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' MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION FOR PRELIMINARY INJUNCTION

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

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INTRODUCTION

Since his confirmation as Secretary of the United States Department of Health and Human Services ("HHS") on February 13, 2025, Defendant Robert F. Kennedy, Jr. (the "Secretary"), along with HHS and the agencies and officials acting under his leadership (collectively, "Defendants"), have engaged in a series of final agency actions to significantly change the nation's vaccine policy. These arbitrary and capricious actions sow confusion and undermine public health, purposefully disregard and contravene required process, and ignore decades of established science. Because the Defendants have 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) ("*State Farm*"), the final actions challenged herein violate the Administrative Procedure Act, 5 U.S.C. §§ 701, *et seq.*, and must be set aside.

The final agency actions that Defendants, including the Secretary and co-Defendant Jim O'Neill, Acting Director of the Centers for Disease Control and Prevention ("O'Neill" or "Acting CDC Director"), have taken to date to change vaccine policy include (collectively, the "Challenged Actions"):

1. A Secretarial Directive, announced in a video posted on X on **May 27, 2025**, instructing the Centers for Disease Control and Prevention ("CDC") to remove the recommendations from CDC immunization schedules that pregnant women and children receive the Covid vaccine (the **"May 2025 Action"**);[1]

2. The terminations of all 17 sitting members of the Advisory Committee on Immunization Practices ("ACIP") on **June 9, 2025**, and replacement of them, starting

[1] Plaintiffs submit their Appendix of Evidence with this Motion, containing Exhibits 1-53. **May 2025 Action** materials are attached as Exhibits 1–4. *See Secretarial Directive on the Pediatric COVID-19 Vaccines for Children Less Than 18 Years of Age and Pregnant Women* (May 19, 2025) (attached as Ex. 1); Robert F. Kennedy, Jr., @SecKennedy, X (May 27, 2025, 10:16 AM), https://x.com/SecKennedy/status/1927368440811008138 (attached as Ex. 2); *Recommended Child and Adolescent Immunization Schedule for Ages 18 Years or Younger, United States, 2025*, CTRS. FOR DISEASE CONTROL & PREVENTION (May 28, 2025), https://www.cdc.gov/vaccines/hcp/imz-schedules/downloads/child/0-18yrs-child-combined-schedule.pdf (attached as Ex. 3); *Recommended Adult Immunization Schedule for Ages 19 Years or Older*, United States, 2025, CTRS. FOR DISEASE CONTROL & PREVENTION (May 28, 2025), https://www.cdc.gov/vaccines/hcp/imz-schedules/downloads/adult/adult-combined-schedule.pdf (attached as Ex. 4).

on **June 11, 2025**, with new members who either do not possess the requisite qualifications or expertise or who have publicly stated anti-vaccine views that align with the Secretary's (the **"ACIP Appointments**").[2]

3. A **June 26, 2025**, vote of the ACIP to remove thimerosal from all influenza vaccines distributed in the U.S., adopted by the Secretary[3] on July 23, 2025 (the "**June 2025 Thimerosal Action**").[4]

4. A **September 19, 2025** vote of the ACIP to downgrade the Covid vaccine recommendation from routinely recommended for all under age 65 to "shared clinical decision making" ("SCDM"), adopted by the CDC Director on October 6, 2025 (the "**September 2025 Action**").[5]

5. A **December 5, 2025** vote of the ACIP to downgrade the Hepatitis B ("HepB") vaccine recommendation from a routinely recommended three-dose series starting at birth ***for all children*** to SCDM for all doses ***for children born to HepB negative mothers***,

[2] The Secretary made additional unlawful appointments to the ACIP on September 11, 2025, and January 13, 2026.
[3] At the time, the CDC director position was vacant. In the absence of a CDC director, the Secretary decides whether to adopt a vote of the ACIP. *ACIP Recommendations*, CTRS. FOR DISEASE CONTROL & PREVENTION (Aug. 8, 2025), https://www.cdc.gov/acip/vaccine-recommendations/index.html.
[4] The **June 2025 Thimerosal Action** materials are attached as Exhibits 5–9. *See Advisory Committee on Immunization Practices, Final Agenda (June 25–26, 2025)*, CTRS. FOR DISEASE CONTROL & PREVENTION (June 24, 2025), https://www.cdc.gov/acip/downloads/agendas/Final-posted-2025-06-24-508.pdf (attached as Ex. 5); *Meeting of the Advisory Committee on Immunization Practices* (ACIP), June 25–26, 2025 Meeting Summary (June 25–26, 2025), CTRS. FOR DISEASE CONTROL & PREVENTION https://www.cdc.gov/acip/downloads/minutes/summary-2025-06-25-26-508.pdf (attached as Ex. 6);
Press Release, U.S. Dep't of Health & Human Servs., *Thimerosal (Mercury) Removed from U.S. Flu Vaccines Following ACIP Recommendation* (July 23, 2025), https://www.hhs.gov/press-room/thimerosal-mercury-removed-from-us-flu-vaccines-acip.html (attached as Ex. 7); *Recommended Child and Adolescent Immunization Schedule for Ages 18 Years or Younger, United States, 2025*, CTRS. FOR DISEASE CONTROL & PREVENTION (July 2, 2025), archived at https://web.archive.org/web/20250703123549/https://www.cdc.gov/vaccines/hcp/imz-schedules/downloads/child/0-18yrs-child-combined-schedule.pdf (attached as Ex. 8); *Recommended Adult Immunization Schedule for Ages 19 Years or Older; United States 2025*, CTRS. FOR DISEASE CONTROL & PREVENTION (July 2, 2025), archived at https://web.archive.org/web/20250715024339/https://www.cdc.gov/vaccines/hcp/imzschedules/downloads/adult/adult-combined-schedule.pdf (attached as Ex. 9).
[5] The **September 2025 Action** materials are attached as Exhibits 10–14. *See Advisory Committee on Immunization Practices, Final Agenda (Sept. 18–19, 2025)*, CTRS. FOR DISEASE CONTROL & PREVENTION (Sept. 19, 2025), https://www.cdc.gov/acip/downloads/agendas/final-posted-2025-09-19-508.pdf (attached as Ex. 10); *Meeting of the Advisory Committee on Immunization Practices* (ACIP), Sept. 18-19 2025 Meeting Summary (Sept. 18-29, 2025), CTRS. FOR DISEASE CONTROL & PREVENTION https://www.cdc.gov/acip/downloads/minutes/summary-2025-9-18-19-508.pdf (attached as Ex. 11); Press Release, Ctrs. for Disease Control & Prevention, *CDC Immunization Schedule Adopts Individual-Based Decision-Making for COVID-19 and Standalone Vaccination for Chickenpox in Toddlers* (Oct. 6, 2025), https://www.cdc.gov/media/releases/2025/cdc-immunization-schedule-adopts-individual-based-decision.html (attached as Ex. 12); *Recommended Adult Immunization Schedule for Ages 19 Years or Older; United States 2025*, CTRS. FOR DISEASE CONTROL & PREVENTION (Oct. 7, 2025), https://www.cdc.gov/vaccines/hcp/imz-schedules/downloads/adult/adult-combined-schedule.pdf (attached as Ex. 13); *Recommended Child and Adolescent Immunization Schedule for Ages 18 Years or Younger, United States, 2025*, CTRS. FOR DISEASE CONTROL & PREVENTION (Oct. 7, 2025), https://www.cdc.gov/vaccines/hcp/imz-schedules/downloads/child/0-18yrs-child-combined-schedule.pdf (attached as Ex. 14).

adopted by the Acting CDC Director on December 16, 2025 (the "**December 2025 HepB Action**").[6]

6. A Decision Memo signed by O'Neill on **January 5, 2026**, downgrading immunization recommendations for six (6) conditions on the CDC's Recommended Immunization Schedule for Child and Adolescent Ages 18 Years or Younger (the "Childhood Schedule"): (i) Downgrade to Risk-Based; Hepatitis A, Hepatitis B, MenACWY, RSV; and (ii) Downgrade to SCDM: Hepatitis A, Influenza, MenACWY, Rotavirus. The January 5, 2026 Action also removed from the Childhood Schedule the second dose of the HPV vaccine and the birth dose of HepB for infants in the SCDM recommendation category, and limited the age range of the SCDM recommendation for MenB. (The January 5, 2026 final agency action is hereafter referred to as the **"January 2026 Action"**).[7]

For both the May 2025 Action and January 2026 Action (collectively, the "Non-ACIP Actions"), the Secretary and Acting CDC Director bypassed without explanation the longstanding process that stakeholders in the health care system have come to rely on by which subgroups of the ACIP, known as Work Groups, study "disease epidemiology and burden of disease, vaccine safety, vaccine efficacy and effectiveness, the quality of the evidence reviewed, economic analyses, and implementation issues;"[8] Work Groups make "Evidence to Recommendation" framework ("EtR") presentations at public meetings of the ACIP; the ACIP as a whole then

[6] The **December 2025 HepB Action** materials are attached as Exhibits 15-17. *See Meeting of the Advisory Committee on Immunization Practices, Agenda (Dec. 4–5, 2025)*, CTRS. FOR DISEASE CONTROL & PREVENTION (Dec. 4, 2025), https://www.cdc.gov/acip/downloads/agendas/final-posted-2025-12-04-508.pdf (attached as Ex. 15); Press Release, U.S. Dep't of Health & Human Servs., *ACIP Recommends Individual-Based Decision-Making for Hepatitis B Vaccine for Infants Born to Women Who Test Negative for the Virus* (Dec. 5, 2025), https://www.hhs.gov/press-room/acip-recommends-individual-based-decision-making-hepatitis-b-vaccine-birth-dose-infants-born-women-test-negative-virus.html (attached as Ex. 16); Press Release, Ctrs. for Disease Control & Prevention, *CDC Adopts Individual-Based Decision-Making for Hepatitis B Immunization for Infants Born to Women Who Test Negative for Hepatitis B Virus* (Dec. 16, 2025), https://www.cdc.gov/media/releases/2025/2025-hepatitis-b-immunization.html (attached as Ex. 17).

[7] The **January 2026 Action** materials are attached as Exhibits 18-20. *See* Ex. 18, U.S. Dep't of Health & Human Servs., *Decision Memorandum Adopting Revised Childhood and Adolescent Immunization Schedule* (Jan. 5, 2026), https://www.hhs.gov/sites/default/files/decision-memo-adopting-revised-childhood-adolescent-immunization-schedule.pdf; Ex. 19, U.S. Dep't of Health & Human Servs., *Assessment of the U.S. Childhood and Adolescent Immunization Schedule Compared to Other Countries* (Jan. 5, 2026), https://www.hhs.gov/sites/default/files/assessment-of-the-us-childhood-and-adolescent-immunization-schedule-compared-to-other-countries.pdf.; Ex. 20, Childhood Immunization Schedule by Recommendation Group, CDC (Jan. 5 2026), https://www.hhs.gov/childhood-immunization-schedule/index.html

[8] *See Amendment to the Charter of the Advisory Committee on Immunization Practices*, CTRS. FOR DISEASE CONTROL & PREVENTION (Dec. 3, 2025), https://www.cdc.gov/acip/downloads/acip-charter.pdf (attached as Ex. 21).

considers the evidence, data, and presentations, often at multiple meetings; and, when ready, votes on how immunizations are recommended for use in the U.S. and listed on CDC schedules (the "ACIP Process"). The May 2025 Action targeted vaccines against one infectious disease; the January 2026 Action targeted immunizations against several diseases. These two actions suffer from the same legal defects under the APA: Defendants failed to examine relevant data and failed to provide a reasoned explanation for changing the CDC schedules while bypassing the ACIP Process in doing so. The May 2025 Action injected disruption and confusion into the health care system that has harmed the Plaintiffs specifically, as well as the broader public. The January 2026 Action has significantly amplified these harms.

Plaintiffs also seek to set aside the votes taken by the current ACIP whose members were appointed in violation of the Federal Advisory Committee Act, 5 U.S.C. §§ 1001, et seq. ("FACA"), and the ACIP Charter (the "ACIP Actions"). The current ACIP took those votes without following ACIP best practices, including consulting with Work Groups or following the EtR framework.

Finally, Plaintiffs seek to enjoin the current ACIP from holding a public meeting (the next scheduled meeting is February 25–26, 2026) until an adjudication on the merits of the lawfulness of the appointments of the current ACIP members (the "ACIP Appointments"). The current ACIP held three public meetings in 2025 at which speakers made many false and misleading statements about vaccines and infectious disease that have harmed the Plaintiffs and the public health.

Plaintiff public health organizations, medical associations, and clinician-members have had to divert resources from their core missions of protecting public health to combat the false and misleading statements emanating from the federal advisory committee that is charged with providing "advice and guidance to the Director of the CDC regarding use of vaccines and related

agents for *effective control of vaccine-preventable diseases in the civilian population of the United States*."[9] The membership and conduct of the current ACIP at public meetings are wholly at odds with this charge. The Plaintiffs and the public are harmed when false and misleading health-related information is spread at a public ACIP meeting. People die from believing health-related misinformation. Future meetings of the ACIP must be enjoined until a decision on the merits of whether the current ACIP membership must be set aside.

BACKGROUND AND STATEMENT OF FACTS

I. U.S. Vaccine Approval and Recommendation Processes

Two agencies housed inside of HHS—the Food and Drug Administration ("FDA") and the CDC—oversee the process that results in a vaccine being licensed and recommended for use in the United States. The FDA reviews Biologics License Applications ("BLA") submitted by manufacturers for approval to market new vaccines for use in the United States. 42 U.S.C. § 262(a)(2). A BLA is a comprehensive submission that includes preclinical and clinical data and information, as well as details of the manufacturing process and facilities. Licensure requires a demonstration that (1) the vaccine is safe, pure, and potent, and (2) the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent. 42 U.S.C. § 262(a)(2)(C).

