squarespace.com/static/68435457c33bc03421c23ff7/t/696beaa8cb9b640a609a510f/1768680104162/2025+ACIP+Falsehoods+Recap_Highlights.pdf.

[92] INST. OF MED. OF THE NAT'L ACADEMIES, *Hepatitis B Vaccines in* ADVERSE EVENTS OF VACCINES: EVIDENCE AND CAUSALITY 435, 435–91 (2012), https://www.nationalacademies.org/read/13164/chapter/10#437.

[93] *Advisory Committee on Immunization Practices (ACIP) – September 19, 2025 – Day 2 of 2*, CDC, at 2:12:06 (Sept. 19, 2025) https://www.youtube.com/watch?v=_9ChY9SpPlY.

Claim	Statements	Correction
		suggest SV40 infection may be associated with cancer development. But these vaccine claims related to SV40 are false. COVID-19 vaccines do not contain the SV40 virus. The sequence in question is a small DNA piece from SV40 used during the manufacturing process of mRNA vaccines. This fragment cannot cause infection or cancer because it does not encode the full SV40 virus or any of its proteins. Moreover, during the manufacturing process, the vaccine undergoes treatments with enzymes that destroy DNA. This means the sequences remaining in the vaccines are short and uninformative. Even in the historical case where the SV40 virus contaminated some polio vaccines in the 1950s and 1960s, large U.S. studies found no increased cancer risk among people who received them, and subsequent data showing links were later shown to reflect reagent issues and laboratory contamination. The quoted section also describes integration—when a virus's genome (or parts of it) becomes part of the cell's genome, allowing it to persist. Integration has been observed in cells infected with SV40, but SV40 lacks the specific machinery some other viruses have for this. When it does happen, it's a random event: the cell's normal DNA repair

Claim	Statements	Correction
		processes accidentally incorporate nearby DNA. There's no evidence that the SV40 fragment in the vaccines plays any special role in making this happen."[94]
CDC lacks proper safety evaluations of vaccines.	Levi, September 19, at 4:46:16: "Do we have a culture of safety? And what would it take for us to acknowledge that there is a problem...?"[95]	"CDC operates multiple robust safety monitoring systems, including VAERS, VSD, and V-safe, which have successfully identified even extremely rare side effects, such as myocarditis (occurring at approximately 1-17 per 100,000 doses in the highest-risk groups). These systems lead to immediate investigation and transparent communication about risks. They also led to the detection of vaccine-induced immune thrombotic thrombocytopenia (a rare but devastating clotting complication that can readily be fatal if not recognized quickly) after the Janssen vaccine, based on 6 cases out of 6.8 million doses given (this later led to more capture of cases, giving an overall rate of approximately 1 in 330,000 doses). This safety signal was first identified by the CDC and FDA on April 9, 2021, and triggered a nationwide "pause" announced on April 13, 2021, followed by an emergency ACIP meeting on April 14. The detection of

[94] Marisa Donnelly, *et al.*, *Summary Of 2025 ACIP Meetings*, THE EVIDENCE COLLECTIVE (Jan. 2026) (emphasis added) https://static1.squarespace.com/static/68435457c33bc03421c23ff7/t/696beaa8cb9b640a609a510f/1768680104162/2025+ACIP+Falsehoods+Recap_Highlights.pdf.

[95] *Advisory Committee on Immunization Practices (ACIP) – September 19, 2025 – Day 2 of 2*, CDC, at 4:46:16 (Sept. 19, 2025) https://www.youtube.com/watch?v=_9ChY9SpPlY.

Claim	Statements	Correction
		these rare events and swift action demonstrated that safety monitoring is prioritized and works as intended."[96]

88. **The Covid Vote:** on September 19, the ACIP voted to change the Covid-19 vaccine recommendation for adults from routine to SCDM.

(a) Defendant O'Neill finalized this agency action on or about October 6 when he announced on X that he had adopted the September 19 vote of the ACIP on the Covid-19 vaccine recommendation for adults. In an October 6 post on X, O'Neill stated: "[i]nformed consent is back. CDC's 2022 blanket recommendation for perpetual COVID-19 boosters deterred health care providers from talking about the risks and benefits of vaccination for the individual patient or parent. That changes today." Informed consent and SCDM are not the same thing. Doctors have always had discussions and obtained informed consent from patients before performing procedures, including administering a vaccine. In contrast, the CDC's website states that, "[u]nlike routine, catch-up, and risk-based recommendations, shared clinical decision-making vaccinations are individually based and informed by a decision process between the health care provider and the patient or parent/guardian."[97]

(b) The ACIP did not apply GRADE criteria or follow the EtR framework prior to voting to change the CDC's immunization schedule in September, 2025 to designate the Covid-

[96] Marisa Donnelly, *et al.*, *Summary Of 2025 ACIP Meetings*, THE EVIDENCE COLLECTIVE (Jan. 2026) (emphasis added) https://static1.squarespace.com/static/68435457c33bc03421c23ff7/t/696beaa8cb9b640a609a510f/1768680104162/2025+ACIP+Falsehoods+Recap_Highlights.pdf.

[97] *ACIP Shared Clinical Decision-Making Recommendations*, CDC (Jan. 7, 2025), https://www.cdc.gov/acip/vaccine-recommendations/shared-clinical-decision-making.html.

19 vaccine as SCDM.

(c) The ACIP did not consult with the Covid-19 Work Group prior to voting to designate the Covid-19 vaccine as SCDM for adults.

(d) Unlike the four previous occasions that the ACIP voted to designate a vaccine as SCDM, the CDC published no explanation or guidance in the MMWR as to how clinicians should engage in SCDM with patients.

June 25-26, 2025 Meeting

89. At the June 25-26 ACIP meeting, voting members and presenters made numerous false or misleading statements, including the following:

Claim	Statements	Correction
Emphasis on myocarditis risk from COVID vaccines without considering myocarditis risk from Covid-19 disease.	Høeg, June 25, at 4:13:08: "..concern about ongoing myocardial damage that was seen with late gadolinium enhancement or MRI imaging about a half a year after, about a half a year after vaccination with uncertain clinical significance. But because of that, we did, we did announce that there was a safety label change today to the mRNA vaccines."[98]	"Covid-19 vaccination reduces the risk of myocarditis associated with SARS-CoV-2 infection. SARS-CoV-2 poses a much greater myocarditis risk than vaccines for nearly all demographics. Newer analyses have also shown that rates of vaccine-associated myocarditis have dropped to levels comparable to the background incidence (i.e., an increased risk is not observed), suggesting a role for dosing intervals in myocarditis risk. The evolution of the long-term prognosis of vaccine myocarditis is being actively monitored, but thus far, post-vaccination myocarditis outcomes are much better than post-infection outcomes."[99]

[98] *Advisory Committee on Immunization Practices (ACIP) – Day 1 of 2* CDC, at 4:13:08 (June 25, 2025), https://www.youtube.com/watch?v=_9ChY9SpPlY.

[99] Marisa Donnelly, *et al.*, *Summary Of 2025 ACIP Meetings*, THE EVIDENCE COLLECTIVE (Jan. 2026) (emphasis added), https://static1.squarespace.com/static/68435457c33bc03421c23ff7/t/696beaa8cb9b640a609a510f/1768680104162/2025+ACIP+Falsehoods+Recap_Highlights.pdf.

Claim	Statements	Correction
RSV monoclonal antibodies show concerning infant death signals.	Levi, June 26, at 6:42 "Now, if I look on the clinical trials of the product we are supposed to vote on today, this is the clesrovimab, again, a trial of two-to-one with healthy children. There is, again, imbalance on the deaths, seven to three,...So, when I look on all of this, I would like to hear maybe from our colleagues at the CDC, should we not be concerned that maybe there are some safety, potential safety signals?"[100]	"There were 3 deaths in the MELODY trial among the group that received nirsevimab (the name of the monoclonal antibodies). None were deemed related to nirsevimab (2 were from gastroenteritis with no medical encounter, and 1 in a child with failure to thrive and multiple comorbidities). Though two of these deaths both occurred at around 140 days, they had different causes, and the gastroenteritis cases did not cluster together in time. It is difficult to argue that the deaths could plausibly be related to nirsevimab. Levi also cited an imbalance of deaths in the phase 3 trials for clesrovimab (a second RSV monoclonal antibody — 7 deaths vs 3 for clesrovimab vs placebo). This is misleading, given that the trial used a 2:1 randomization ratio (clecivimab:placebo). With twice as many participants in the clesrovimab group, you would statistically expect approximately twice as many deaths in that group. These rates are too similar to be able to conclude that they aren't more than random chance."[101]
Thimerosal is not an effective preservative and was never adequately safety tested before widespread use.	Redwood, June 26, at 2:34:24: "They also found evidence that thimerosal was no better than water	"Thimerosal was introduced after repeated outbreaks of fatal bacterial contamination associated with multi-dose

[100] *Advisory Committee on Immunization Practices (ACIP) – Day 2 of 2* CDC, at 6:24 (June 26, 2025), https://www.youtube.com/watch?v=z-16fImZoEc.

[101] Marisa Donnelly, *et al.*, *Summary Of 2025 ACIP Meetings*, THE EVIDENCE COLLECTIVE (Jan. 2026) (emphasis added), https://static1.squarespace.com/static/68435457c33bc03421c23ff7/t/696beaa8cb9b640a609a510f/1768680104162/2025+ACIP+Falsehoods+Recap_Highlights.pdf.

Claim	Statements	Correction
	in protecting mice from potential fatal streptococcal infections. Redwood at 2:32:38: "FDA grandfathered in thimerosal without formal submission of any animal safety data."[102]	vaccine vials in the early 20th century. Multiple studies demonstrated that thimerosal was highly effective at preventing bacterial and fungal growth, outperforming alternative preservatives available at the time and doing so at much lower concentrations. Following the introduction of thimerosal, contamination-related deaths linked to vaccination dramatically declined. Claims that it is "no better than water" selectively reference short-term vial-entry experiments while ignoring real-world evidence and decades of safe use in vaccines. No evidence shows higher contamination rates in thimerosal-containing vaccines compared with alternatives. The claim that thimerosal was 'grandfathered in' without adequate testing misrepresents the regulatory and scientific history. Before widespread use, thimerosal underwent extensive animal testing. Following licensure, thimerosal-containing vaccines were among the most intensively studied products in vaccinology, with large epidemiologic studies conducted across multiple countries. Post-licensure surveillance and population-based studies consistently found no association between thimerosal-containing vaccines

[102] *Advisory Committee on Immunization Practices (ACIP) – Day 2 of 2* CDC, at 2:34:24, 2:32:38 (June 26, 2025), https://www.youtube.com/watch?v=z-16fImZoEc.

Claim	Statements	Correction
		and neurologic, developmental, or systemic harms. Characterizing this as 'insufficient testing' ignores both preclinical toxicology and decades of real-world safety data."[103]

90. **The thimerosal vote**: on June 26, the brand new ACIP "passed three recommendations requiring that flu shot manufacturers discontinue the use of thimerosal in the production of influenza vaccine doses aimed at children, pregnant people, and adults. There was no explanation for why three separate recommendations were voted on when the end goal was to stop using the preservation in all flu vaccines brought to the U.S. market."[104]

91. This vote was based on cherry-picked data and long-debunked junk science.

92. The Secretary adopted the ACIP's vote on thimerosal on July 23, finalizing this agency action.

F. THE MAY 19 DIRECTIVE

93. The announcement that the Secretary made on May 27[105] instructing the CDC to remove the Covid-19 vaccine recommendation for pregnant women and children came as a surprise to officials at the CDC, who five hours after the video was posted on X, received the written May 19 Directive for the first time.[106]

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[103] Marisa Donnelly, *et al.*, *Summary Of 2025 ACIP Meetings*, THE EVIDENCE COLLECTIVE (Jan. 2026) (emphasis added), https://static1.squarespace.com/static/68435457c33bc03421c23ff7/t/696beaa8cb9b640a609a510f/1768680104162/2025+ACIP+Falsehoods+Recap_Highlights.pdf.

[104] Helen Branswell, *HHS Secretary RFK Jr. accepts recommendations to drop thimerosal from U.S. flu vaccines*, STAT (July 23, 2025), https://www.statnews.com/2025/07/23/kennedy-approves-acip-recommendation-thimerosal-removed-from-flu-vaccines/.

[105] Robert F. Kennedy, Jr. (@SecKennedy), X (May 27, 2025, 10:16 AM), https://x.com/SecKennedy/status/1927368440811008138

[106] Lena H. Sun, *CDC blindsided as RFK Jr. changes covid-19 vaccine recommendations*, THE WASH. POST (May 28, 2025), https://www.washingtonpost.com/health/2025/05/28/vaccines-cdc-rfk-jr-covid/.

94. Just a week before this video appeared on X, and a day after the Directive is dated, FDA Commissioner Marty Makary published an article dated May 20, 2025 in The New England Journal of Medicine that he co-authored with Vinay Prasad, the Director of the Center for Biologics Evaluation and Research in the FDA, stating that "pregnancy and recent pregnancy" are factors which "increase a person's risk of severe COVID-19."[107] Thus, the Directive, announced one week later, shows that "'they literally contradicted themselves over the course of a couple of days.' … 'It appears RFK Jr. reversed his own FDA's decision.'"[108]

95. The CDC's immunization schedules were changed the same day as the May 27 announcement. Although the Directive ordered the CDC "to remove Covid-19 vaccines from the recommended Child and Adolescent Immunization Schedule by Age," the CDC, however, strangely did not entirely remove the recommendation that children be routinely vaccinated against Covid-19. Instead, on May 29, 2025, the CDC downgraded the designation to SCDM.

96. The Secretary did not consult with the ACIP before he signed the Directive.

97. The Secretary did not consult with the Covid-19 Work Group before he signed the Directive.

98. The Secretary did not consult with the CDC about the Directive. In fact, at the April 15, 2025 open meeting of the ACIP, Dr. Lakshmi Panagiotakopoulos, an epidemiologist at the CDC, presented recommendations on use of Covid-19 vaccines for 2025-2026 for different population groups for which there is conclusive evidence of a higher risk of severe illness from the Covid-19 virus.[109] Dr. Panagiotakopoulos noted that pregnant individuals continued to face an

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[107] Vinay Prasad & Martin Makary, *An Evidence-Based Approach to Covid-19 Vaccination*, 392 THE NEW ENGLAND J. MED. 2484, 2485, fig. 2 (2025).
[108] Louis Jacobson, Amy Sherman, *RFK Jr. Ended COVID Vaccine Recommendation for Kids, Pregnant Women. What do Facts Show About Risk?* POLITIFACT (May 29, 2025), https://www.politifact.com/article/2025/may/29/COVID-19-vaccine-RFK-children-pregnant/.
[109] Lakshmi Panagiotakopoulos, Use of 2025–2026 COVID-19 Vaccines: Work Group Considerations (Apr. 15, 2025), https://www.cdc.gov/acip/downloads/slides-2025-04-15-16/05-Panagiotakopoulos-COVID-508.pdf.

increased risk of severe outcomes from contracting Covid-19.[110] Not only does a Covid-19 vaccine protect the mother, but it also protects infants less than six months of age because infants less than six months old cannot receive the Covid-19 vaccine, but the mother can protect the infant by passing antibodies to the fetus from a Covid-19 vaccine administered during pregnancy.[111] Dr. Fiona Havers, also an epidemiologist at the CDC, presented findings at the April 25, 2025 ACIP meeting on the impact of Covid-19 on children in the United States in the past year. "She found that at least 7,000 children were hospitalized with Covid. About 20 percent of those hospitalized were admitted to the intensive care unit, half were previously healthy, virtually none had been vaccinated, and 152 had died, most less than 4 years of age. The conclusion was clear; all children in the United States, whether they were previously healthy or not, should receive the primary series of Covid vaccines."[112]

99. The Secretary cited no emergency, let alone change in circumstances, to justify the Directive.

100. There is no indication that the Secretary engaged in any formal evidence review, applied the GRADE criteria to assure the quality of the evidence relied upon, or applied the EtR framework.

101. The Secretary signed the Directive only five days after he testified before Congress that: "what I would say is my opinions about vaccines are irrelevant," and "I don't think people should be taking medical advice from me."[113]

102. The Directive is contrary to the wealth of data and peer-reviewed studies that

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[110] *Id.* at 11.
[111] *Id.*
[112] Paul Offit, This CDC Resignation Should Scare You, SUBSTACK (July, 8, 2025) https://pauloffit.substack.com/p/this-cdc-resignation-should-scare.
[113] Sara Moniuszko, *RFK Jr. says people shouldn't take his medical advice when asked about vaccines at hearing*, CBS News (May 14, 2025), https://www.cbsnews.com/news/rfk-jr-medical-advice-vaccine-question-hearing/.

demonstrate the safety and efficacy of Covid-19 vaccines for children and pregnant women.