The CDC, in turn, provides public health guidance for safe use of the vaccine. In 1964, the Surgeon General of the United States established the ACIP due to mounting interest in national immunization policy and the absence of a consistent panel of technical expertise available to advise

[9] *See ACIP Charter*, CTRS. FOR DISEASE CONTROL & PREVENTION (Dec. 3, 2025), https://www.cdc.gov/acip/about/acip-charter.html (emphasis added) (ACIP Charter); *see also ACIP Charter*, CTRS. FOR DISEASE CONTROL & PREVENTION (Apr. 1, 2024), https://restoredcdc.org/www.cdc.gov/acip/downloads/acip-charter.pdf (previous ACIP Charter containing same language).

the federal government on immunization-related issues as they arose.[10] The ACIP was designated a federal advisory committee in 1972.[11] The role of the ACIP is "to assist the [CDC] and the [HHS] in development of public policy related to immunization of the civilian population in the United States,"[12] and to provide "advice and guidance to the Director of the CDC regarding use of vaccines and related agents for *effective control of vaccine-preventable diseases in the civilian population of the United States*."[13]

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

> 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.[14]

While the BLA is under review at the FDA, which can take several years, an ACIP Work Group thoroughly reviews public and nonpublic information about the vaccine, so that the Work Group will be prepared to present information to the ACIP about the vaccine as soon as it is licensed. The Standard Operating Procedures manual for ACIP Work Groups provides: "*WGs*

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[10] *See* 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

[11] *See id.*

[12] *Advisory Committee on Immunization Practices: Work Groups: Standard Operating Procedures (August 2018)*, CTRS. FOR DISEASE CONTROL & PREVENTION 1, 2 (2018), https://www.cdc.gov/acip/downloads/Work-Group-Guidance-508.pdf

[13] *ACIP Charter*, CTRS. FOR DISEASE CONTROL & PREVENTION (Dec. 3, 2025), https://www.cdc the traditional American values of hard work, excellence, and individual achievement .gov/acip/about/acip-charter.html (emphasis added).

[14] *Advisory Committee on Immunization Practices: Work Groups: Standard Operating Procedures (August 2018)*, CTRS. FOR DISEASE CONTROL & PREVENTION 1, 2 (2018), https://www.cdc.gov/acip/downloads/Work-Group-Guidance-508.pdf.

*should begin reviewing data **12-18 months prior to a potential decision on [FDA] licensure**; the length of time required for the WG to review data in anticipation of vaccine licensure will depend upon the complexity of the topic, and the amount of available data that exists".*[15]

In 2010, the ACIP adopted a best practice called the "GRADE" approach—Grading of Recommendations, Assessment, Development, and Evaluation—for Work Groups to assess the quality of evidence and develop evidence-based recommendations.[16] 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).[17]

In 2018, the ACIP adopted by unanimous vote another best practice, the Evidence to Recommendation ("EtR") framework. As explained in the ACIP EtR 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 (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."[18]

The 21st Century Cures Act, 130 Stat. 1033, requires the ACIP to take up consideration of a newly-FDA-approved vaccine at the next public ACIP meeting after FDA approval is

[15] *Id.* (italics in original, bold added).
[16] *See Introduction in ACIP GRADE Handbook*, CTRS. FOR DISEASE CONTROL & PREVENTION (April 22, 2024) https://www.cdc.gov/acip-grade-handbook/hcp/chapter-1-introduction/index.html.
[17] *See id.*
[18] *See ACIP Evidence to Recommendation User's Guide*, CTRS. FOR DISEASE CONTROL & PREVENTION 1, 3 (Oct. 1, 2020), https://www.cdc.gov/acip/media/pdfs/2024/09/acip-etr-users-guide_october-1-2020.pdf.

announced.[19] By that time, the vaccine already has undergone several phases of testing for safety and efficacy with thousands of volunteers.[20]

Dr. Jason Goldman, current President of Plaintiff American College of Physicians ("ACP"), became an ACP liaison representative to the Pneumonia Vaccine Work Group in 2019 and to the Covid Vaccines Work Group in 2020.[21] He served on these Work Groups until the Secretary terminated liaison participation in Work Groups on July 31, 2025.[22] During his five years of service on the Covid Vaccines Work Group, his Work Group:

> would have weekly, robust discussions regarding scientific data about the developing COVID-19 vaccines. … 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 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 … [and] would come up with a specific set of recommendation

[19] 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").
[20] *See Role of the Advisory Committee on Immunization Practices in CDC's Vaccine Recommendations*, CTRS. FOR DISEASE CONTROL AND PREVENTION RESTORED (Sept. 17, 2024), https://restoredcdc.org/www.cdc.gov/acip/about/role-in-vaccine-recommendations.html.
[21] *See* Ex. 35 (Goldman Decl.) ¶ 6.
[22] Dr. Goldman received an email that liaison organizations were terminated from participating in ACIP Work Groups because liaison organizations like the ACP allegedly were "special interest groups and therefore are expected to have a 'bias.'" *See* Ex. 35 (Goldman Decl.) ¶ 6.

> 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 . . . .[23]

Once the ACIP votes on a recommended use of a vaccine, the CDC director has the authority to adopt ACIP recommendations, and, once adopted, the CDC publishes all ACIP recommendations on its website in a "Policy Note" in the Morbidity and Mortality Weekly Report ("MMWR") that is authored by the Work Group Chair and other ACIP or Work Group members.[24]

After the ACIP recommends how immunizations should be used, the FDA, ACIP, and the CDC continue to monitor and review the safety of all vaccines on the CDC's immunization schedules to ensure they remain up-to-date and comport with emerging peer-reviewed, evidence-based data and studies. For example, the Work Group Standard Operating Procedures manual provides that Work Groups should examine when "[u]pdates to existing recommendations are anticipated based on availability of new data (regarding safety, effectiveness, and/or programmatic issues, e.g., vaccine administration or storage)."[25]

II. The Final Agency Actions for Which Plaintiffs Seek Preliminary Injunctive Relief

The final agency actions that Plaintiffs challenge here can be separated into three categories: (a) changes to the CDC immunization schedules that bypassed the ACIP Process, (b) votes taken by the current ACIP and subsequently adopted by the CDC Director, and (c) meetings of an unlawfully constituted ACIP.

A. Changes to the CDC Immunization Schedules That Bypassed the ACIP Process (the "Non-ACIP Actions")

[23] Goldman Decl., ECF No. 75-18 at ¶ 16.
[24] 45 C.F.R. § 147.130(a)(1)(ii); *see Advisory Committee on Immunization Practices: Work Groups: Standard Operating Procedures (August 2018)*, CTRS. FOR DISEASE CONTROL & PREVENTION 1, 16 (2018), https://www.cdc.gov/acip/downloads/Work-Group-Guidance-508.pdf.
[25] *Advisory Committee on Immunization Practices: Work Groups: Standard Operating Procedures (August 2018)*, CTRS. FOR DISEASE CONTROL & PREVENTION 1, 3 (2018), https://www.cdc.gov/acip/downloads/Work-Group-Guidance-508.pdf.

1. The May 2025 Action

On May 27, 2025, the Secretary posted a video on his X social media account in which he, FDA Commissioner Marty Makary, and the Director of the National Institutes of Health, Jay Bhattacharya, appeared. In the video, the Secretary announced that he was directing the CDC to remove from its schedules the recommendation that "healthy children" and "healthy pregnant women" receive the Covid vaccine.[26] That same day, the Secretary published a Directive, dated May 19, 2025, instructing the CDC to remove these vaccines from the Schedules.[27]

The Directive does not match the science that was reported only weeks before. 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."[28] 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.'"[29]

At the April 15, 2025 public meeting of the ACIP, Dr. Lakshmi Panagiotakopoulos, an epidemiologist at the CDC, presented recommendations on use of Covid vaccines for 2025-2026 for different population groups for which there is conclusive evidence of a higher risk of severe

[26] *See* Robert F. Kennedy, Jr., @SecKennedy, X (May 27, 2025, 10:16 AM), https://x.com/SecKennedy/status/1927368440811008138 (attached as Ex. 2).
[27] *See Secretarial Directive on the Pediatric COVID-19 Vaccines for Children Less Than 18 Years of Age and Pregnant Women* (May 19, 2025) (attached as Ex. 1).
[28] Vinay Prasad & Martin Makary, *An Evidence-Based Approach to Covid-19 Vaccination*, 392 NEJM 2484, 2485, fig. 2 (2025).
[29] 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/.

illness from the Covid virus.[30] Dr. Panagiotakopoulos noted that pregnant individuals continued to face an increased risk of severe outcomes from contracting Covid.[31] Not only does a Covid 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 vaccine, but the mother can protect the infant by passing antibodies to the fetus from a Covid vaccine administered during pregnancy.[32] Dr. Fiona Havers, also an epidemiologist at the CDC, presented findings at the April 25, 2025 ACIP meeting on the impact of Covid 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."[33]

Despite these findings, 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, did not remove the recommendation that children be routinely vaccinated against Covid. Instead, on May 29, 2025, the CDC downgraded the designation for children to SCDM without explanation or supporting scientific evidence.[34]

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[30] *See* Lakshmi Panagiotakopoulos, *Use of 2025–2026 COVID-19 Vaccines: Work Group Considerations*, CTRS. FOR DISEASE CONTROL & PREVENTION (Apr. 15, 2025), https://www.cdc.gov/acip/downloads/slides-2025-04-15-16/05-Panagiotakopoulos-COVID-508.pdf.
[31] *See id.* at 11.
[32] *See id.*
[33] Paul Offit, This CDC Resignation Should Scare You, SUBSTACK (July, 8, 2025) https://pauloffit.substack.com/p/this-cdc-resignation-should-scare.
[34] *See Child and Adolescent Immunization Schedule by Age*, CTRS. FOR DISEASE CONTROL & PREVENTION (May 29, 2025), https://web.archive.org/web/20250530173732/https://www.cdc.gov/vaccines/hcp/imz-schedules/child-adolescent-age.html.

2. The January 2026 Action

On January 5, 2026, Defendants announced that immunization recommendations for six diseases had been downgraded, effective immediately.

- Downgrade from Routine Recommendation to Certain High-Risk Groups or Populations only: Hepatitis A ("HepA"), HepB, Meningococcal ACWY ("MenACWY"), Respiratory Syncytial Virus ("RSV")

- Downgrade from Routine Recommendation to SCDM: HepA, Influenza, MenACWY, Rotavirus

The January 2026 Action made other substantive changes to the Childhood Schedule:

- Prior to the January 2026 Action, the Human Papillomavirus ("HPV") vaccine was routinely recommended in a two-dose or three-dose series, with the first dose recommended to be given as early as 9 years old. The January 2026 Action increases the minimum age for the first dose to 11 years old and removes recommendations for any subsequent doses.

- Prior to the January 2026 Action, the HepB vaccine was recommended on the basis of SCDM, including the birth dose. The January 2026 Action removes the option for a birth dose of HepB vaccine and instead increases the minimum age of the first dose to two months old.

- Prior to the January 2026 Action, Meningococcal B ("MenB") vaccines were recommended on the basis of SCDM for adolescents aged 16-23 years old. The January 2026 Action changes the recommendation for the MenB vaccine to certain high-risk groups or populations aged 10-17 years old and limits the SCDM recommendation to adolescents aged 16-17 years old only.

For each of these newly downgraded immunizations, before FDA approval and subsequent ACIP recommendation on use, both the FDA and the ACIP thoroughly evaluated the evidence on the immunizations against the target diseases. All were rigorously evaluated before licensing and recommendation for use and have, since then, been carefully monitored. The Decision Memo announcing the January 2026 Action, however, does not cite any new data that calls into question the safety or efficacy of any of the downgraded immunizations.

Like the May 2025 Action, the January 2026 Action bypassed the ACIP Process to change the CDC's Childhood Schedule.[35] Defendants have provided no explanation for why they bypassed the ACIP Process and instead resorted to relying on individuals who have no responsibility for determining how a vaccine is recommended for use and listed on a CDC schedule. The authors of the Decision Memo to O'Neill are Jay Bhattacharya, Director of the National Institutes of Health, Mehmet Oz, Administrator of the Centers for Medicare and Medicaid Services, and Marty Makary, FDA Commissioner. Neither the CMS Administrator, the FDA Commissioner, the NIH Director, nor the agencies they run have any responsibility for revising the CDC's immunization schedules.

The Decision Memo articulates three bases for changing the Childhood Schedule:

(a) O'Neill's discussions of childhood immunization recommendations and policy with health officials from Japan, Germany, and Denmark;

(b) O'Neill's discussions with CDC and FDA officials with duties and responsibilities related to vaccine safety and efficacy; and

(c) a document titled "Assessment of the U.S. Childhood and Adolescent Immunization Schedule Compared to Other Countries," (the "Assessment") authored by Hoeg and Martin Kulldorff, Chief Science and Data Officer for the Assistant Secretary for Planning and Evaluation whom the Secretary appointed Chair of the ACIP in June, 2025.