G. HARM

Harm To the Plaintiffs Since The Third Amended Complaint

103. Plaintiffs initiated this action on July 7, 2025, challenging the May 19 Directive. (ECF # 1). Within 21 days of filing and serving the original complaint, Plaintiffs amended the original complaint pursuant to Federal Rule of Civil Procedure 15(a)(1)(A) to add a Plaintiff Organization (the Massachusetts Chapter of the AAP) and Jane Doe 2 as Plaintiffs. (ECF # 63). Plaintiffs filed a Second Amended Complaint on September 3, 2025, to add Jane Doe 3 as a Plaintiff. (ECF # 99). Defendants moved to dismiss the Second Amended Complaint that same day. (ECF # 102). The government's reply brief in support of the motion to dismiss the Second Amended Complaint was due October 3, 2025, and a hearing on the Motion to Dismiss the Second Amended Complaint was scheduled for October 8. The U.S. government, however, shutdown on October 1, and the government's reply brief and the hearing on the motion to dismiss were stayed as a result. (ECF # 121, 122). Plaintiffs moved to lift the stay on this case on October 20 when there appeared to be no end in sight of the shutdown. (ECF # 127). This Court held a hearing on that motion on October 30 and lifted the stay that day. (ECF # 134). At the October 20 hearing, the parties conferred on a briefing schedule on a motion to dismiss a Third Amended Complaint that Plaintiffs informed Defendants and the Court that they intended to file to challenge the final agency action of October 6, 2025 that changed the classification of the Covid vaccine from routine to SCDM for everyone under 65. (*Id.*). Defendants did not object to the filing of a Third Amended Complaint, which was filed on November 5. (ECF # 139). Defendants, however, moved to dismiss the Third Amended Complaint on standing grounds on November 19 (ECF # 144), the Court held a hearing on the motion to dismiss on December 17, 2025 (ECF # 164), and in a January 6, 2026, Memorandum and Order, denied Defendants' Motion to Dismiss. (ECF # 168).

104. Plaintiffs originally filed this action because of the harm that the May 19 Directive caused them and the public. Since then, Defendants' actions with regard to vaccines have been increasingly egregious and have amplified the harm to the Plaintiffs and the public by many orders of magnitude.

105. The final agency actions challenged herein, particularly the December 5 ACIP vote on the hepatitis B vaccine and the January 5 changes to the Childhood Schedule, have forced AAP to divert substantial time, staff attention, and financial resources away from core child-health initiatives and toward emergency mitigation work. AAP is now revising, developing, and distributing materials specifically to address the confusion created by the January 5 Action to counteract the rapid spread of misinformation that the changes to the Childhood Schedule has triggered. The AAP is being asked, in real time, to advise its members on how to meet the needs of children in their communities when the system is not prepared for the sudden, drastic changes recently made to the Childhood Schedule, where the healthcare system was not given time to plan for the changes.

106. Instead of advancing children's health, AAP is now spending time trying to mitigate damage caused by Defendants' actions. For example, the January 5 Action is causing AAP to re-examine clinical practice guidelines that were developed with the assumption that children are routinely vaccinated. Many clinical decision pathways implicitly rely on vaccination status, even when not stated explicitly. For example, in acute otitis media, also known as an ear infection, which affects almost all children, widespread vaccination shifted the epidemiology toward viral causes, supporting guidance that it is often safe to have an observation period before starting antibiotics. If vaccination rates drop and bacterial disease becomes more common again, those assumptions may no longer be valid. That means re-examining the guidelines and changing them

if indicated. The AAP is in the process of inventorying its full catalog of clinical guidance to determine where vaccination assumptions are embedded or where decision points need to be added. This is extensive work that was unanticipated, brought on by the January 5 Action.

107. The January 5 Action has had an immediate impact on AAP member and pediatrician in Michigan who owns two practices outside of Detroit, **Dr. Molly O'Shea**. Within 24 hours of the announcement and adoption of the Schedule Change, she was forced to reorganize her practice. To do so, she had to carve out time away from other duties to meet and discuss how the Schedule Change would impact their practice and the operational changes that would be necessary to ensure compliance. This meeting would not have been necessary but for the announcement and immediate adoption of the Schedule Change, which required corresponding immediate action by our practice.

108. Based on the Schedule Change, her practice has been forced to change operations and develop new protocols to ensure compliance with the new categorization of childhood vaccines. Because previously routinely recommended vaccines are now subject to SCDM, her practice's protocol must be replaced with a new, revised protocol. Under the new, revised protocol, the time and professional input of a provider will now be required in order to satisfy and comply with the SCDM component of the Schedule Change. This means patients will be required to make an appointment to see a provider, who in turn must now dedicate time specifically to SCDM and vaccine administration. Operationalizing this new protocol will require her practice to set aside one dedicated provider every day who will be solely responsible for handling SCDM appointments. This dedicated provider will conduct 30-minute appointments for any vaccines that now fall under the SCDM category. This change to office operations will disrupt the workflow of her practice and that of the dedicated provider because at least two to three sick visits, or one to

two well child visits, which otherwise be conducted by that dedicated provider in that same time frame, will now be displaced by SCDM appointments. An increasing number of her patients are already requesting to be vaccinated on an alternate schedule. This trend, combined with the effects of the Schedule Change and the need to change the practice's operations, will make it more difficult to see or treat patients in the regular course and scope of her business.

109. An AAP member and pediatrician in a Massachusetts town about 30 miles east of Providence, **Dr. Aaron Bornstein**, has felt an immediate impact from the messaging about vaccines from Defendants spread through various channels, including livestreamed ACIP meetings. The publicity accompanying the January 5 Action has been plentiful. Since December 18, 2025, after reports began to circulate about the Schedule Change, and Dr. Robert Malone, vice chair of ACIP, published an article anticipating the Schedule Change, he and his colleagues have observed a noticeable increase in parent concerns regarding vaccination. These questions have arisen during visits unrelated to vaccination, such as behavioral health visits. Among parents who support vaccinating their children, many parents have expressed anxiety about potential loss of access to vaccines and concern that their children may no longer be recommended for or able to receive routine immunizations due to the January 5 Action. He has also seen many parents who were on the fence about vaccinating their children and are now choosing not to vaccinate, directly attributable to the January 5 Action and public messaging from HHS, CDC, and ACIP. When these questions and concerns arise, he and his colleagues have been required to spend time to address them, often without compensation. This time is time he and his colleagues now cannot spend seeing other patients for sick visits or well child visits.

110. One recent example involved a family with three children who were visiting his clinic for an initial, unpaid "meet-and-greet" consultation. The two older children were fully

immunized, but the parents were now considering delaying or declining vaccines for their youngest child. During that visit, the father brought up party affiliation, cited CDC language suggesting that there are "too many vaccines," and asserted that the CDC no longer recommends certain immunizations. The doctor attempted to direct the conversation toward established medical recommendations, but the father was unwilling to engage. The encounter ended without resolution, and it remains unclear whether the family will ultimately transfer care to his practice. The practice was uncompensated for the extra time required to engage with the parents on vaccinations.

111. Visits with parents have become increasingly confrontational. After news about changes to the Childhood Schedule broke in December but before the January 5 Action, a teenage patient, accompanied by the father, was being seen by a young, female nurse practitioner. The nurse practitioner noted that the teenager was due for a second dose of a meningococcal vaccine. When she brought this up, the father became agitated and confrontational, accusing the clinician of recommending vaccines for financial reasons and refusing to allow the vaccine to be given. The interaction became sufficiently aggressive that the nurse practitioner focused on de-escalation rather than clinical counseling. The patient left without receiving the routinely recommended vaccine. An interaction like this would not have occurred but for the messaging on vaccines from Defendants.