The Decision Memo does not state what O'Neill discussed with health officials from Japan, Germany, and Denmark; nor does it state what O'Neill discussed with CDC and FDA officials. Neither the Decision Memo nor the Assessment state what "scientific evidence underlying [the] practices" of peer countries was evaluated, what conclusions were drawn from that evaluation, and what, if any, best practices of peer countries were superior to those of the United States, as the Presidential Memoranda instructed. Neither document discusses or cites new data, evidence, or studies of any of the immunizations changed on the Childhood Schedule. The Assessment is not

[35] The events leading up to the January 5 Action are set forth in the pending Fourth Amended Complaint, ¶¶ 38–57.

peer reviewed. Neither document states that Defendants considered important factors such as differences in health care systems and populations between countries, the impact on the U.S. health care system, or input from the public or independent experts. Despite the failure to consider these and many other factors, the Secretary proclaimed that an "exhaustive review of the evidence" had been conducted before changing the Childhood Schedule.[36]

B. Votes Taken by the Current ACIP (The "ACIP Actions")

The second category of final agency actions challenged in this case are the votes by the current ACIP and subsequently adopted by the CDC Director. Pertinent facts regarding the appointments of the current ACIP members are as follows. On June 9, 2025, the Secretary sent shockwaves through the U.S. health care system when he announced in a *Wall Street Journal* Opinion Commentary that he was "totally reconstituting the [ACIP]" and "retiring the 17 current members of the committee," based on alleged "persistent conflicts of interest."[37] Two days later, the Secretary announced the appointment of eight new members to the ACIP whom he claimed 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."[38] He has made two subsequent sets of appointments: four more members on September 11, 2025, and two on January 13, 2026.[39]

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[36] *CDC Acts on Presidential Memorandum to Update Childhood Immunization Schedule*, CTRS. FOR DISEASE CONTROL & PREVENTION (Jan. 5, 2026), https://www.hhs.gov/press-room/cdc-acts-presidential-memorandum-update-childhood-immunization-schedule.html.

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

[38] *Advisory Committee on Immunization Practices Policies and Procedures*, CDC, at 14–15 (June 2022), https://www.cdc.gov/acip/downloads/policies-procedures-508.pdf [https://perma.cc/93ZW-2J68].

[39] *See* Robert F. Kennedy, Jr. (@SecKennedy), X (June 11, 2025, 4:36 PM), https://x.com/SecKennedy/status/1932899858920120692?s=20.

Although members of the ACIP should have expertise in "*vaccines and related agents for effective control of vaccine-preventable diseases,*"[40] the Secretary's appointees to the ACIP include three obstetrician-gynecologists, one psychiatrist, one operations management professional, a cardiologist, and an emergency medical physician.[41] Ten of the 14 ACIP members have publicly stated views on vaccines that align with the Secretary's anti-vaccine views.[42] At least four are members or otherwise affiliated with openly anti-vaccine organizations, including the Independent Medical Alliance, the National Vaccine Information Center, and Children's Health Defense, which was founded by Robert F. Kennedy, Jr. himself.[43]

The current ACIP members' credentials pale in comparison to those of the ACIP members terminated on June 9, 2025, all of whom had relevant subject-matter expertise and credentials.[44] The Secretary's termination of the ACIP and the ACIP Appointments are consistent with his publicly stated distrust of experts.[45]

Accordingly, the votes taken by the current ACIP that Plaintiffs request that the Court set aside are as follows:

1. The June 2025 Thimerosal Action

At the first meeting of this ACIP in June 2025, Lyn Redwood, the former long-time President of Children's Health Defense, gave a presentation on thimerosal that resuscitated the

[40] *See Advisory Committee on Immunization Practices Policies and Procedures,* CTRS. FOR DISEASE CONTROL & PREVENTION 1,4 (June 2022), https://www.cdc.gov/acip/downloads/policies-procedures-508.pdf.
[41] *See* Fourth Amended Complaint for Declaratory & Injunctive Relief, Am. Acad. of Pediatrics v. Kennedy, No. 25-11916 (D. Mass. Jan. 19, 2026), ECF 180-1, ¶ 77.
[42] *See id.* at ¶ 78.
[43] *See id.*
[44] *See ACIP Committee Members July 1, 2024–June 2025,* CTRS. FOR DISEASE CONTROL & PREVENTION (Apr. 14, 2025), https://archive.cdc.gov/#/details?url=https://www.cdc.gov/acip/membership/archive/members-2024-jul-2025-jun.html.
[45] Very recently (Jan. 13, 2026), the Secretary said on *The Katie Miller Podcast*: "we need to stop trusting the experts," and "this idea that you should trust the experts. A good mother doesn't do that." The Katie Miller Podcast, *RFK Jr. on Dietary Guidelines, Vaccines & Trump*, at 16:52─17:17 (Jan. 13, 2026), https://www.youtube.com/watch?v=w_fzlwxJZAA&t=843s.

long-debunked, settled issue of whether thimerosal in vaccines caused autism—a theory that Children's Health Defense has long-promoted and that was an impetus for its founding.[46] At that meeting, Redwood made that claim that thimerosal is not an effective preservative and was never adequately tested before widespread use. She said: "[th]ey also found evidence that thimerosal was no better than water in protecting mice from potential fatal streptococcal infections," and the "FDA grandfathered in thimerosal without formal submission of any animal safety data."[47] However, Redwood's presentation on thimerosal was highly misleading:

> Thimerosal was introduced after repeated outbreaks of fatal bacterial contamination associated with multi-dose 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 and neurologic, developmental, or systemic harms. Characterizing this as 'insufficient testing' ignores both preclinical toxicology and decades of real-world safety data.[48]

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[46] *See History of CHD*, CHILD.'S HEALTH DEF., https://childrenshealthdefense.org/about-us/history-of-chd/ (last visited Jan. 25, 2026).

[47] Ctrs. for Disease Control & Prevention, *Advisory Committee on Immunization Practices (ACIP)–Day 2 of 2*, YOUTUBE, at 2:34:24, 2:32:38 (June 26, 2025), https://www.youtube.com/watch?v=z-16fImZoEc.

[48] 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.

Nonetheless, on June 26, 2025, the ACIP, whose members had been appointed only two weeks before, "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 or when the end goal was to stop using the preservation in all flu vaccines brought to the U.S. market."[49] No new data or study on the presence of thimerosal in vaccines was presented at the meeting.

2. The September 2025 Action

On September 19, 2025, the ACIP voted to change the Covid vaccine recommendation for adults from routine to SCDM, consistent with the May 2025 Directive. At that meeting, misleading information was presented that the Covid vaccine contained unacceptable amounts of DNA contaminant.[50] The ACIP did not apply the GRADE Approach or follow the EtR framework, and it did not consult with the Covid Work Group prior to the vote. The CDC Director adopted the September 19 vote on October 6, 2025.[51] Unlike the four previous occasions that the ACIP voted to designate a vaccine as SCDM,[52] the CDC published no explanation or guidance in the MMWR as to how clinicians should engage in SCDM with patients.

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[49] *See* 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/.

[50] *See infra* Section III.C.

[51] *See CDC Immunization Schedule Adopts Individual-Based Decision-Making for COVID-19 and Standalone Vaccination for Chickenpox in Toddlers*, CTRS. FOR DISEASE CONTROL & PREVENTION (Oct. 6, 2025), https://www.cdc.gov/media/releases/2025/cdc-immunization-schedule-adopts-individual-based-decision.html.

[52] *See* Lauren E. Roper, et al., *Use of Additional Doses of 2024-2025 COVID-19 Vaccine for Adults*, 73 MORBIDITY & MORTALITY WKLY REP. 1118, 1121, (Dec. 12, 2024), https://www.cdc.gov/mmwr/volumes/73/wr/pdfs/mm7349a2-H.pdf; Sarah Schillie, et al., *New Dosing Interval and Schedule for the Bexsero Men B-4C Vaccine: Updated Recommendations of the Advisory Committee on Immunization Practices–United States, October 2024*, 73 MORBIDITY & MORTALITY WKLY REP. 1124, 1124–1125 (Dec. 12, 2024), https://www.cdc.gov/mmwr/volumes/73/wr/pdfs/mm7349a3-H.pdf; Almea Matanock, et al., *Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal Polysaccharide Vaccine Among Adults*, 68 MORBIDITY & MORTALITY WKLY REP. 1069, 1074 (Nov. 22, 2019), https://www.cdc.gov/mmwr/volumes/68/wr/pdfs/mm6846a5-H.pdf; Elissa Meites, et al., *Human Papillomavirus*

3. The December 2025 HepB Action

On December 4, 2025, a current member of the ACIP and two outside presenters presented on the HepB vaccine. The first outside presenter, Cynthia Nevison, a climate scientist, presented on the "Burden of Disease." The second, Mark Blaxill, who has no medical training or professional experience, presented on the safety of the HepB vaccine.[53] None of the presenters on the HepB vaccine presented new safety concerns or effectiveness issues that would prompt reconsideration of the HepB 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."[54] No Work Group presented at this ACIP meeting on HepB (or on any other vaccine). No EtR analysis was conducted or presented at this meeting.

The next day, the ACIP voted "8 to 3 to recommend individual-based decision-making for parents deciding whether to give the HepB vaccine, including the birth dose, to infants born to women who test negative for the virus."[55] The new recommendation is that parents discuss with their doctors whether to give the HepB 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. This deviates from the recommendation (in place since 1991) that all babies receive a dose of the HepB vaccine within 24 hours of birth, including mothers who test negative for the HepB surface antigen

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Vaccination for Adults, 68 MORBIDITY & MORTALITY WKLY REP. 698, 700 (Aug. 16, 2019), https://www.cdc.gov/mmwr/volumes/68/wr/pdfs/mm6832a3-H.pdf.

[53] Nevison and Blaxill were co-authors of an article connecting autism to vaccines that the journal later retracted because of misrepresentations of data. *See* Mark Blaxill, Toby Rogers, & Cynthia Nevison, *Retraction Note: Autism: The Impact of Rising Prevalence on the Societal Cost of Autism in the United States*, 53 J. AUTISM DEV. DISORD. 3315 (2023).

[54] 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/.

[55] *ACIP Recommends Individual Based Decision-Making for Hepatitis B Vaccine for Infants Born to Women Who Test Negative for the Virus*, CTRS. FOR DISEASE CONTROL & PREVENTION (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.

(HBsAg-negative).[56] No evidence or data was presented justifying the two-month age restriction for the first dose of the HepB vaccine.

C. Meetings of The Unlawfully Constituted ACIP

The current ACIP's public meetings have been filled with false and misleading statements on vaccines and infectious disease. The presentation on thimerosal at the June 2025 meeting discussed above is a case in point.

At the September 2025 ACIP meeting, more inaccurate and misleading statements were made. At least 50 falsehoods were stated at the September meeting on the MMRV (measles, mumps, rubella, varicella) vaccine, the HepB vaccine, the Covid vaccine, and other topics.[57] For example, a claim was made at the September meeting that Covid vaccines contain dangerous levels of DNA contaminant exceeding regulatory limits. The truth, however, is that "[m]anufacturing impurities, including DNA, are carefully monitored because the FDA requires that residual DNA in vaccines be 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

[56] *See* Aliza Rosen, *Hepatitis B Vaccination is an Essential Safety Net for Newborns*, JOHNS HOPKINS BLOOMBERG SCHOOL OF PUB. HEALTH (Sept. 24, 2025), https://publichealth.jhu.edu/2025/why-hepatitis-b-vaccination-begins-at-birth; *Hepatitis B Perinatal Vaccine Information*, CTRS. FOR DISEASE CONTROL & PREVENTION (Aug. 27, 2025), https://www.cdc.gov/hepatitis-b/hcp/perinatal-provider-overview/vaccine-administration.html#:~:text=Birth%20dose,a%20parent%20with%20HBV%20infection.

[57] *See* Marisa Donnelly, et al., *Sept ACIP Meeting Fact Checking (Days 1-2)*, THE EVIDENCE COLLECTIVE (Sept. 19, 2025), https://static1.squarespace.com/static/68435457c33bc03421c23ff7/t/68cde5ebaf4b826126e40899/1758324203698/Sept+ACIP+days+1+and+2.pdf.

methods. Despite this, they found that vaccine lots with DNA levels above regulatory limits had fewer VAERS reports than those below the limits."[58]

The December 2025 meeting was even worse. There, "ACIP members and presenters made at least 60 (we lost count after this) false, misleading, or unsupported claims about vaccine-preventable disease epidemiology, vaccine safety, and the rationale for universal vaccination."[59] Many false claims were made that testing before licensing and marketing of the HepB vaccine was inadequate and that surveillance has been inadequate since listing on CDC schedules. In fact, however, more than 15 safety studies were conducted on HepB vaccines, including randomized control studies, and there has been continuous safety monitoring in millions of recipients post-marketing.[60] In addition, Nevison made the claim that "targeted measures" to vaccinate against Hepatitis B have been more effective than universal vaccination for Hepatitis B disease. Nevison either does not know or ignores the historical fact that:

> "[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%https://www.cdc.gov/mmwr/preview/mmwrhtml/00000036.htmof 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)***".[61]

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

[59] Marisa Donnelly, et al., *Debunk Briefing: December Meeting of the Advisory Committee on Immunization Practices (ACIP)*, The Evidence Collective (Dec. 5, 2025), https://static1.squarespace.com/static/68435457c33bc03421c23ff7/t/693347ab2b70aa78cc908df3/1764968363179/Dec+ACIP_TEC+Brief.pdf.

[60] *See id.*

[61] 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.

ARGUMENT

I. Plaintiffs Meet the Elements for a Preliminary Injunction

A. Preliminary Injunction Standard

For the Court to grant a preliminary injunction, plaintiffs must show four elements: "(i) the movant's likelihood of success on the merits of its claims; (ii) whether and to what extent the movant will suffer irreparable harm if the injunction is withheld; (iii) the balance of hardships as between the parties; and (iv) the effect, if any, that an injunction (or the withholding of one) may have on the public interest." *Corp. Techs., Inc. v. Harnett*, 731 F.3d 6, 9 (1st Cir. 2013). Where the Government opposes the preliminary injunction, the last two factors merge. *Nken v. Holder*, 556 U.S. 418, 435–36 (2009). The most important of the four elements is the likelihood of success on the merits. *See Massachusetts v. Nat'l Insts. of Health*, 770 F.Supp.3d 277, 295 (D. Mass. 2025) ("*NIH I*").

B. Plaintiffs are Likely to Succeed on the Merits.

1. Plaintiffs Have Standing to Seek the Requested Injunctive Relief.

In its January 6, 2026 Memorandum and Order on Defendants' Motion to Dismiss (ECF No. 168), this Court denied Defendants' Motion to Dismiss the Third Amended Complaint that was premised largely on the argument that Plaintiffs did not have standing to continue with any of their claims.[62] The Third Amended Complaint alleged that the following final agency actions violated the APA: (a) the May 2025 Action (one of the Non-ACIP Actions); (b) the September 2025 Action (one of the ACIP Actions); and (c) the ACIP Appointments for violations of FACA. In the Order on the Motion to Dismiss, this Court held that "there is no question that, but for the

[62] The Court also denied Defendants' Federal Rule of Civil Procedure 12(b)(6) motion on Plaintiffs' FACA claim.

change in vaccine recommendations and ACIP appointments, AAP would not have expended the resources that it did." Order on Defs.' Mot. to Dismiss, at 13, ECF No. 168.

If the Court grants leave to file the Fourth Amended Complaint, the allegations in that complaint will likewise be sufficient to establish standing as to the additional challenged actions.[63] The additional Non-ACIP Actions and ACIP Actions continue and magnify the harm that the Plaintiffs identified in the Third Amended Complaint,[64] since they impacted the immunizations for several additional conditions, whereas the May 2025 Action and September 2025 Action changed the recommendation regarding the immunization for ***one*** condition.

And as to the ACIP Appointments, Defendants' dismantling of Charter-mandated liaison groups, including AAP, deprived Plaintiffs of their legal right to participate in ACIP activities. *See See NAACP Legal Defense Fund, Inc. v. Barr*, 496 F.Supp.3d 116 (D.D.C. 2020) (plaintiffs' membership denial was sufficient to confer fair balance claim under FACA) (citing *Nat'l Anti-Hunger Coal. v. Exec. Comm. of President's Private Sector Survey on Cost Control*, 711 F.2d 1071, 1074 n.2 (D.C. Cir. 1983) (denial of access to representation on an advisory committee is a sufficiently concrete harm to constitute an injury in fact)); *see, e.g., Nat. Res. Def. Council v. Dep't of Interior*, 410 F. Supp. 3d 582, 601–02 (S.D.N.Y. 2019) (noting that "the weight of the caselaw" holds that parties with direct interests in an advisory committees work is denied membership, then the party has standing to challenge). Further compounding the harm is the fact that the current

[63] *See* Fourth Am. Compl., Am. Acad. Of Pediatrics v. Kennedy, No. 25-11916 (D. Mass. Jan. 19, 2026) ECF No. 180-1, ¶¶ 1–6, 35, 38–42, 44–45, 49, 52–71, 74–79, 82–119; *see also* Ex. 27 (Kressly Decl.), ¶¶ 13, 15–18, 26–31, 36, 39–42, 51; Ex. 34 (Racine Decl.), ¶¶ 11, 13–18, 20, 39–40; Ex. 42 (Pring Decl.), ¶¶ 10, 12, 14, 16, 19, 23–31, 39–40, 46–47; Ex. 43 (Bornstein Decl.), ¶¶ 9, 13, 15–17, 19, 22, 26, 33, 40 45, 50; Ex. 31 (Berman Decl.), ¶¶ 8–19; Ex. 40 (Nahass Decl.), ¶¶ 12–13, 15–17; Ex. 41 (Chen Decl.), ¶¶ 22, 24–25; Ex. 45 (Jaeger Decl.), ¶¶ 10–11, 13, 16, 26, 31, 33–34; Ex. 44 (Pavlos Decl.), ¶¶ 16–20, 22–24, 29–30, 32–33, 35–37; Ex. 25 (Benjamin Decl.), ¶¶ 20–27, 29–32; Ex 39 (Martinello Decl.), ¶¶ 8–10, 12–13; Ex. 46 (Srinivas Decl.), ¶ 14; Ex. 28 (O'Shea Decl.), ¶¶ 19, 23–26; Ex. 38 (Wheeler Decl.), ¶ 17; Ex. 37 (Jhaveri Decl.): ¶¶ 25, 28; Ex. 49 (Jane Doe 3 Decl.) ¶¶ 24-25; Ex. 50 (Jane Doe, MD Decl.) ¶¶ 13-14, 20; Ex. 53 (Jane Doe 2 Decl.) ¶¶ 31–32.

[64] *See id.*, ¶¶ 120–45.

ACIP has continued to spread significant misinformation at their public meetings, which creates more confusion, uncertainty, and disruption to the operations of the Plaintiffs and causes them to divert more resources to address the increased confusion and misinformation.[65]

In short, the key standing issues in this case regarding both a Non-ACIP Action and an ACIP Action, as well as the ACIP Appointments, have already been litigated and decided, so it is now the law of the case. *See U.S. v. Vigneau*, 337 F.3d 62, 67 (1st Cir. 2003) (noting that the law of the case doctrine "is a prudential principle that precludes relitigation of the legal issues presented in successive stages of a single case once those issues have been decided").

2. The Challenged Actions are Final Agency Actions.

Each of the Challenged Actions in this case are final agency actions because they (1) "mark the consummation of the agency's decision making process"; and (2) are those "by which rights or obligations have been determined, or from which legal consequences will flow." *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997). As a preliminary matter, the Defendants have waived any contention that the Challenged Actions are not final agency actions: they did not argue in their Motion to Dismiss that any of the final agency actions identified in the Third Amended Complaint—which included a Non-ACIP Action, an ACIP Action, and the ACIP Appointments—were not final agency actions, and, consistent with that position, Defendants conceded the challenged actions were final agency actions at the January 12, 2026 status conference before the Court ("[Mr. Belfer] I think something to keep in mind is that this case is really almost four cases ripened into one. We've got many different final agency actions"/ "So that's at least five different final agencies actions, each of which has its own record . . . we're basically talking about five

[65] Ex. 27 (Kressly Decl.), ¶¶ 16, 26–31, 39; Ex. 25 (Benjamin Decl.), ¶ 31; Ex. 42 (Pring Decl.), ¶¶ 16, 23–24, 30, 46–47; Ex. 43 (Bornstein Decl.), ¶¶ 26, 45; Ex. 40 (Nahass Decl.), ¶¶ 12, 16, 17; Ex. 41 (Chen Decl.), ¶ 24; Ex. 45 (Jaeger Decl.), ¶ 31; Ex. 44 (Pavlos Decl.), ¶¶ 17–18, 22–24, 29, 33, 36–37; Ex. 34 (Racine Decl.), ¶¶ 13–18, 39.

different agency actions that are potentially being challenged."[66] In addition, in the Joint Status Report filed on January 21, 2026, which was filed after Plaintiffs' Motion for Leave to File a Fourth Amended Complaint, Defendants stated that, of the actions challenged in the Fourth Amended Complaint, they "may explain why ACIP's June 26, 2025, and December 5, 2025, recommendations are not final agency actions,"[67] but were silent as to any other action. Joint Status Report, at 3 ECF No. 181. As such, any objection on this ground has been waived.

In any event, the Challenged Actions have imposed immediate and irreparable legal consequences on Plaintiffs, who are forced to grapple with the daily and long-term public health and economic effects that flow from (1) Defendants' deliberate decision not to follow well-established vaccine policy and procedures, and (2) the improper ACIP Appointments. These actions are ripe for review by the court to determine "an actual or immediately threatened effect." *See Greater Bos. Legal Servs. v. United States Dep't of Homeland Sec.*, No. 21-CV-10083-DJC, 2023 WL 2540892, at *2 (D. Mass. Mar. 16, 2023) (citation modified); *see also Biden v. Texas*, 597 U.S. 785, 808–09 (2022) (holding agency memoranda were final agency action, noting they "bound" agency staff by preventing them from continuing certain programs); *Student Loan Marketing Ass'n v. Riley*, 104 F.3d 397 (D.C. Cir. 1997) (finding agency letter had all of the indicia of finality because (1) it was signed by the Acting General Counsel on behalf of the Secretary of Education; (2) it was based on full deliberation at the highest level and reflected the agency's consideration of the contrary views expressed by the petitioner; and (3) the position was stated unequivocally).

[66] Transcript of Hearing at pp. 28:9–22:25; 29:5–13, Am. Acad. of Pediatrics v. Kennedy, No. 25-11916 (D. Mass. Jan. 12, 2026) (ECF No. 178).

[67] For the purposes of this analysis under *Bennett*, these two ACIP Actions are indistinguishable from the ACIP Action referenced in the Third Amended Complaint—the September 2025 Action—that Defendants previously conceded are final agency actions.

3. Both the Non-ACIP Actions and the ACIP Actions Violate the APA Because They are Arbitrary and Capricious.

When determining whether an agency acted arbitrarily or capriciously, the court must conduct "a thorough, probing, in-depth review" through a "searching and careful inquiry into the record." *Penobscot Air Servs., Ltd. v. FAA*, 164 F.3d 713, 720 (1st Cir. 1999) (citation modified). An agency action is arbitrary and capricious under 5 U.S.C. § 706 (2)(A) if it "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." *State Farm,* 463 U.S. at 43; *see also Dep't of Homeland Security v. Regents of the Univ. of Cal.*, 591 U.S. 1, 16 (2020). Agency action must be "founded on a reasoned evaluation of the relevant factors." *See NIH I,* 770 F.Supp.3d at 304. At bottom, arbitrary and capricious review is a search for "a satisfactory explanation" for an agency's action. *Am. Pub. Health Ass'n v. Nat'l Inst. of Health* ("*NIH II*"), 791 F.Supp.3d 119, 178 (D. Mass. 2025) (quoting *Ohio v. Env't Prot. Agency*, 603 U.S. 279, 292 (2024)); *see also Int'l Ladies' Garment Workers' Union v. Donovan*, 722 F.2d 795, 814 (D.C. Cir. 1983) ("[T]he agency must examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made.").

Further, when an agency changes its policy, not only must it provide a reasoned explanation; it must also "be cognizant that longstanding policies may have engendered serious reliance interests that must be taken into account." *Dep't of Homeland Sec.*, 591 U.S. 1 at 30 (quoting *Encino Motorcars, LLC v. Navarro*, 579 U.S. at 222); *see Food & Drug Admin. v. Wages & White Lion Invs., LLC*, 604 U.S. 542, 570 (2025); *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 106 (2015) ("[T]he APA requires an agency to provide more substantial justification when . . . its

prior policy has engendered serious reliance interests that must be taken into account. It would be arbitrary and capricious to ignore such matters."). When a challenged action constitutes a change in policy, the question is: "Did [Defendants] display awareness that [they were] changing position and offer good reasons for the new policy?" *See Wages & White Lion Invs.*, 604 U.S. at 570.

First, both the Non-ACIP Actions and the ACIP Actions were arbitrary and capricious because the Defendants failed to engage in reasoned decision-making as required by the APA. In the context of immunization actions, the ACIP Process provides a framework for engaging in a "reasoned evaluation of the relevant factors" through the GRADE approach, the EtR framework, and consultation with ACIP Work Groups. *See NIH I*, 770 F.Supp.3d at 304. For decades, the CDC schedules have been governed by these processes, which provide a structured, transparent, evidence-based review process requiring the ACIP to evaluate disease burden, morbidity and mortality, vaccine effectiveness, safety, and population-level impact under established analytical frameworks before adopting or modifying a recommendation.

Before prior ACIPs voted to adopt the routine recommendations for each of the now-downgraded vaccines, those ACIPs conducted multi-stage, data-driven reviews over multiple meetings, with the evidentiary basis for each recommendation documented and transparently evaluated. The charts attached as Exhibits 23[68] and 24[69] detail these processes as to two of the downgraded vaccines to serve as exemplars: HepB and RSV, respectively.

[68] As demonstrated in Ex. 23, ACIP subjected HepB vaccines to a long and rigorous evidence-based process, beginning in 1981 with review of double-blind, placebo-controlled clinical trial data even before FDA licensure. Over the next decade, ACIP revisited HepB vaccination recommendations in more than 20 formal meetings, repeatedly evaluating factors including safety, immunogenicity, duration of protection, adverse event reports, cost-effectiveness, and real-world implementation data across infants, children, adolescents, and high-risk adults. This spanned roughly 10 years from first data review to the unanimous 1991 universal recommendation. Even after the first universal recommendation, ACIP continued to assess and revise HepB vaccination recommendations, expanding the recommendation to all unvaccinated children aged 0-18 years of age in 1997.