112. APHA's mission is to: "Build public health capacity and promote effective policy and practice." APHA members include more than 23,000 individual public health professional members, as well as state and local health departments, organizations interested in health, and health-related businesses. APHA also coordinates with state and regional APHA affiliates across the nation. APHA members work in every discipline of public health, in every state, and in countries across the globe. Unless the February 2026 meetings of the ACIP and CDC pediatric

childhood immunization schedule changes announced on January 5, 2026, including the accompanying decision memorandum and assessment, are immediately enjoined, these actions will cause immediate harm to APHA, its members, and the public's health of the United States. The public health system that APHA and APHA members are dedicated to building and protecting is, quite literally, a house on fire, and the challenged actions pour gasoline on that fire. The system is an essential component of ensuring optimal health for all.

113. The Executive Director of the APHA, **Georges C. Benjamin, M.D**., states that abrupt changes to the CDC childhood immunization schedule effects the overall public health messaging in the United States and completely harms how public health vaccination campaigns that are run by APHA and APHA members need to operate to protect the public's health nationwide. Public health messaging is based on consistency and process that has relied on the evidence-based GRADE and EtR frameworks that guide the decision making that resulted in the previous CDC immunization schedule recommendations. These recommendations have been in place for years and are embedded into every part of the public health guidance that APHA and APHA members use to ensure evidenced based protection of the public's health. The HHS Secretary and Acting CDC Directors approval of the abrupt change to the CDC childhood immunization schedule breaks this evidence-based process that APHA and APHA's members have trusted and invested their time, effort, and money in for years as they conduct the on-ground outreach and campaigns necessary to prevent or respond to, preventable infectious disease outbreaks across the United States. The January 5, 2026 change in the CDC childhood immunization schedule simultaneously downgraded multiple long-standing routine pediatric vaccine recommendations causing severe disruptions in the procedures, vaccine availability and usability as well as procedures used to provide lifesaving protections to children and adolescents

in the United States. The accompanying decision memorandum and alleged multinational policy review used to explain their decision making process is flawed. The scientific policy review document includes numerous factual errors, misquotes findings from referenced studies and cherry picks the research and other data used to inform this policy decision. The supporting documentation is incomplete and fails to answer many questions essential to making such a radical policy recommendation change. This immediately forces APHA and APHA members to divert resources to explain and address the immediate policy, operational and program changes proposed by this abrupt, action by HHS leadership and the CDC. This change has nationwide impact.

114. APHA members report that APHA members are immediately required to review and when needed, revise counseling practices, educational materials, and public-facing guidance to explain the conflicts with well accepted evidenced based guidance with the new flawed federal recommendations changing the CDC childhood immunization schedule. State and local health departments staffed by APHA members are now reallocating personnel away from outbreak surveillance, emergency preparedness, and seasonal respiratory-virus response to address confusion created by the revised schedule. These diversions are occurring during peak respiratory-virus season and amid ongoing measles, influenza, RSV, and pertussis outbreaks, leaving APHA members understaffed in areas where delays or lapses directly increase morbidity and mortality. Once herd-immunity thresholds are reduced and preventable outbreaks begin, those harms are costly and difficult to control.

115. APHA members who provide vaccinations are also experiencing immediate financial and logistical harm as a direct result of the January 5, 2026, childhood immunization schedule changes because it has disrupted vaccine procurement decisions already made months earlier in reliance on routine CDC recommendations. APHA members who are public-health

agencies and physician practices purchase pediatric vaccines, including combination vaccines, well in advance based on established schedules. APHA members report that the downgrade of component vaccines, including hepatitis B, has rendered previously purchased combination vaccines unusable when parents decline a single component, forcing agencies to discard doses purchased with federal and state funds. At the same time, the CDC's mid-season changes to influenza recommendations have destabilized influenza vaccination programs already in progress. APHA members had ordered vaccines, printed materials, scheduled clinics, and launched outreach campaigns encouraging vaccination. Changing federal guidance in January and February during the peak in the influenza season has required APHA members to alter clinics, train staff on the implications of the altered guidance and patient eligibility, and respond to public confusion, which are actions that increase the likelihood of reduced influenza vaccine uptake. Decreased vaccination rates results in higher hospitalization rates and potentially more deaths from influenza or influenza related complications. Increased influenza hospitalizations during peak season strain emergency departments, and hospital inpatient capacity, producing additional harms such as delayed treatment for other critical health conditions like strokes, heart attacks, serious trauma and other time-sensitive conditions.

116. The CDC's downgrade of rotavirus and meningococcal vaccinations has created particularly acute and irreversible harms for APHA members responsible for pediatric and adolescent disease prevention. Rotavirus vaccination is the primary means of preventing severe diarrheal disease in infants. It is a highly contagious infection causing severe diarrhea, vomiting and abdominal pain. It has not known antiviral therapy but is easily prevented through vaccination APHA members report that the shift of rotavirus vaccination to shared clinical decision-making has already led parents to decline or delay vaccination. Because rotavirus vaccines must be

administered within a narrow age window, missed doses cannot be recovered, permanently increasing the risk of dehydration-related hospitalizations and preventable pediatric morbidity. APHA members are actively diverting staff and resources to prepare for rotavirus outbreaks now, rather than engaging in routine preventive care. Similarly, meningococcal disease progresses rapidly and carries a high fatality rate, with catastrophic consequences for survivors. APHA members have also long relied on routine meningococcal vaccination recommendations to protect adolescents and college-bound students in congregate housing. The January 5 schedule introduced confusion just as students return to dormitories nationwide, forcing APHA members to devote substantial time to addressing questions from parents, clinicians, and school administrators. Any delay or reduction in meningococcal vaccination during this period materially increases outbreak risk.

117. The CDC's actions have also inflicted immediate harm on APHA itself by compelling the organization to abandon planned mission-critical work and operate in a constant crisis-response mode. APHA leadership, scientific staff, and communications teams are now spending hours each day responding to misinformation, correcting federal pronouncements, and briefing members on the internally inconsistent CDC materials. APHA has been forced to divert staff and expert contributors to review its flagship publications, including the Control of Communicable Diseases Manual, because those works utilize the evidence-based ACIP framework that the CDC schedule change process abandoned here. At the same time, the CDC's unexplained departure from established scientific processes has damaged APHA's credibility as a reliable disseminator of evidence-based guidance, because of the confusion, misinformation and disinformation caused by the abrupt unscientific change in federal guidance. This is requiring APHA to expend additional resources to ensure trust with members, partners, and the public. Loss

of public trust is very difficult to remedy after the fact.

118. The misinformation arising from both the January 5 Action and the meetings of this ACIP have caused MPHA to divert resources to correct falsehoods about vaccines. Addressing misinformation consumes almost three to four hours of the time of the Executive Director of the MPHA each day and requires sustained attention from MPHA leadership and staff, which is time diverted from MPHA's core mission and leadership's core duties, such as program development, member services, fundraising, and strategic planning. This diversion of resources is substantial and ongoing.

119. If the February 25-26, 2026 ACIP meeting proceeds as scheduled, this ACIP meeting will spread more misinformation and confusion throughout the United States, thereby causing more harm to the Plaintiff Organizations and their members. Each Plaintiff Organization represents frontline clinicians and public-health professionals who will be forced to divert substantial time, expertise, and organizational resources away from patient care, disease prevention, and core public-health functions to address confusion, misinformation, and erosion of trust caused by an illegitimate ACIP. Each additional meeting of this ACIP, and each vote this ACIP takes, compound the injury: clinicians must counsel patients amid uncertainty created by unstable federal guidance; clinicians must spend additional uncompensated time counseling patients and explaining ACIP changes to the CDC immunization schedule that fail to follow the established GRADE and EtR evidence framework; public-health agencies and practitioners must respond to and prepare guidance, outreach, and communication materials that have relied on the CDC immunization schedule and EtR framework to prevent the spread of infectious diseases across the country; and Plaintiff organizations must redirect staff and funding to crisis response rather than their core missions. These harms occur the moment ACIP votes to endorse or ratify

changes to the CDC immunization schedule, which are immediately treated as authoritative federal guidance nationwide. Once such guidance issues, the resulting damage to vaccine confidence, clinical reliance, and coordinated public-health infrastructure cannot be fully reversed through later litigation or post-hoc agency reconsideration. Absent immediate injunctive relief, Plaintiff organizations and their members will remain trapped in perpetual crisis-response mode, sustaining ongoing injuries to their missions, their members, and the public health of the United States.

Harm Alleged In The Third Amended Complaint

120. Although this Court has found that the allegations of harm in Plaintiffs' Third Amended Complaint were sufficient to survive Defendants' Motion to Dismiss on standing grounds (ECF # 168), Plaintiffs repeat the allegations of harm set forth in their Third Amended Complaint below for the sake of completeness and because this Fourth Amended Complaint now becomes the operative complaint for this action.

121. The difficulties that the Directive created for Jane Doe 1, who was expecting her first child, to get the Covid-19 vaccine earlier this year caused her to lose sleep, suffer headaches, and endure fatigue. Jane Doe 1's headaches and fatigue negatively affected her productivity at work, which was already compromised by her need to redirect hours of time and energy to coordinate with her healthcare providers about their recommendations and logistics for obtaining a Covid-19 vaccine while pregnant.

122. When the Secretary announced on May 27 that he was ordering the CDC to remove the recommendation from the CDC's immunization schedule that pregnant women get the Covid-19 vaccine, Jane Doe 2 was also expecting her first child. From May 30 to July 23, 2025, Jane Doe 2 tried at least ten times (either by driving to or calling her doctor's office, urgent care, or pharmacies) to get the Covid-19 vaccine but could not because of the chaos and confusion that the

Directive injected into the healthcare system. At one of her trips to a pharmacy, the pharmacist told her that she could not administer the Covid-19 vaccine to a pregnant woman because of the change in CDC guidance. Jane Doe 2 suffered clinically-significant sleep disturbances as a result of the stress directly-attributable to the Directive. She required a dental intervention to address stress-induced tooth-grinding because she was so stressed about having access to the Covid-19 vaccine and being vulnerable to the disease personally and for her baby. She still suffers from anxiety, depression, and clinically-significant sleep disturbances as a result of being denied the Covid-19 vaccine between June 2025 and July 2025. She also was forced to incur gasoline expense because of the multiple different times she went to her doctor's office, urgent care, or to pharmacies to try, unsuccessfully, to get the vaccine.

123. Plaintiff Jane Doe 3 is the mother of two neurodivergent teenage boys, one of whom suffers anxiety attacks. When Jane Doe 3 took her sons to a pharmacy in August to get a Covid-19 booster before school resumed in September, the pharmacist refused to vaccinate them because, according to the pharmacist, they were not in the eligible age group. Jane Doe 3 scheduled another appointment for her sons to get vaccinated in September, and the night before that appointment, her son had an anxiety attack about getting a shot the next day. He would not have had that anxiety attack but for the confusion that the Directive created that forced a repeated attempt to get vaccinated.

124. Because the Plaintiff medical and public health organizations ("Plaintiff Organizations") do not trust the Secretary or his reconstituted ACIP,[114] the Plaintiff Organizations

[114] Nor do many state governments. For example, several Northeastern states, including Massachusetts, announced in September the formation of the Northeast Public Health Cooperative, which will issue joint vaccine recommendations, coordinate public-health efforts, and share data. Joseph Ax, *Northeast US states form health alliance in response to federal vaccine limits*, REUTERS (Sept. 18, 2025), https://www.reuters.com/business/healthcare-pharmaceuticals/northeast-us-states-form-health-alliance-response-federal-vaccine-limits-2025-09-18/. Similarly, the West Coast states of California, Oregon, and Washington formed the West Coase Health Alliance because of concerns the "'CDC has become a political tool that increasingly peddles

have had to divert resources to develop new infrastructures, processes, and guidance to fulfill their mission to their members.[115] For example, on August 19, 2025, the AAP "published an independent evidence-based immunization schedule for children and adolescents in the wake of federal officials undermining the rigorous scientific process for making recommendations. … The biggest difference between the AAP and CDC schedules is around COVID-19 vaccination. The CDC no longer recommends routine vaccination for healthy children, although children can get vaccinated after a conversation with their doctor. In contrast, the AAP recommends all young children ages 6-23 months get vaccinated as well as children ages 2-18 years in certain risk groups. It also calls for children whose parent or guardian desire protection from COVID-19 to have access to the vaccine."[116] The same day that the AAP published its own immunization schedule, the Secretary made the following threat: "AAP today released its own list of corporate-friendly vaccine recommendations. … AAP should also be candid with doctors and hospitals that recommendations that diverge from the CDC's official list are not shielded from liability under the 1986 Vaccine Injury Act."[117]

125. The Final Agency Actions have adversely affected the physician-patient relationship because, *inter alia*, they have injected mistrust, misinformation, uncertainty, and confusion into that relationship, putting physicians in the conflicting position of either advising

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ideology instead of science, ideology that will lead to severe health consequences.'" Amelia Templeton and Michelle Wiley, *Oregon, Washington, California form health care alliance to protect vaccine access*, OREGON PUBLIC BROADCASTING (Sept. 3, 2025), https://www.opb.org/article/2025/09/03/vaccines-oregon-washington-california-cdc/.

[115] *See, e.g.*, Decl. of Mark Del Monte, ECF No. 118-9 at ¶5 ("Multiple different teams within AAP have had to divert their attention from other urgent matters related to child health to contend with the impact of the Directive, including staff at all levels on the Senior Leadership Team, the Pediatric Practice and Healthcare Delivery Team, the Quality Team, the Finance and Payment Strategy Team, the Public Affairs Team, the Communications Team, the Publishing Team, and the Information Technology Team.").

[116] Melissa Jenco, *AAP releases evidence-based immunization schedules; calls on payers to cover recommendations*, AAP NEWS (Aug. 19, 2025), https://publications.aap.org/aapnews/news/32835.

[117] Robert F. Kennedy, Jr. (@SecKennedy), X (Aug. 19, 2025, 5:17 PM), https://x.com/SecKennedy/status/1957914911415153107.

patients on what they believe is the proper standard of care or adhering to inconsistent federal guidance. The Final Agency Actions will also result in decreased rates of vaccination, increased rates of transmission, long-lasting illness, and ultimately preventable deaths. The Final Agency Actions have and will put more stress on an already taxed healthcare system in this country at a time when many are uninsured, under-insured, or who may lose their health insurance coverage.

126. Dr. Robert H. Hopkins, Jr., is an Internal Medicine and Pediatrics physician in Arkansas. He is an active ACP member and current chair of the ACP Immunization Committee. He has served on several ACIP vaccine Work Groups. Early in July 2025, Dr. Hopkins saw a parent and child for a wellness visit for the child. The parent wanted the Covid-19 vaccine for the child, who was eligible for the VFC program. Dr. Hopkins, however, was unable to order the Covid-19 vaccine for the child through the VFC portal. He was able to find the vaccine through another source, but told the parent that the parent would have to pay out of pocket for the vaccine. The parent could not afford to pay, so the parent and child left without getting the vaccine. Further, because of the Final Agency Actions, Dr. Hopkins has been required to spend more time counseling patients regarding the safety of the Covid-19 vaccine. Approximately half of the patients he sees in a given day require counseling on Covid-19 vaccines. In such discussions, Dr. Hopkins has counseled patients that, based on the evidence, the Covid-19 vaccine is safe and beneficial. However, after these discussions, several patients, such as parents of young children, have decided to trust the Secretary's advice and refused to get the Covid-19 vaccine for their child. His relationship with these patients has deteriorated as a result of the Final Agency Actions.

127. Dr. Susan J. Kressly is the current President of the AAP. She learned from AAP members that, because of the Directive, AAP members experienced great frustration and new barriers in effectively counseling patients and their families regarding the Covid-19 vaccine. AAP

members believe that they are compromising the standard of care that they should be providing to their patients due to the confusion and distrust created by the Final Agency Actions, which have caused physician members to spend more time counseling patients regarding the effectiveness of the Covid-19 vaccines that, in turn, diverts time and resources from other patients. Due to the confusion and lack of evidence-based data supporting the Directive, the AAP ceased its endorsement of the CDC's current Child and Adolescent Schedule, and instead published and endorsed the CDC Child and Adolescent Immunization Schedule in effect in November 2024. The Final Agency Actions have put all AAP members (and, indeed, all other physicians in this country) in the untenable position of telling their patients that the country's top-ranking government health official's advice and recommendations from the new ACIP are wrong and that we are right. This erodes trust, which is the foundation of a healthy physician-patient relationship and vital to the success of AAP members' medical practices.