[69] As demonstrated in Ex. 24, RSV monoclonal antibodies were recommended only recently by ACIP, with the first recommendation coming from ACIP on August 3, 2023, and the most recent recommendation for a monoclonal antibody coming on June 25, 2025. The monoclonal antibodies went through rigorous review by ACIP, including

The one time a routine vaccine was downgraded on a CDC schedule to SCDM—the Prevnar vaccine ("PCV13"), which treats pneumococcal pneumonia—the ACIP went through the same rigor and analysis it would go through for any newly issued recommendation.[70] PCV13 was recommended for routine use on June 20, 2012. By June 2015, ACIP was already revisiting that recommendation and considering rigorously constructed Work Group presentations and rationale on proposed changes to the PCV13 recommendation. The Work Group presented numerous times on not only the vaccine, but the disease it was designed to prevent, and the effects of the disease within particular age groups over the years since PCV13's routine recommendation. ACIP voted to change the recommendation on June 26, 2019, after considering no less than 34 such presentations on PCV13 and pneumococcal pneumonia. These presentations covered topics including suggested intervals between vaccinations, changes in the epidemiology of pneumococcal pneumonia, policy considerations, safety and efficacy of PCV13, direct and indirect effects of PCV13, the incidence and burden of pneumococcal pneumonia amongst adults in the US, EtR framework analyses for differing adult age groups, economic analyses of the current and adjusted recommendations, and alternative recommendations. Further, as with every prior instance in which the ACIP adopted an SCDM designation, PCV13's downgrade from routine to SCDM was accompanied by explanatory guidance published in the MMWR, describing both the evidentiary

through the EtR Framework. The ACIP Maternal & Pediatric RSV Work Group met regularly leading up to the August 3m, 2023 ACIP vote, with presentations beginning at ACIP meetings as early as February 23, 2022, well before the monoclonal antibody received FDA approval on July 17, 2023. At least 19 presentations on topics including numerous presentations on clinical considerations of the immunization, safety and efficacy, economic analyses, the ability of the monoclonal antibody to prevent RSV in all infants, the feasibility of the product, implementation considerations, the interplay between maternal and infant immunization, numerous EtR Framework presentations, and regular presentations on analyses conducted by the ACIP Maternal & Pediatric RSV Work Group. This rigorous, years-long process ultimately culminated in a vote and recommendation for the regular use of the RSV monoclonal antibody in infants, which itself resulted in numerous follow-up research and real-world studies of the effects of the immunization.

[70] *See* Plaintiff's FED. R. EVID. 1006 Summary Chart for Prevnar-13 (attached as Ex. 22)

basis for the designation and providing guidance on how SCDM should be applied in practice for that recommendation.[71]

Defendants have not offered a scintilla of explanation for why they bypassed the ACIP Process entirely as to the Non-ACIP Actions. Nor have they explained why they did not apply the GRADE approach, utilize the EtR framework, or consult with ACIP Work Groups to examine relevant data before adopting the ACIP Actions. This blatant disregard for the established process for methodically assessing and reviewing evidence-based data to adopt or modify immunization recommendations is exactly the kind of "unexplained inconsistency" that espouses arbitrary and capricious action. *See Encino Motorcars, LLC*, 579 U.S. at 222; *see also Data Marketing P'ship, LP v. U.S. Dep't of Labor*, 45 F.4th 846, 857 (5th Cir. 2022) (holding that an advisory opinion that adopted a definition of "working owner" that was materially different from the definitions in prior opinions was arbitrary and capricious because of the unexplained inconsistency).

Second, regardless of this failure of process, Defendants have failed to otherwise provide a satisfactory explanation for their actions based on any sort of reasoned evaluation or rational connection between the facts found and choices made. In the May 27 video posted on X, the Secretary justified the May 2025 Action with the conclusory assertion that "healthy kids" and "healthy pregnant women" don't need the Covid vaccine.[72] This explanation "fails under the APA because it is merely conclusory." *See Ass'n of Am. Univs. v. Dep't of Defense*, 792 F.Supp.3d 143, 171 (D. Mass. 2025) (holding that the Department of Defense's justification for a change to reimbursement rate policy related to university research was arbitrary and capricious because its

[71] *See* Almea Matanock, et al., *Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal Polysaccharide Vaccine Among Adults*, 68 MORBIDITY & MORTALITY WKLY REP. 1069, 1074 (Nov. 22, 2019), https://www.cdc.gov/mmwr/volumes/68/wr/pdfs/mm6846a5-H.pdf.
[72] Robert F. Kennedy, Jr. (@SecKennedy), X (May 27, 2025, 10:16 AM), https://x.com/SecKennedy/status/1927368440811008138.

conclusory justification did not provide a reasoned basis for the change); *NIH I*, 770 F.Supp.3d at 305 (holding that NIH's justification for a change to reimbursement rate policy related to university research was arbitrary and capricious because it was conclusory given that it did not "provide any reasoning, rationale, or justification at all").

Moreover, at the ACIP meeting the month before, CDC subject-matter experts reported that healthy children and pregnant women were very much still at risk from Covid and presented a wealth of uncontroverted data on the safety and efficacy of Covid vaccines for these populations. Fourth Am. Compl., ¶ 98, ECF 180-1. Accordingly, the Secretary's claim that there isn't "any clinical data to support the repeat booster strategy in children"[3] lacks any foundation. As in *Department of Commerce v. New York*, 588 U.S. 752 (2019), "the evidence tells a story that does not match the explanation the Secretary gave for his decision." 588 U.S. at 784 (holding pretextual the Secretary of Commerce's explanation why he decided to reinstate a citizenship question on the census).

Nor is there any reasoned explanation for the January 2026 Action. As noted above, the changes to the Childhood Schedule identified in the January 2026 Action were based only on (a) discussions with health officials in Japan, Germany, and Denmark and with CDC and FDA officials[73]; (b) a Decision Memo signed by Defendant O'Neill[74]; and (c) an allegedly scientific Assessment drafted by two individuals who are not part of the CDC and who lack education and professional backgrounds in vaccine science.[75] None of the stated reasons for the January 2026

[73] *See Decision Making Memorandum Adopting Revised Childhood and Adolescent Immunization Schedule*, U.S. DEPT OF HEALTH & HUMAN SERVS., 1 (Jan. 5, 2026), https://www.hhs.gov/sites/default/files/decision-memo-adopting-revised-childhood-adolescent-immunization-schedu/index.html (attached as Ex. 18).
[74] *See Id.*
[75] *See Id.*

Action offer a reasoned evaluation or rational connection between the facts found and choices made.

As also noted above, the Decision Memo does not state what Acting Director O'Neill discussed with health officials from Japan, Germany, and Denmark, nor does it state what Acting Director O'Neill discussed with CDC and FDA officials. The Assessment cites no new data, evidence, or studies of any of the immunizations changed on the Childhood Schedule. Additionally, neither the Decision Memorandum nor the Assessment document—which were apparently created in only a few weeks—were peer-reviewed before they were used as the basis to significantly change the Childhood Schedule. They also fail to explain why Japan, Germany, and Denmark serve as good immunization models for the United States. Therefore, Defendants have failed to offer any satisfactory explanation for the January 2026 Action to suggest it was the product of reasoned decision-making. *See State Farm*, 463 U.S. at 51 (holding that the National Highway Traffic Safety Administration ("NHTSA")'s decision to rescind the rule that new motor vehicles be equipped with automatic seatbelts or airbags was arbitrary and capricious because the agency was "too quick to dismiss the safety benefits of automatic seatbelts" for the court to conclude that the rescission was the product of reasoned decision-making); *see also NIH I*, 770 F.Supp.3d at 306 (holding that the failure to explain why bringing the federal government in line with private foundations in terms of funding indirect cost rates in the research grant context rendered the policy change arbitrary and capricious).

There is also no satisfactory explanation for the Defendants' actions relative to the ACIP Actions. The process that the ACIP followed leading up to the June 2025 Thimerosal Action, the September 2025 Action, and the December 2025 HepB Action demonstrate additional failures to examine relevant data or to provide reasonable explanation for the Defendants' actions. No new

data or studies were reviewed, considered, or identified to justify or provide any reasonable connection to the decisions on these three actions. Again, "the evidence tells a story that does not match the explanation the Secretary gave for his decision." *Dep't of Commerce*, 588 U.S. at 784.

Third, the Non-ACIP Actions and the ACIP Actions are arbitrary and capricious because they fail to consider important aspects of the problem the agency itself said it was trying to solve. For example, the purported problem the Defendants were trying to solve with the January 2026 Action was: to "restore trust in public health recommendations made by the CDC" that allegedly was lost because of governmental action during the pandemic.[76] In *New York v. Trump*, 769 F.Supp.3d 119, 141 (D.R.I. 2025), the court held that the defendants federal funding freeze was arbitrary and capricious because the defendants failed to provide "a rational reason for how their alleged goal of safeguarding taxpayer funds justified a de facto suspension of nearly all federal funding." Likewise, here, the Non-ACIP and ACIP Actions are arbitrary and capricious because Defendants have failed to provide a rational reason for how their alleged goal of "restor[ing] trust in the public health" justifies dramatic changes to the CDC schedules. None of the documents or statements supposedly justifying the Non-ACIP Actions or the ACIP Actions—including the May 2025 Directive; the Decision Memo; the Assessment; and the presentations during the June, September and December ACIP meetings—cite to any surveys, studies, or data to support Defendants' assertion that their actions will "restore trust in public health." Indeed, doctors who see patients every day report that the Non-ACIP Actions and ACIP Actions have made their patients *more* distrustful of the public health system, not less.[77]

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[76] Tracy Beth Høeg, MD, Ph.D and Martin Kulldorff, Ph.D., *Assessment of the U.S. Childhood and Adolescent Immunization Schedule Compared to Other Countries*, U.S. DEP'T OF HEALTH & HUMAN SERVS. (Jan. 2, 2026), https://www.hhs.gov/sites/default/files/assessment-of-the-us-childhood-and-adolescent-immunization-schedule-compared-to-other-countries.pdf (attached as Ex. 19).

[77] *See* Ex. 25 (Benjamin Decl.), ¶¶ 11, 15–16, 20, 31–32; Ex. 27 (Kressly Decl.) ¶¶ 13, 26; Ex.40 (Nahass Decl.) ¶¶ 13–15; Ex. 41 (Chen Decl.) ¶¶ 22, 24–25; Ex. 43 (Borenstein Decl.) ¶¶ 9; Ex. 45 (Jaeger Decl.) ¶¶ 10, 33–34; Ex. 44 (Pavlos Decl.) ¶¶ 16–18, 20, 22, 33.

Further, neither the Decision Memo nor the Assessment considered any of the following essential factors for evaluating immunization recommendation decisions: (1) epidemiological data comparing the incidence and prevalence of diseases on the schedule in the United States and other countries; (2) socioeconomic data demonstrating that the populations of the alleged peer nations are comparable; (3) data establishing that any of the vaccines on the schedule are harmful; (4) data on screening programs for diseases in other countries; (5) citations to peer-reviewed published research concluding that the vaccines administered under prior iterations of the schedule were ineffective in preventing disease or mitigating symptoms of disease or the need for hospitalization; (6) any evidence from the FDA that any of the vaccines are not safe and effective; (7) changes to practice guidelines published by Plaintiffs or other professional organizations; (8) evidence of consultations with professional organizations; (9) modeling of potential outbreaks if there is a reduction in vaccination rates or loss of herd immunity; (10) cited evidence of superior outcomes in other nations, (11) consideration of other variables in other nations such as widespread screening for diseases that confound nation to nation comparisons such as universal health access; and (12) data on the reductions of the incidence and prevalence of diseases following widespread vaccination.[78] The same is true for the May 2025 Directive and the presentations at the ACIP meetings that preceded the ACIP Actions.

The outright failure to address or even consider these important issues before undertaking dramatic changes to the CDC schedules renders the Defendants' actions arbitrary and capricious. In *State Farm*, the agency, NHTSA, did not "cast doubt" on the "efficacy of airbag technology" or on "the need for a passive restraint standard." 463 U.S. at 47. Therefore, because of NHTSA's prior position that "airbags are an effective and cost-beneficial lifesaving technology," the

[78] *See* Ex. 34 (Racine Decl.), ¶¶ 29–38; Ex. 27 (Kressly Decl.), ¶¶ 25, 30, 33.

Supreme Court held that it would be arbitrary and capricious to abandon the mandatory passive restraint rule "without any consideration whatsoever of an airbags-only requirement." *See id.* at 51. Likewise here, because none of the stated justifications for the Non-ACIP Actions or the ACIP Actions included new data or evidence-based analysis casting doubt on the safety or efficacy of the subject immunizations and vaccine ingredient, and because the CDC's prior position was that the immunizations and vaccine ingredient were safe and effective, the recommendation and use of the immunizations and vaccine ingredient cannot be modified without consideration of the relevant data, evidence, analyses, and public health impacts related to such decisions. *See id.* Put simply, Defendants provide no "reasoned analysis for the change[s]." *See id.* at 42.

Finally, with respect to both the Non-ACIP Actions and the ACIP Actions, Defendants failed to take into account serious reliance interests before unleashing devastating consequences on Plaintiffs, their members, and the U.S. public health system. These Actions set into motion a vaccine policy that disrupts multiple parts of the American health care ecosystem. These changes have wide-ranging effects far beyond when and to whom a vaccine may be administered. The complex landscape of federal and state laws that govern American health care rely on the CDC schedules to inform many aspects of operations. For example, VFC providers are only required to stock vaccines designated as "routine."[79] The change in classification of multiple vaccines from "routine" to SCDM jeopardizes access to these vaccines for children in the VFC program,[80] and more broadly.[81]

[79] *See VFC Operations Guide*, CTRS. FOR DISEASE CONTROL & PREVENTION at 82 (July 1, 2024), https://www.cdc.gov/vaccines-for-children/media/pdfs/2024/08/vfc-ops-guide_version-4.0_july-2024_low-res-508-rev-2.pdf.
[80] *See* Ex. 42 (Pring Decl) ¶ 17 (describing the delay in children covered by the VFC program receiving access to the 2025–26 Covid vaccine).
[81] *See, e.g.*, Ex. 34 (Racine Decl.) ¶ 17; Ex. 44 (Pavlos Decl.) ¶ 24.

Similarly, how immunizations are listed on the CDC schedules can affect health insurance coverage and cost-sharing obligations under the Affordable Care Act. Children and pregnant women who were previously able to receive the vaccine free of charge or without difficulty may now face potential out-of-pocket expenses or an outright inability to receive life-saving vaccinations because of the Defendants' actions. And perhaps most importantly, the public at large relies on the safety and efficacy of routine immunizations to protect our population from serious illness, hospitalization, and death.