128. AAP member Dr. Mary Doherty-O'Shea Galluci is a pediatrician and owns two practices in Michigan. The Final Agency Actions have led to an increase in vaccine hesitancy in her patients. Parents are now questioning Dr. Galluci whether they should vaccinate their children against Covid-19, or worse, whether they can. Parents are now distressed and unsure about Covid-19 vaccines where they were not before. Dr. Galluci is especially concerned about pregnant patients and infants under 12 months old whom she sees at her clinics. During pregnancy, the immune system undergoes significant changes to protect the developing fetus. This puts pregnant women at high risk for severe Covid-19 complications, and the only way to protect their infants is through maternal vaccination and early-life immunization. Covid-19 infection in infants can be severe or fatal. Denying or delaying access to the Covid-19 vaccine in this population is medically dangerous and ethically indefensible. The Final Agency Actions are immediately and irreparably

endangering the lives of patients she is seeing right now at her clinics. The CDC's current emphasis on "shared decision-making" for the Covid-19 vaccine for children has put a chilling effect on her practice. Shared decision-making implies that the Covid-19 vaccine is optional or suspect, making it harder to hold Covid-19 vaccine clinics, limiting her practice's ability to order vaccines in bulk, and creating reimbursement challenges. Her billing team is spending excessive time navigating unclear insurance coverage rules. Parents also fear receiving unexpected co-pays for the Covid-19 vaccine due to the fluctuating, inconsistent messaging from the CDC. Access to Covid-19 vaccines is being reduced as a result of the Final Agency Actions. In addition to all of this, Dr. Galluci now must also confront and navigate the prospect of potential legal liability in light of the Secretary's post on his official X account in which he warned that "recommendations that diverge from the CDC's official list are not shielded from liability under the 1986 Vaccine Injury Act." Dr. Galluci understands this post to be as a threat to her and her colleagues who follow the AAP's, not the CDC's, immunization schedule. This prompted Dr. Galluci to consult her malpractice coverage, and she now worries whether her commitment to the standard of care she has followed for years will expose her to liability because of the contrary, conflicting messages that the Final Agency Actions send. Dr. Galluci is also being forced to perform uncompensated work in the face of increased SCDM she must now engage in with patients who previously trusted in routine vaccination. This is detracting from other aspects of her practice and results in loss of compensation. In short, the Final Agency Actions are interfering with her ability to provide the standard of care recommended by the AAP and interfering with her ability to comply with the oath she took as a doctor to do no harm.

129. Dr. Jason Goldman is the current President of the ACP and owns his own internal medicine practice in Florida. Since Covid-19 vaccines were first approved, physician members of

ACP have been routinely recommending and administering the Covid-19 vaccine. This routine administration of the vaccine has become the standard of care for physician members of the ACP. ACP physician members informed Dr. Goldman that the Directive placed them in an untenable situation of providing medical advice that some patients believe is inconsistent with federal guidance. ACP physicians face financial harm because some insurers do not cover vaccines that are designated SCDM on the CDC immunization schedules.

130. Dr. Georges C. Benjamin is the current Executive Director of the APHA. He has discovered that APHA members across the country face increasing difficulty because of the Final Agency Actions with providing the optimal standard of care that members have been following since the Covid-19 vaccines were approved. The Final Agency Actions have frustrated the ability of clinicians and other public health members to advise the communities that they serve regarding the effectiveness of the Covid-19 vaccine at preventing serious illness and death, thus compromising APHA members' ability to practice consistent with their standard of care. The Final Agency Actions have increased vaccine hesitancy and diminished trust in sound medical advice, which has caused APHA members to spend more time correcting misinformation with individuals and families regarding the effectiveness of the Covid-19 vaccines, thus diverting time and resources away from other important health care or public health duties.

131. J. Edward Johnson is the Assistant Health Commissioner for External Affairs at the Columbus Department of Public Health ("Columbus Public Health"), which is a member of APHA. Columbus Public Health's mission is to "Build public health capacity and promote effective policy and practice." In particular, Columbus Public Health endeavors to curb transmission of infectious diseases by operating an immunization clinic that offers several immunizations, including against Covid-19, through its Columbus Public Health Vaccine

Preventable Diseases Clinic and Program (the "CPH Clinic"). The Final Agency Actions frustrate this purpose and mission of Columbus Public Health because they are at odds with the mission, vision, and values of Columbus Public Health.

132. Dr. Andrew Pavia is an infectious disease doctor in Utah, has served as a Board member for IDSA, and is an active member of IDSA as Chair of the Avian Influenza Task Force and co-Chair of the IDSA Influenza Treatment Guidelines Committee. Consistent with ACIP recommendations before the Secretary took office this year, IDSA adopted ACIP's recommendations on the Covid-19 vaccine, which had become the standard of care for IDSA physician members and which IDSA has adopted into its guidelines. The Directive, however, places IDSA members in an ethical quandary because they are now required to discuss recommendations from the current ACIP and CDC that are no longer evidence-based. The Final Agency Actions have increased the number of encounters with parents who express increasing concern and confusion about whether their infants and children should get the Covid-19 vaccine. The Final Agency Action's creation of mistrust has damaged the cornerstone of the physician-patient relationship.

133. Dr. Ravi Jhaveri is an infectious disease expert, board certified in Pediatrics and Infectious diseases, and practices in Illinois. He is a member of both the Pediatric Infectious Disease Society ("PIDS") and the IDSA. It is his clinical judgment to recommend routine Covid-19 vaccination for pediatric patients ages six months to 17 years, as he has seen that the vaccine protects children from getting the disease and/or from suffering the effects of long Covid. The Final Agency Actions have placed him in the untenable position of attempting to dispel the misinformation and disinformation coming out of the current ACIP and CDC when he sees his patients. The Final Agency Actions have damaged his practice and relationships with his patients.

134. Regina LaRocque, M.D., M.P.H., FIDSA, is a physician board certified in infectious diseases. She is a member of IDSA and presently treats patients, including pediatric patients and pregnant individuals, in a traveler's advice and immunization clinic. The Secretary's Directive disincentivized physicians from recommending Covid-19 vaccines for pregnant individuals and children ages 6 months through 17 years and created uncertainty about eligibility for and access to this vaccination. Based on her more than 20 years in the field of infectious disease, she asserts confidently and without qualification, that based on her professional experience, more patients of all ages will contract Covid-19 and experience severe symptoms, including death, due to the barriers to vaccination that the Final Agency Actions are erecting. The Final Agency Actions are disrupting her practice and compromising her ability to provide the highest level of care to her patients.

135. Carlene Pavlos is the Executive Director of the Massachusetts Public Health Alliance ("MPHA"), a nonprofit organization that advocates for health equality and strong public systems across the Commonwealth of Massachusetts. The Final Agency Actions irreparably harm MPHA members by frustrating the work they do to support maternal and child health, vaccine delivery, and pandemic response in Massachusetts. The Final Agency Actions undermine MPHA members' independent medical judgment and critically weaken the public health infrastructure MPHA members rely on to perform their jobs.

136. Dr. Sindhu K. Srinivas is a physician and board certified in Obstetrics and Gynecology and Maternal Fetal Medicine. She is the President of the Society of Maternal Fetal Medicine ("SMFM"). The Final Agency Actions have frustrated SMFM's members' ability to effectively counsel patients regarding the effectiveness of the Covid-19 vaccine at preventing serious illness and compromise the standard of care to which SMFM members adhere. The Final

Agency Actions harm SMFM members' practices by undermining and eroding the physician-patient relationship and requires SMFM members to divert resources to addressing confusion about the Covid-19 vaccine.

137. SMFM member Dr. Caroline Rouse is a board-certified maternal-fetal specialist in Indiana who treats high-risk pregnant patients. The Directive had harmful effects on her practice because it disrupted vaccination schedules for her patients and caused dangerous confusion for her clinical practice. Many of her current patients have an altered immune system, and they are now presenting at her practice as afraid, misinformed and at increased risk of preventable illness and death as a result of the Final Agency Actions. In short, the Final Agency Actions are endangering the health and lives of her patients as well as undermining the trust and confidence upon which the physician-patient relationship is built. The Final Agency Actions are disrupting her practice and compromising her ability to provide the highest level of care to her patients.

138. The Directive created an ethical and legal dilemma for an SMFM member who is a maternal-fetal specialist in Massachusetts. The day after the Directive was publicized, this SMFM member assisted in preparing a statement in response to requests from SMFM members requesting clarification of the appropriate standard of care in light of the Directive and seeking affirmation that SMFM still recommended the Covid-19 vaccine during pregnancy. That statement provides:

> As the experts in high-risk pregnancy, the Society for Maternal-Fetal Medicine (SMFM) strongly reaffirms its recommendation that pregnant patients receive the COVID-19 vaccine. Pregnancy increases the risk of developing severe illness compared with nonpregnant patients. Maternal immunization remains the best way to reduce maternal, fetal, and infant complications from COVID-19 infection, and is safe to be given at any point during pregnancy. Maternal immunization is also associated with

> improved infant outcomes and decreased complications, including maternal and infant hospitalizations.
>
> SMFM recommends that all people who are considering pregnancy, pregnant, recently pregnant, or breastfeeding receive vaccination against COVID-19. Surveillance data collected since the beginning of the COVID-19 pandemic, which started in 2020, clearly demonstrates the safety and efficacy of mRNA vaccines in pregnancy.
>
> All physicians and other health care partners, along with health insurers, should continue recommending COVID-19 vaccination to pregnant patients. Maternal immunization is proven to protect patients and their infants against severe illness and death from infectious diseases.[118]

139. An SMFM member who is a maternal-fetal specialist in Texas and treats high-risk pregnancies has experienced an undermining of trust, disruption of immunization schedules for his patients, and dangerous confusion in the clinical setting. He is being forced to spend more time in counseling on the Covid-19 and other vaccines, which diverts time from seeing other patients.

140. Dr. Margie Andreae, another AAP member, is a board-certified pediatrician who practices at the Pediatric Clinic of the Canton Health Center in Canton, Michigan. Over her more than three decades of experience, Dr. Andreae has trusted the ACIP and its recommendations because she trusted that the appointments to the ACIP were made in good faith and that ACIP members had legitimate, relevant qualifications. The Final Agency Actions have changed that. She and her colleagues must now spend more time counseling patients over the safety and effectiveness of the Covid-19 vaccine. While routine counseling is part of a physician's job, the time spent engaging in SCDM has increased the counseling aspect of her job due to the confusion and distrust it has fomented over the Covid-19 vaccine. She, however, is not able to bill for the additional time

[118] *SMFM Continues to Recommend Influenza, COVID-19, and RSV Vaccine During Pregnancy*, SOC'Y FOR MATERNAL-FETAL MED. (June 25, 2025), https://www.smfm.org/news/smfm-continues-to-recommend-influenza-covid-19-and-rsv-vaccine-during-pregnancy.

that she spends in SCDM with her patients. The Secretary's actions deprive her of income and force her to perform uncompensated work.

141. Mary-Cassie Shaw, M.D., F.A.A.P., is a practicing pediatrician in Raleigh, North Carolina, Dr. Shaw has experienced increased chaos and confusion in her practice due to the Final Agency Actions. The chaos and confusion have resulted in she and her colleagues spending more time than before calling drug stores, local health departments, and other providers to determine the availability of the Covid-19 vaccine. The Final Agency Actions now require her to engage in more in-depth conversations with parents about the safety and efficacy of the Covid-19 vaccine, conversations that were not occurring before the changed to SCDM. None of this time has been compensable. Dr. Shaw has also seen patient numbers drop, which she attributes to the mistrust that the Final Agency Actions have sown. This loss in patients has caused her financial harm.

142. Dr. Suzanne Berman is another board-certified pediatrician and AAP member who has seen more and more parents unwilling to vaccine their children with the Covid-19 vaccine since the issuance of the Directive. This has caused financial harm to her practice, harm that is compounded by the SCDM counseling that she must now engage in, time which often is not reimbursable. She now expects to be left with unused vaccines that she cannot return, further deepening her financial harms as co-owner of her clinical practice.

143. James Lewis, M.D., M.P.H., is a board-certified physician in internal medicine, infectious diseases, and preventative medicine. In addition to his role as an adjunct professor at the University of Washinton's Division of Allergy and Infectious Diseases. Dr. Lewis also serves as the Health Officer for the Snohomish County Health Department in the State of Washington. He is also a member of APHA. Like the other physicians mentioned here, the Secretary's action have concretely harmed Dr. Lewis. Because of the Directive, Dr. Lewis now reallocates his time

to projects that otherwise would not be necessary. These include efforts to change local and state laws and Snohomish County policies that tie vaccine recommendations to ACIP and CDC guidance. Dr. Lewis and his colleagues undertake this work because he can no longer trust in the integrity or judgment of the new ACIP, its recommendations, or CDC guidance.

144. Thomas Boyce, M.D., is a physician board certified in infectious diseases and pediatrics. Like Dr. Jhaveri, Dr. Boyce is a member of both IDSA and PIDS. Dr. Boyce treats patients in a large, rural healthcare system in Wisconsin that serves approximately 310,000 patients, of whom 46,500 are children. As a pediatric infectious disease physician, Dr. Boyce's primary duty is to consult with providers and patients about infectious diseases. Over his more than 30 years in practice, Dr. Boyce trusted in the process that ACIP followed that resulted in vaccines being listed on the CDC immunization schedules. He had confidence in the nonpartisan and apolitical nature of the important work federal public health agencies undertake. The Final Agency Actions have changed that. Now, because of the change to SCDM for both children and adults, and the misinformation and disinformation that the Secretary and his reconstituted ACIP have spread on vaccines, Dr. Boyce is required to engage in much lengthier discussions as to the benefits and risks of the Covid-19 vaccine, a discussion he struggles with because the Secretary and his reconstituted ACIP have identified no new data on either safety or efficacy justifying the changes they have made to the CDC's immunization schedules. The increased time spent in counseling is work for which he is not compensated because he is unable to bill or code for this SCDM time. Dr. Boyce estimate that he spends an average of 1.5 hours per day in uncompensated time engaging in SCDM over the Covid-19 vaccine that diverts him from other, more urgent and pressing work.

145. David A. Wheeler, M.D., is a practicing physician in Northern Virginia with an

emphasis in infectious diseases and internal medicine. He is a fellow of the ACP and the IDSA. Since the designation of the Covid-19 vaccine as SCDM for adults under 65, Dr. Wheeler has seen an increase in calls from primary care physicians asking him for guidance on how to conduct SCDM for healthy adults under 65. As the infectious disease expert in his community, these primary care physicians and other practitioners increasingly turn to him for advice on questions about how to counsel patients. One primary care physician went so far as to ask Dr. Wheeler to write a prescription for the Covid-19 vaccine. Dr. Wheeler, however, cannot bill for any of this time spent counseling fellow practitioners on the risks and benefits of the Covid-19 vaccine. Thus, the Directive and the designation of the Covid-19 vaccine for adults as SCDM have forced Dr. Wheeler to perform work without compensation.

CAUSES OF ACTION

COUNT I
Violation of the Administrative Procedure Act – The Childhood Schedule

146. Plaintiffs incorporate by reference the foregoing paragraphs of this Complaint as if set forth herein.

147. The APA authorizes courts to "hold unlawful and set aside agency action, findings, and conclusions found to be" "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law or that are taken "without observance of procedure required by law[.]" 5 U.S.C. § 706(2)(A). An agency action is arbitrary and capricious if the agency has "relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicle Mfrs. Ass'n v. State Farm*, 463 U.S. 29, 43 (1983).

Under the APA, Defendants must "examine the relevant data and articulate a satisfactory explanation for [their] action[s]." *Id.*

148. The January 5 Action was a final agency action.

149. With respect to the January 5 Action, the agency "relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicle Mfrs. Ass'n v. State Farm*, 463 U.S. 29, 43 (1983).

150. When undertaking the January 5 Action, Defendants failed to "examine the relevant data and articulate a satisfactory explanation for [their] action[s]." *Id*.

151. The January 5 Action was a final agency action that caused and continues to cause harm to the Plaintiffs.

152. The January 5 Action was unlawful and must be set aside.

153. Plaintiffs are entitled to a declaratory judgment that the January 5 Action was unlawful.

154. Plaintiffs are entitled to preliminary and permanent injunctive relief enjoining Defendants from implementing or otherwise giving effect to the January 5 Action.

155. The facts pled herein demonstrate that Plaintiffs are likely to succeed and will succeed on the merits of Count I, that they have suffered and will suffer irreparable harm, that the balance of equities are in their favor, and that injunctive relief would be in the public interest.