The APA requires the Secretary to consider these reliance interests when changing its mind, but the Defendants failed to do so here. *See Dep't of Homeland Sec.*, 591 U.S. 1 at 30; *see also Orr v. Trump*, 778 F.Supp.3d 394, 423–24 (D. Mass. 2025) (holding that the State Department's passport policy removing the options for individuals to receive a passport with a sex marker reflective of their gender identity or to select a sex marker of "X" rather than "M" or "F" was arbitrary and capricious because there was no evidence that, in adopting the policy, the defendants "took steps to identify facts bearing on [the] policy change, attempted to identify potential reliance interests, or sought to determine how any such interests may be impacted by the policy changes").

For these reasons, Plaintiffs are likely to succeed on their arbitrary and capricious claims regarding the Non-ACIP Actions and ACIP Actions.

4. The ACIP Appointments Violate the APA Because They Were Not Made in Accordance with FACA.

With a growing number of advisory committees appointed to guide national policy and decision making, concerns mounted that advisory committees' operations were not consistent or transparent across all committees. Congress responded by enacting FACA in 1972 to impose "administrative guidelines [] to justify the investment of time, effort and expense in the use of

advisory groups as an instrument of Government."[82] Congress recognized the value of having non-governmental individuals "furnish[] expert advice, ideas and diverse opinions to the Federal Government," *Cummock v. Gore*, 180 F.3d 282, 284 (D.C. Cir. 1999), and, through FACA, implemented mandatory requirements to ensure committees did not go unchecked.[83] The APA provides a cause of action for review of agency decisions that violate federal law, including FACA. *See* 5 U.S.C. § 706(2)(A), (C) (authorizing review of and "set aside" relief for agency actions taken "not in accordance with law" or taken "in excess of statutory jurisdiction, authority, or limitations"); *Union of Concerned Scientists v. Wheeler*, 954 F.3d 11, 19 (1st Cir. 2020); *see also Physicians for Soc. Resp. v. Wheeler*, 956 F.3d 634, 643 (D.C.C. 2020).[84]

Not only do courts have the authority to review FACA violations, an advisory committee's work product that resulted from FACA violations may be enjoined. *See, e.g.*, *Alabama-Tombigbee Rivers Coal. v. Dep't of Interior*, 26 F.3d 1103, 1107 (11th Cir. 1994) ("We find injunctive relief as the only vehicle that carries the sufficient remedial effect to ensure future compliance with FACA's clear requirements. Anything less would be tantamount to nothing."); *Cal. Forestry Ass'n v. U.S. Forest Serv.*, 102 F.3d 609, 614 (D.C.C. 1996) (injunctive relief is appropriate if the absence of a remedy renders FACA a nullity); *Western Org. of Resource Councils v. Bernhardt*, 412 F.Supp.3d 1227, 1243–44 (D. Mont. 2019) ("A use injunction [preventing the agency from relying

[82] *See The Federal Advisory Committee Act (FACA): Overview and Considerations for Congress*, Cong. Rsch. Servs., *citing Hearing on the Role and Effectiveness of Federal Advisory Committees Before the H. Comm. on Gov't Op.*, 91st Cong. (1970).

[83] The APA provides a vehicle for reviewing agency decisions that violate federal law. *Union of Concerned Scientists v. Wheeler*, 954 F.3d 11 (1st Cir. 2020) (*citing Cowels v. Fed. Bureau of Investigation*, 936 F. 3d 62, 66 (1st Cir. 2019) and other cases). Where, as here, plaintiffs allege that change to membership on an advisory committee alters the balance and role of special influence over that committee, courts rely on FACA to inform "what Congress intended the [Secretary] to consider;" and the "APA's reasoned decision-making standards" inform the rationality of any changes to policy that the committee recommends. *Id.* at 20.

[84] The Court acknowledged this in denying the Defendants' Motion to Dismiss the Third Amended Complaint. *See* Memorandum and Order on Defendant's Motion to Dismiss, No. 25-11916-BEM (D. Mass. Jan. 6, 2026), ECF No. 168, at 20–22.

on an advisory committee's recommendations or work product] is the only way to achieve FACA's purpose[] of enhancing public accountability . . . .").

i. FACA and Its Regulations Require Safeguards Against Inappropriate Influence.

Just as the binding regulations require FACA committees to be fairly balanced, the agency head "must" safeguard against inappropriate influence by the agency or any special interest. 41 C.F.R. § 102-3.105(g). The word "must" denotes a nondiscretionary obligation. *Bank of Nova Scotia v. United States*, 487 U.S. 250, 255 (1988). FACA requires federal agencies to make "appropriate provision[] to assure that the advice and recommendations of the advisory committee will not be inappropriately influenced by the appointing authority or by any special interest, but will instead be the result of the advisory committee's independent judgment." 41 CFR § 102-3.105(g). Advisory committee members whose professional interests or job prospects are directly affected by the committee's output raise a strong potential for inappropriate influence. *See Cargill, Inc. v. United States*, 173 F.3d 323, 339–340 (5th Cir. 1999) (expressing concern that committee members were negotiating job positions with agencies whose regulatory authority will be directly affected by the results of the committee's study).

ii. The ACIP Appointments Have Resulted in an Unfairly Balanced Federal Advisory Committee in Violation of FACA.

The Secretary's appointments to the ACIP contravene FACA in at least three different ways. The ACIP's operative document on membership—the Membership Balance Plan ("MBP")—implements written safeguards to ensure the committee operates in a fairly balanced manner.[85] The Secretary failed to follow the MBP's Candidate Identification Process, which requires widespread solicitation and ACIP Steering Committee review of proposed ACIP

[85] *See* U.S. DEP'T OF HEALTH AND HUM. SERVS., FEDERAL ADVISORY COMMITTEE (FAC) MEMBERSHIP BALANCE PLAN (2024).

members.[86] The Secretary failed "to ensure the committee is balanced" consistent with the MBP's "Point of View" and "Other Balance Factors" requirements.[87] As a result, the Secretarial appointment process filled the ACIP with individuals publicly espousing similar (anti-vaccine) views and preconceived hypotheses that vaccines are categorically unsafe to the exclusion of vaccinologists, epidemiologists, and other expert specialists and clinicians who do not hold such views.

First, the Secretary failed to follow the Candidate Identification Process. The MBP provides a detailed candidate identification process that "describe[s] the process" for achieving and evaluating ACIP balance as well as "how [ACIP] vacancies, if any, will be handled by the agency."[88] The Candidate Identification Process provides three methods through which the Secretary can solicit names for new ACIP members: (1) email solicitation "distributed widely on an annual basis, sent to all 30 ACIP liaison organizations, ex officio members, current and past ACIP members, professional organizations [], academic centers, and other contacts in the field of vaccinology; (2) annual postings on the Federal Register; (3) announcements at ACIP meetings via a web link broadcast to all virtual attendees. Membership applications must be reviewed by the ACIP Steering Committee, which in turn, selects two candidates for each vacant position based on "the quality of the candidate's technical expertise, balance of specialty areas[], and geographic distribution."[89] The ACIP Steering Committee must "finalize[] a proposed nomination package annually during November or December."

The Secretary's appointments of new ACIP members has occurred completely outside this framework. On June 9, 2025, the Secretary announced to the Wall Street Journal that he was

[86] *See id.* at ¶ 6.
[87] *Id.* at ¶¶ 4-5.
[88] *Id.* at ¶¶ 4-6.
[89] *Id.*

"totally reconstituting the [ACIP]."[90] Two days later, the Secretary appointed eight new members. Subsequent ACIP members were appointed on September 15, 2025, and January 13, 2026.[91] For each set of appointments, no email solicitations were sent out, including not to liaison organizations, who were all terminated and cut off from participation by June 9, 2025. No notices were posted in the Federal Register. No applications were reviewed by the ACIP Steering Committee nor, upon information and belief, were two candidates identified for each vacancy before selecting one. Rather, the Secretary, upon information and belief, sought out individual members through a targeted campaign based on political affiliation and lack of public criticism of the President or Secretary.

This practice violates the core of the MBP whose purpose is to ensure fair balance across ACIP. The Secretary's unequivocal failure to properly identify candidates consistent with the MBP's objectives alone renders the resulting ACIP (the current ACIP membership) not fairly balanced.

Second, the Secretary failed to obtain fair point-of-view balance. The MBP's "Points of View" section "describes the process that will be used to ensure the committee is balanced, and identify the categories (e.g. individual expertise or represented interests) from which candidates will be considered."[92] The MBP explicitly states that "ACIP members are selected based on their expertise and experience and qualifications necessary to contribute to the accomplishments of the

[90] Robert F. Kennedy, Jr., *HHS Moves to Restore Public Trust in Vaccines*, WALL ST. J. (June 9, 2025), https://www.wsj.com/opinion/rfk-jr-hhs-moves-to-restore-public-trust-in-vaccines-45495112.
[91] *HHS, CDC Announce New ACIP Members*, U.S. DEP'T OF HEALTH & HUM. SERVS. (Sept. 15, 2025), https://www.hhs.gov/press-room/hhs-cdc-announce-new-acip-members-sept-2025.html; *Secretary Kennedy Appoints Two OB-GYNs to CDC's Advisory Committee on Immunization Practices*, U.S. DEP'T OF HEALTH & HUM. SERVS. (Jan. 13, 2026), https://www.hhs.gov/press-room/secretary-kennedy-appoints-two-ob-gyns-cdc-advisory-committee-immunization-practices.html.
[92] U.S. DEP'T OF HEALTH AND HUM. SERVS., FEDERAL ADVISORY COMMITTEE (FAC) MEMBERSHIP BALANCE PLAN (2024) at ¶ 4.

Committee's objectives."[93] The requisite expertise and experience is captured through the four-part criteria upon which members are selected: (1) expertise in the field of immunization practices;" (2) "multi-disciplinary expertise in public health;" (3) "expertise in the use of vaccines and immunologic agents;" (4) "knowledge of vaccine development, evaluation, safety and delivery;" or (5) "[in the case of a consumer representative] knowledge about consumer perspectives and/or social and community aspects of immunization programs."[94]

With one exception,[95] the remaining ACIP members appointed by the Secretary categorically do not meet the requirement in the MBP. The Secretary's appointments to the ACIP lack the requisite expertise, background, and credentials: three are obstetrician-gynecologists, one is a psychiatrist, one is an operations management professor, one is a cardiologist, and one is an emergency medical physician. Five current members have never engaged in vaccine-related research or publication. Another member (Levi) has published only two papers in which vaccines are discussed, both in 2025, just months before his appointment. In fact, at least three members (Blackburn, Pagano, and Pollack) have no discernable vaccine related experience at all.[96] To appreciate the extent to which the current ACIP members fail to satisfy this requirement, one need only look to the credentials of the ACIP members whom the Secretary fired on June 9, 2025. Those 17 former ACIP members held a variety of positions in infectious diseases; epidemiology; vaccinology; immunology; and pediatrics, geriatrics, or maternal health.[97]

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[93] *Id.*
[94] *Id.*
[95] H. Cody Meissner, M.D., is professor of pediatrics at the Geisel School of Medicine at Dartmouth College and a nationally recognized expert in pediatric infectious disease epidemiology, vaccine development, and immunization safety. Fourth Am. Compl., Am. Acad. Of Pediatrics v. Kennedy, No. 25-11916 (D. Mass. Jan. 19, 2026) ECF No. 180-1, ¶ 77.
[96] *See id.*
[97] The positions of the former ACIP members included: (i) Professor of Pediatrics and Infectious Diseases Epidemiology, University of Colorado School of Medicine and Colorado School of Public Health, Jules Amer Chair in Community Pediatrics; (ii) The Gillings Distinguished Professor in Public Health, Department of Health Behavior, Gillings School of Public Health, University of North Carolina; (iii) The Chief Medical Officer at a

Finally, the ACIP Appointments fail to achieve the "Other Balance Factors" set forth in the MBP. A factor that the MBP "identifies as important in achieving a balanced [ACIP]" is a "balance of specialty areas."[98] The specialty areas enumerated in the MBP that a balanced ACIP would have include: "pediatrics, internal medicine, family medicine, nursing, consumer issues, state and local health department perspective, public health perspective, etc."[99] Of the Secretary's appointees, there is one expert in pediatric infectious disease who is operating in academia at Dartmouth College, but no practicing pediatricians or family medicine practitioners. There is one

community health center in Watts, CA; and formerly a clinical professor of pediatrics at the Charles R. Drew University of Medicine and Science and past-president of the California Immunization Coalition; (iv) Director, Mount Auburn Travel Medicine Center, Division of Infectious Diseases and Travel Medicine, Mount Auburn Hospital; Associate Professor of Medicine, Harvard Medical School; Lecturer, Massachusetts Institute of Technology; (v) Professor of Medicine, University of Washington School of Medicine; Professor of Epidemiology, University of Washington School of Public Health; Attending Physician, Harborview Medical Center; (vi) Associate Professor of Medicine, Pediatrics, and Medical Science (Clinical), The Warren Alpert Medical School of Brown University; Associate Program Director, Brown Combined Residency in Internal Medicine and Pediatrics; (vii) Attending Physician and Chief Medical Epidemiologist, Memorial Sloan Kettering Cancer Center; Professor of Medicine, Weill Cornell Medical College; (viii) Professor and Travelers Chair in Geriatrics and Gerontology; Director, UConn Center on Aging; Claude D. Pepper Older Americans Independence Center (OAIC), UConn Health; publisher of articles on vaccines for older adults and influenza vaccines; (ix) Vice President for Medical Affairs, Dean, Carver College of Medicine, University of Iowa, with significant scholarship on maternal health, vaccines and infectious diseases in pregnancy, and vaccine-preventable diseases such as influenza, Ebola, Zika, dengue, and COVID; (x) Owner of a family medicine practice in New York state and former liaison to the ACIP for the American Academy of Family Practitioners; (xi) Chief, Immunization Section, Illinois Department of Public Health, Division of Infectious Diseases; (xii) Senior Associate Dean for Faculty Development and Diversity, Taube Endowed Professor of Global Health and Infectious Diseases; Professor of Pediatrics and of Epidemiology and Population Health; Interim Chair, Department of Medicine, Stanford University School of Medicine; Medical Director, Infection Prevention and Control and Attending Physician, Lucile Packard Children's Hospital at Stanford, Department of Pediatrics; (xiii) Co-Director, Vaccine Education Center, Children's Hospital of Philadelphia; (xiv) Chief, Immunization Branch, California Department of Public Health; (xv) Professor of Medicine, Section of Infectious Diseases, Yale School of Medicine; (xvi) Professor of Medicine, Vanderbilt University, with significant scholarship in influenza and other viral respiratory infections, including studies of vaccine immunogenicity, safety, and effectiveness in older adults; clinical and molecular epidemiology of respiratory viruses; diagnostic testing and antiviral use; immunologic mechanisms of vaccine response and immunosenescence; and vaccine policy, evaluation, and prevention strategies for high-risk populations; (xvii) Adjunct Professor, Department of Community Health Sciences at SUNY Downstate School of Public Health, and former Assistant Commissioner for the Bureau of Immunization New York City Department of Health and Mental Hygiene; former Director of the Vaccine Operations Center for the NYC Health Department's COVID's response; former Epidemic Intelligence Service Officer in the Malaria Branch, Division of Parasitic Diseases, CDC; former Bureau of Immunization as Medical Director. *See ACIP Committee Members July 1, 2024–June 9, 2025*, CTRS. FOR DISEASE CONTROL & PREVENTION (Apr. 14, 2025), https://archive.cdc.gov/#/details?url=https://www.cdc.gov/acip/membership/archive/members-2024-jul-2025-jun.html.

[98] U.S. DEPT OF HEALTH AND HUM. SERVS., FEDERAL ADVISORY COMMITTEE (FAC) MEMBERSHIP BALANCE PLAN (2024) at ¶ 5.
[99] *See id.*

member trained in epidemiology, but not with prior focus on immunology. There are no representatives from state or local health departments, or from public health, or clinician pediatricians. Worse, as described above, there is a dearth of vaccine-related experience at all. The complete absence of experts in key areas critical to ACIP's mission underscores the manner in which FACA has been ignored. This is exactly the type of imbalance that FACA sought to prevent. *See NAACP Legal Defense Fund, Inc. v. Barr*, 496 F.Supp.3d at 136–137 (D.D.C. 2020) (finding advisory committee consisting only of law enforcement personnel was not fairly balanced as it related to its role in advising on policing policy changes.)

Additionally, Defendants have failed to avoid inappropriate influence through the ACIP Appointments. Rather, Defendants have created new channels of influence to the ACIP. The 1978 amendment to the ACIP Charter requiring the ACIP chair be appointed from within the committee rather than from a governmental agency (like the CDC, as had been the case) was a deliberate action to depoliticize the ACIP. The ACIP was intended to be an independent body of experts providing independent advice to the federal agencies they serve. But the Secretary's deliberate appointments of special interest-affiliated persons to the ACIP has undermined this important safeguard.

The ACIP Appointments fails to meet the minimum requirements set forth in the statute requiring the avoidance of special interest groups. *Id.* at 136–137 (and citations therein). Ten of the 14 ACIP members have publicly stated views on vaccines that align with the Secretary's anti-vaccine views. At least four are members or otherwise affiliated with openly anti-vaccine organizations. The new ACIP members include individuals who have stated that they will not allow their grandchildren to be vaccinated, several individuals who have a history of spreading patently false information about vaccines, and one member who boasted that she has "probably

been anti-vax longer than RFK has."[100] These unambiguous facts cannot be squared with the requirement of a fair balance, and there is ample evidence that special interests are being favored by the Secretary's influence.

These multiple instances where the intent of FACA and the directives in the statute and implementing regulations have been disregarded fit well within the scope of those cases where injunctive relief is necessary to prevent an advisory committee from turning FACA's safeguards into a nullity. The composition of the current ACIP and the actions it has taken stand the intent of the law on its head and are no more than a rubber stamp for Defendants' agenda to create and spread public health misinformation. Accordingly, Plaintiffs are likely to succeed on their FACA claim.

II. Plaintiffs Have Suffered and Will Continue to Suffer Irreparable Harm from the Challenged Actions

Plaintiffs have endured significant and irreversible harm from the beginning of Defendants' targeted campaign to undermine vaccination protocols in the United States, beginning with the May 2025 Action. Those harms—which include the diversion of resources to combat misinformation, confusion, and distrust, as well as non-compensable economic harms and imminent threats to public health—have compounded and escalated with each Non-ACIP Action, ACIP Action, and ACIP meeting. Such harms will continue and compound if the Challenged Actions are not enjoined. *See New Hampshire Indonesian Cmty. Support v. Trump*, 157 F.4th 29, 35 (1st Cir. 2025) (citing *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 22–23 (2008)).

A. Plaintiffs Have Suffered Harms from Having to Combat Misinformation, Confusion, and Distrust.

[100] *See* Fourth Am. Compl., Am. Acad. of Pediatrics v. Kennedy, No. 25-11916 (D. Mass. Jan. 19, 2026) ECF No. 180-1, ¶¶ 76–77.

Rule and policy changes that directly impact organizational "burdens, costs, and effectiveness" pose a "real and substantial threat of imminent harm." *See Mass. Fair Housing Ctr. v. U.S. Dep't of Hous. & Urban Dev.*, 496 F.Supp.3d 600 (D. Mass. 2020). Further, "actions by a defendant that make it more difficult for an organization to accomplish its primary mission provide injury for purposes of irreparable harm." *New York v. McMahon*, 784 F.Supp.3d 311, 362 (D. Mass 2025); *NIH I*, 770 F.Supp.3d at 322 (holding that the degradation of vital infrastructure, loss of imperative staff, loss of human capital, and uncertainty around the ability to sustain future grant applications qualified as irreparable harms to the plaintiff institutions' primary research missions).

The Non-ACIP Actions, the ACIP Actions, and the misinformation spread by the unbalanced ACIP have caused mass confusion among health care providers and patients.[101] The process to effectuate the Non-ACIP Actions and ACIP Actions departed in significant ways from the ACIP's and Defendants' typical practices of compiling and evaluating evidence in support of reasoned recommendations. Further, none of the Non-ACIP Actions or ACIP Actions were accompanied by an MMWR publication or comparable guidance explaining the scientific rationale or clearly defining core elements of vaccination practice, such as dosing, target populations, or the circumstances under which vaccination should be offered under SCDM.[102] The Challenged Actions have resulted in the spread of significant misinformation regarding the safety, efficacy, and utility of vaccines, as well as the erosion of trust between patients and their providers.[103]

[101] *See* Ex. 27 (Kressly Decl.), ¶¶ 15, 26; Ex. 34 (Racine Decl.), ¶¶ 11, 15, 20, 40; Ex. 42 (Pring Decl.), ¶¶ 12, 14, 19, 24, 31, 46; Ex. 43 (Borenstein Decl.), ¶¶ 9, 19, 26; Ex. 31 (Berman Decl.), ¶¶ 15–17; Ex. 40 (Nahass Decl.), ¶ 14; Ex. 41 (Chen Decl.), ¶¶ 22, 24; Ex. 45 (Jeager Decl.), ¶¶ 16, 31, 34; Ex. 44 (Pavlos Decl.), ¶¶ 18, 29, 32, 33, 35.
[102] *See* Ex. 25 (Benjamin Decl.), ¶ 20; Ex. 34 (Racine Decl.) ¶ 15; Ex. 43 (Borenstein Decl.) ¶¶ 22, 26; Ex. 31 (Berman Decl.) ¶ 9, 14–15; Ex. 41 (Chen Decl.) ¶ 25; Ex. 49 (Jane Doe 3 Decl.) ¶¶ 15-16, 17 (child refused vaccine because of confusion caused by a schedule change); Ex. 50 (Jane Doe 1 Decl.) ¶¶ 1-5, 20 (required to navigate a fragmented public health landscape, spanning her providers, pharmacies, and online resources, rife with confusion following a schedule change); Ex. 52 (Jane Doe 2 Decl.) ¶¶ 14, 31–32.
[103] *See* Ex. 34 (Racine Decl.) ¶¶ 14, 40; Ex. 42 (Pring Decl.) ¶¶ 24, 46; Ex. 43 (Borenstein Decl.) ¶¶ 9, 15, 19, 26, 33, 45, 50; Ex. 27 (Kressly Decl.) ¶¶ 13, 26, 40; Ex. 31 (Berman Decl.) ¶¶ 12, 16, 18; Ex. 40 (Nahass Decl.) ¶¶ 12,

As a result, Plaintiff Organizations and their members have been required to divert significant resources—including time, staff attention, and financial resources—from their core initiatives, primary missions, and patient care to engage in emergency mitigation work addressing the Non-ACIP Actions and ACIP Actions; to address the misinformation, confusion, and distrust resulting from the Challenged Actions; and to develop methods for navigating the implications of the same.[104] Such mitigation efforts include urgently working towards developing, revising, and distributing educational materials, guidance, websites, and publications to address the confusion created by the CDC schedule changes and responding to numerous member inquiries about the same.[105] It also includes having to re-examine voluminous clinical practice guidelines that were based on the assumption that children are routinely vaccinated to determine where additional decision points need to be added.[106] This work, which is already extraordinarily extensive, burdensome, and costly (of time, financial resources, and opportunity) is just beginning: Plaintiffs and their members must continue doing it—incurring substantially more and more harms in the process—absent an injunction.

Moreover, for both the Plaintiffs Organizations and their members, the mitigation efforts require diverting time and resources to combat the reputational harm and erosion of public trust in the organizations, in physicians, and in vaccines more generally due to the Challenged Actions.[107]

14; Ex. 41 (Chen Decl.) ¶¶ 22, 24, 25; Ex. 45 (Jaeger Decl.) ¶¶ 10, 16, 31, 33, 34; Ex. 44 (Pavlos Decl.) ¶¶ 16–18, 20, 22, 24, 33, 36.

[104] *See* Ex. 27 (Kressly Decl.) ¶¶ 16, 26–31, 39; Ex. 25 (Benjamin Decl.) ¶ 31; Ex. 42 (Pring Decl.) ¶¶ 16, 23–24, 30, 46–47; Ex. 43 (Borenstein Decl.) ¶¶ 26, 45; Ex. 40 (Nahass Decl.) ¶¶ 12, 16, 17; Ex. 41 (Chen Decl.) ¶ 24; Ex. 45 (Jaeger Decl.) ¶ 31; Ex. 44 (Pavlos Decl.) ¶¶ 17–18, 22–24, 29, 33, 36–37; Ex. 34 (Racine Decl.) ¶¶ 13–18, 39.

[105] *See* Ex. 27 (Kressly Decl.) ¶¶ 26–28; Ex. 25 (Benjamin Decl.) ¶ 31; Ex. 42 (Pring Decl.) ¶¶ 23–30, 46; Ex. 44 (Pavlos Decl.) ¶¶ 23–24, 29–30, 35, 37; Ex. 31 (Berman Decl.) ¶¶ 14–15; Ex. 40 (Nahass Decl.) ¶¶ 15–17; Ex. 34 (Racine Decl.) ¶¶ 15, 18, 39.

[106] *See* Ex. 27 (Kressly Decl.) ¶ 31.

[107] *See* Ex. 25 (Benjamin Decl.) ¶ 31; Ex. 27 (Kressly Decl.) ¶¶ 13, 26, 40; Ex. 43 (Borenstein Decl.) ¶ 9; Ex. 40 (Nahass Decl.) ¶ 16; Ex. 34 (Racine Decl.) ¶ 40; Ex. 41 (Chen Decl.) ¶¶ 22, 24; Ex. 45 (Jaeger Decl.) ¶¶ 10, 16, 33–34; Ex. 44 (Pavlos Decl.) ¶¶ 16–18, 20, 22, 32–33.

This imposes significant burdens on physicians who are already burnt out and stretched thin, and it impairs their ability to provide safe, efficient, clear, evidence-based care to patients.[108] The CDC schedule changes also expose physicians to potential malpractice liability, regardless of whether they do or do not administer the vaccine. If they do not administer downgraded vaccines, then under current CDC recommendations, they can be subject to liability, ***even if a parent refuses the vaccine***.[109] If they do administer downgraded vaccines, they can be subject to liability or disciplinary action by their applicable Board of Medicine for failing to follow the current CDC schedules.[110] The environment resulting from the Challenged Actions is also causing safety concerns for physicians who are facing increasingly distrustful, hostile patients.[111]

"There can be no do over and no redress" for the time and resources the Plaintiff Organizations and their members have had to divert—and will have to continue to divert absent an injunction—from their primary missions and patient care to address the confusion, misinformation, and distrust stemming from the Challenged Actions. *See McMahon*, 784 F.Supp.3d at 362; *Nat'l Insts. Of Health*, 770 F.Supp.3d at 322. And if the February ACIP meeting were to go forward, Plaintiff Organizations and their members anticipate even more confusion, misinformation, and distrust, which would have compounding effects on all of these harms.[112]

B. Plaintiffs Have Suffered Further Economic Harms that Cannot be Compensated.

This court has recognized that "[t]he costs of complying with challenged regulations" may be irreparable, given the obstacle faced in pursuing monetary damages. *California v. Kennedy*,

[108] *See* Ex. 27 (Kressly Decl.) ¶¶ 18, 42, 51; Ex. 42 (Pring Decl.) ¶ 31, Ex. 43 (Borenstein Decl.) ¶¶ 9, 13, 15, 19, 26, 33, 40, 45, 50; Ex. 31 (Berman Decl.) ¶¶ 8, 10, 12, 16, 17–19; Ex. 40 (Nahass Decl.) ¶¶ 13, 16; Ex. 45 (Jaeger Decl.) ¶¶ 10, 33; Ex. 34 (Racine Decl.) ¶ 20; Ex. 44 (Pavlos Decl.) ¶ 19.
[109] *See* Ex. 27 (Kressly Decl.) ¶¶ 17, 51; Ex. 43 (Borenstein Decl.) ¶¶ 15, 19.
[110] *See* Ex. 43 (Borenstein Decl.) ¶ 19; Ex. 45 (Jaeger Decl.) ¶ 16; Ex. 44 (Pavlos Decl.) ¶ 19.
[111] *See* Ex. 31 (Berman Decl.) ¶ 18; Ex. 43 (Borenstein Decl.) ¶ 33; Ex. 45 (Jaeger Decl.) ¶ 33.
[112] *See* Ex. 27 (Kressly Decl.) ¶¶ 41–42; Ex. 42 (Pring Decl.) ¶¶ 46–47.