COUNT II
Violation of the Administrative Procedure Act – The ACIP

156. Plaintiffs incorporate by reference the foregoing paragraphs of this Complaint as if set forth herein.

157. Under FACA, the ACIP must be fairly balanced and not subject to inappropriate influence. Violations of FACA are justiciable under the APA.

158. The Secretary's appointments to this ACIP have resulted in an unfairly balanced ACIP.

159. The Secretary has inappropriately influenced this ACIP.

160. The Secretary's appointments to this ACIP are arbitrary, capricious, and not in accordance law.

161. The public meetings of this ACIP have harmed and continue to harm the Plaintiffs and the public.

162. Future public meetings of this ACIP will cause additional harm to the Plaintiffs and the public.

163. The Secretary's appointments to the ACIP are unlawful and must be set aside.

164. Plaintiffs are entitled to a declaratory judgment that that this ACIP is unfairly balanced and has been inappropriately influenced in violation of FACA and the APA.

165. Plaintiffs are entitled to a declaratory judgment that public meetings of this ACIP have harmed the Plaintiffs and the public.

166. Plaintiffs are entitled to preliminary and permanent injunctive relief enjoining future meetings of this ACIP.

167. Plaintiffs are entitled to preliminary and permanent injunctive relief enjoining Defendants from giving effect to the Secretary's vacating the Secretary's appointments to this ACIP on June 11, 2025, September 11, 2025, and January 13, 2026.

168. The facts pled herein demonstrate that Plaintiffs are likely to succeed and will succeed on the merits of Count II, that they have suffered and will suffer irreparable harm, that the

balance of equities are in their favor, and that injunctive relief would be in the public interest.

COUNT III
Violation of the Administrative Procedure Act –
The ACIP's December 5, 2025 Hepatitis B Vote, September 19, 2025 Vote
On The Covid Vaccine, and the June 26, 2025 Vote on Thimerosal

169. Plaintiffs incorporate by reference the foregoing paragraphs of this Complaint as if set forth herein.

170. The CDC adopted the ACIP's December 5, 2025 vote on the hepatitis B birth dose on December 16, 2025; adopted the ACIP's September 19 vote on the Covid vaccine on October 6, 2025; and adopted the June 26, 2025 vote on thimerosal on July 23, 2025, thus making all of these votes final agency actions.

171. In taking these final agency action, Defendants "relied on factors which Congress has not intended it to consider, entirely failed to consider [] important aspect[s] of the problem, offered [] explanations for its decision that run[] counter to the evidence before the agency, [and provided explanations] so implausible that [they] could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicle Mfrs. Ass'n v. State Farm*, 463 U.S. 29, 43 (1983).

172. These final agency actions were arbitrary and capricious and not in accordance with law because, inter alia, the ACIP and the Defendants failed to "examine the relevant data and articulate a satisfactory explanation for [their] action[s]." *Id.*

173. These three final agency action caused and continue to cause harm to the Plaintiffs and the public.

174. Plaintiffs are entitled to a declaratory judgment that these three final agency actions were unlawful under the APA.

175. Plaintiffs are entitled to preliminary and permanent injunctive relief enjoining Defendants from implementing and otherwise giving effect to the December 5, 2025, September

19, 2025, and June 26, 2025 votes of the ACIP.

176. The facts pled herein demonstrate that Plaintiffs are likely to succeed and will succeed on the merits of Count III, that they have suffered and will suffer irreparable harm, that the balance of equities are in their favor, and that injunctive relief would be in the public interest.

COUNT IV
Violation of the Administrative Procedure Act – the May 19 Directive

177. Plaintiffs incorporate by reference the foregoing paragraphs of this Complaint as if set forth herein.

178. The May 19 Directive failed to consider relevant evidence.

179. Defendants have failed to articulate reasonable explanation for the May 19 Directive.

180. The May 19 Directive has injured and will continue to injury the Plaintiffs.

181. Plaintiffs are entitled to a declaratory judgment that the May 19 Directive was unlawful.

182. Plaintiffs are entitled to preliminary and permanent injunctive relief enjoining Defendants from implementing and otherwise giving effect to the May 19 Directive.

183. The facts pled herein demonstrate that Plaintiffs are likely to succeed and will succeed on the merits of Count IV, that they have suffered and will suffer irreparable harm, that the balance of equities are in their favor, and that injunctive relief would be in the public interest.

PRAYER FOR RELIEF

184. Plaintiffs respectfully request that this Court enter judgment in their favor and that the Court:

185. **As to Count I:**

(a) Declare that the January 5 Action violated the APA because it was arbitrary and

capricious, not in accordance with law, and failed to consider important aspects of the problem.

(b) Set aside the January 5 Action.

(c) Grant preliminary and permanent injunctive relief enjoining the Defendants from implementing and otherwise giving effect to the January 5 Action.

186. **As to Count II:**

(a) Declare that appointment of this ACIP's members violated FACA, the APA, and the ACIP Charter.

(b) Set aside the appointments of members to this ACIP.

(c) Grant preliminary and permanent injunctive relief enjoining Defendants from implementing and giving effect to the appointments to the ACIP of any and all current members of this ACIP.

(d) Grant preliminary and injunctive relief enjoining the current ACIP from holding any future meetings, including the meeting currently scheduled for February 25-26, 2026.

187. **As to Count III:**

(a) Declare that the December 5, September 19, and June 26, 2025 votes that became final agency actions violated the APA because they were arbitrary and capricious, not in accordance with law, and failed to consider important aspects of the problem.

(b) Set aside the December 5, September 19, and June 26 votes of the ACIP that were adopted by the CDC.

(c) Grant preliminary and permanent injunctive relief enjoining Defendants from

implementing and otherwise giving effect to these votes.

188. **As to Count IV:**

(a) Declare the May 19 Directive violated the APA because it was arbitrary and capricious, not in accordance with law, and failed to consider important aspects of the problem.

(b) Set aside the May 19 Secretarial Directive.

(c) Grant preliminary and permanent injunctive relief enjoining the Secretary from implementing and otherwise giving effect to the May 19 Secretarial Directive.

189. **As to all Counts:**

(a) Award to Plaintiffs reasonable attorney's fees and costs incurred in pursuing this action; and

(b) Grant all such other and further relief as this Court deems just and appropriate.

Dated: January 19, 2026

Respectfully submitted,

By: *James J. Oh*

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CERTIFICATE OF SERVICE

I hereby certify that this document was filed through the ECF system and served upon the following parties by via email on this 19th day of January 2026:

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

Jim O'Neill, in his official capacity as Acting Director of the Centers for Disease Control and Prevention

c/o Issac Belfer
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/s/ James J. Oh
James J. Oh

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS, AMERICAN COLLEGE OF PHYSICIANS, INC., AMERICAN PUBLIC HEALTH ASSOCIATION, INFECTIOUS DISEASES SOCIETY OF AMERICA, MASSACHUSETTS PUBLIC HEALTH ASSOCIATION D/B/A MASSACHUSETTS PUBLIC HEALTH ALLIANCE, SOCIETY FOR MATERNAL-FETAL MEDICINE, THE MASSACHUSETTS CHAPTER OF THE AMERICAN ACADEMY OF PEDIATRICS, JANE DOE 1, JANE DOE 2, and JANE DOE 3, *Plaintiffs,* vs. ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the Department of Health and Human Services; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; JIM O'NEILL, in his official capacity as Acting Director of Centers for Disease Control and Prevention; CENTERS FOR DISEASE CONTROL AND PREVENTION; and DOES 1–50, inclusive, *Defendants.*	Case No. 1:25-cv-11916-BEM

[PROPOSED] ORDER

This matter comes before the Court on Plaintiffs' Motion for Leave to File a Fourth Amended Complaint (the "Motion"). Having reviewed the Motion, and for good cause shown, it is hereby ORDERED that the Motion is GRANTED.

It is hereby ORDERED that Plaintiffs' Motion for Leave to File a Fourth Amended Complaint is GRANTED. Plaintiffs are granted leave to file the Proposed Fourth Amended

Complaint against Defendants which is attached as Exhibit 1 to the Motion for Leave to File a Fourth Amended Complaint. The Proposed Fourth Amended Complaint will be deemed filed and served as of the date the Court signs the Order granting the Motion for Leave to File a Fourth Amended Complaint.

SO ORDERED.

Dated: _____

_____
HON. BRIAN E. MURPHY
U.S. DISTRICT JUDGE