F.Supp.3d, 2025 WL 2807729, at *6 (D. Mass. Oct. 1, 2025) (citing *Rosario-Urdaz v. Rivera-Hernandez*, 350 F.3d 219, 222 (1st Cir. 2003)). This is especially true in the APA context, where monetary damages are not available. *See id.* (citing *Kentucky v. Biden*, 23 F.4th 585, 611 (6th Cir. 2022)); *see also NIH I*, 770 F.Supp.3d at 319–20. Indeed, economic harm can be irreparable where it is not accurately measurable or adequately compensable, or where the losses are compounding and disruptive. *NIH I*, 770 F.Supp.3d at 325–26.

Plaintiffs Organizations' members and medical providers more broadly are experiencing and will continue to experience various financial harms due to the Challenged Actions. These harms include extended, largely uncompensated time spent engaging in SCDM discussions with patients during appointments (which also limits the number of patients that can be seen in a day, thereby also reducing compensation from that which pre-dated the Challenged Actions) as well as expenditures related to hiring additional staff to keep up with the demands on provider time resulting from the CDC schedule changes.[113]

Providers will also continue to experience administrative and financial burdens related to stocking, ordering, and supplying childhood vaccines. Stocking vaccines imposes significant financial and operational burdens on providers because vaccines are expensive upfront purchases, carry inventory loss and spoilage risk, and require expensive, refrigerated storage.[114] Several childhood vaccines are available as combination vaccines, including (1) the diphtheria-tetanus-acellular pertussis (DTaP)-inactivated poliovirus (IPV)-HepB combination vaccine, (2) the DTaP-

[113] *See* Ex. 43 (Borenstein Decl.) ¶¶ 9, 13, 15–17, 19, 22, 33; Ex. 27 (Kressly Decl.) ¶ 16; Ex. 42 (Pring Decl.) ¶ 19; Ex. 31 (Berman Decl.) ¶¶ 11, 13–14, 16–18; Ex. 25 (Benjamin Decl.) ¶¶ 30, 32; Ex. 40 (Nahass Decl.) ¶¶ 13, 15–16; Ex. 41 (Chen Decl.) ¶¶ 22, 24–25; Ex. 45 (Jaeger Decl.) ¶¶ 10, 11, 31, 33, 34; Ex. 51 (Hopkins) ¶¶ 26, 37, 41-43; *see also* Ex. 49 (Jane Doe 3) ¶ 25 (stating that schedule changes to shared clinical decision-making for her children can require a physician visit 45 minutes farther than her local pharmacy for her children's flu and Covid-19 vaccinations, resulting in additional travel and electricity costs to charge her electric vehicle); Ex. 50 (Jane Doe 1) ¶¶ 13-14, 20 (diverting her work time to independently navigate vaccine access amid provider confusion)

[114] *See* Ex. 25 (Benjamin Decl.) ¶ 26; Ex. 42 (Pring Decl.) ¶¶ 10, 39–40; Ex. 43 (Borenstein Decl.) ¶ 40.

IPV-HepB-Haemophilus influenzae type B (Hib) combination vaccine, and (3) the DTaP-IPV-Hib combination vaccine. Previously, all vaccines included in these combination vaccines were routinely recommended. As a result of the new Childhood Schedule implemented on January 5, 2026, which changed the HepB dosing schedule without any consideration of downstream impacts, all HepB-containing combination vaccines are no longer part of routine recommendations.

Physician offices complete vaccine ordering months in advance and may not stock sufficient doses of combination vaccine options that do not contain HepB (*e.g.* Pentacel) or standalone vaccines for DTaP, IPV, and Hib to present as an alternative to parents and caregivers, so they will likely have to dispose of the now-unusable combination vaccines *and* incur additional costs to order more individual vaccines.[115] Further, accommodating the stock for more individual vaccines will require ordering more expensive, medical-grade vaccine refrigerators and freezers.[116] These economic costs of adapting to the Non-ACIP Actions and ACIP Actions are irreparable because they are compounding, disruptive, and not adequately compensable by a later injunction, and Plaintiffs have no means to obtain money damages from Defendants. *See NIH I*, 770 F.Supp.3d at 325 (finding harms irreparable because "[e]ven for those harms that can be measured in dollars and cents, the losses are compounding and will result in even greater disruption"); *see also California*, 802 F.Supp.3d at 283 (D. Mass. 2025).

C. The Challenged Actions Are Causing and Will Continue to Cause Imminent Public Health Harms.

"Threats to public health and safety constitute irreparable harm that will support an injunction." *Cigar Masters Providence, Inc. v. Omni Rhode Island, LLC*, No. 16-471-WES, 2017 WL 4081899, at *14 (D.R.I. Sept. 14, 2017); *Sierra Club v. U.S. Dep't of Agric., Rural Utils.*

[115] *See* Ex. 27 (Kressly Decl.) ¶ 36; Ex. 42 (Pring Decl.) ¶¶ 39–40.
[116] *See* Ex. 42 (Pring Decl.) ¶ 40.

Serv., 841 F.Supp.2d 349, 358 (D.D.C. 2012). Plaintiffs need not wait until there is a significant rise in the rates of infection and hospitalizations in order to seek relief; if anything, waiting until then would be too late. *See, e.g.*, *Silva v. East Providence Housing Authority*, 390 F.Supp. 691, 695 (D.R.I. 1975).

The vaccines for diseases that have been downgraded from routine recommendations have a long track record of improving public health by reducing disease transmission, hospitalization, and vaccine-preventable deaths.[117] Before a vaccine was introduced for rotavirus, there were an estimated 2.7 million rotavirus infections per year in the United States, and rotavirus caused more than 410,000 physician visits and 20–60 deaths annually.[118] Since introduction, rotavirus vaccination prevents an estimated 40,000–50,000 hospitalizations per year among infants and young children and has decreased prevalence of rotavirus among older children and adults that are not vaccinated.[119]

RSV is the leading cause of hospitalization among infants, and nearly all infants contract RSV by age 2.[120,121] Before RSV immunizations were introduced, RSV caused approximately 58,000–80,000 hospitalizations and 100–300 deaths in children under 5 each year.[122] One modeling study estimated that 2.1 million children under 5 years of age with RSV infection

[117] *See* Ex. 25 (Benjamin Decl.) ¶¶ 22–24; Ex. 27 (Kressly Decl.) ¶ 13.
[118] See Margaret Cortese & Penina Haber, *Chapter 19: Rotavirus, in Ctrs. for Disease Control and Prevention: Epidemiology and Prevention of Vaccine-Preventable Diseases*, THE PINK BOOK (last updated Apr. 25, 2024).
[119] *Rotavirus Vaccine Recommendations*, CTRS. FOR DISEASE CONTROL AND PREVENTION (Jul. 15, 2024), https://www.cdc.gov/rotavirus/hcp/vaccine-considerations/index.html.
[120] *See* Danielle L. Moulia, et al., *Evidence to Recommendation Framework: Clesrovimab*, ADVISORY COMM. ON IMMUNIZATION PRACS. (Apr. 16, 2025), https://www.cdc.gov/acip/downloads/slides-2025-04-15-16/02-Moulia-maternal-peds-RSV-508.pdf.
[121] *See* Danielle L. Moulia, et al., *Evidence to Recommendation Framework: Clesrovimab*, ADVISORY COMM. ON IMMUNIZATION PRACS. (Apr. 16, 2025), https://www.cdc.gov/acip/downloads/slides-2025-04-15-16/02-Moulia-maternal-peds-RSV-508.pdf.
[122] *See Increased Respiratory Syncytial Virus (RSV) Activity in Parts of the Southeastern United States: New Prevention Tools Available to Protect Patients*, CTRS. FOR DISEASE CONTROL AND PREVENTION (Sept. 5, 2023), https://www.cdc.gov/han/2023/han00498.html.

required medical attention annually.[123] Following the introduction of RSV immunizations, the burden of disease declined: cumulative RSV-associated hospitalization rates among infants 0–7 months of age fell from an estimated 14.8–15.0 cases per 1,000 children in the 2018–2020 seasons to 8.5–10.7 cases per 1,000 children in the 2024–2025 season.[124] RSV immunization is also demonstrated to be cost-effective; an analysis estimated that if half the US birth cohort received nirsevimab, immunization would avert approximately 100,000+ outpatient visits and avert approximately 14,000+ hospitalizations per year, at a cost of $153,517 per quality-adjusted life year ("QALY") saved.[125]

Similarly, influenza has a significant impact on children; estimates for the 2024–2025 respiratory season indicate that 14.6 million children contracted influenza and 56,000 were hospitalized.[126] During the same season, an estimated 17,400 pediatric hospitalizations were prevented due to vaccination.[127] While influenza causes a continued impact on hospital settings and substantial disease burden, routine vaccination has historically been a proven strategy to reduce severe illness among pediatric populations.[128]

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[123] *See* Caroline Breese Hall, et al., *The Burden of Respiratory Syncytial Virus Infection in Young Children*, 360 NEJM 588 (2009), https://www.nejm.org/doi/10.1056/NEJMoa0804877?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200www.ncbi.nlm.nih.gov.
[124] *See* Megan E. Patton, et al., *Interim Evaluation of Respiratory Syncytial Virus Hospitalization Rates Among Infants and Young Children After Introduction of Respiratory Syncytial Virus Prevention Products — United States, October 2024–February 2025*, 74 MORBIDITY & MORTALITY WKLY. REP. 421 (May 8, 2025), https://www.cdc.gov/mmwr/volumes/74/wr/mm7416a1.htm?s_cid=mm7416a1_w.
[125] *See* David W. Hutton, et al., *Cost-Effectiveness of Nirsevimab for Respiratory Syncytial Virus in Infants and Young Children*, 154 PEDIATRICS (Nov. 5, 2024).
[126] *See* Influenza Division, Ctrs. for Disease Control & Prevention, *Severity, Disease Burden, and Prevented Burden for the 2024-2025 Influenza Season*, CTRS. FOR DISEASE CONTROL & PREVENTION (June 25, 2025), https://www.cdc.gov/acip/downloads/slides-2025-06-25-26/03-dugan-influenza-508.pdf.
[127] *See id.*
[128] *See id.*

HepA occurred in epidemics, the largest of which peaked in 1971 at nearly 60,000 cases.[129] Following the introduction of a vaccine, hospitalization rates declined by more than 68%, and ambulatory care visits declined by more than 40%.[130] Hand-in-hand with a reduction in disease and medical attention was a reduction in medical expenditures: from 1996 to 2004, medical costs associated with HepA dropped by 68%, from $29.1 million to $9.3 million.[131]

Meningococcal disease has high severity: between 10–15% of individuals who contract meningococcal disease die, and among survivors, 20% have permanent sequelae such as neurologic damage, hearing loss, or loss of a limb.[132] Before the MenACWY vaccine was introduced in 2005, an estimated 1,400–2,800 cases of meningococcal disease occurred each year in the U.S.[133] By contrast, in 2024, there were 503 cases of meningococcal disease (this number represents the highest reported annually since 2013).[134]

These public health successes are in jeopardy of being reversed quickly, which would in turn overwhelm the U.S. health care system.[135] Further, if the February ACIP meeting proceeds as scheduled, "it will immediately compound the harms already inflicted on . . . the public health system" by "amplifying confusion, deepening the erosion of trust on which coordinated public health depends, and further destabilizing a stressed public health system."[136] Although an agenda

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[129] *See Hepatitis A, in Ctrs. for Disease Control & Prevention: Epidemiology and Prevention of Vaccine-Preventable Diseases*, THE PINK BOOK (last updated Apr. 2015), https://www.vdh.virginia.gov/content/uploads/sites/114/2019/06/Attachment-1-Hepatitis-A-Chapter-Pink-Book.pdf.
[130] *See id.*
[131] *See id.*
[132] *See* Sarah Mbaeyi, et al., *Chapter 14: Meningococcal Disease, in Ctrs. for Disease Control and Prevention: Epidemiology and Prevention of Vaccine-Preventable Diseases*, THE PINK BOOK (Apr. 25, 2024), https://www.cdc.gov/pinkbook/hcp/table-of-contents/chapter-14-meningococcal-disease.html.
[133] *See Hepatitis A, in Ctrs. for Disease Control & Prevention: Epidemiology and Prevention of Vaccine-Preventable Diseases*, THE PINK BOOK (last updated Apr. 2015), https://www.vdh.virginia.gov/content/uploads/sites/114/2019/06/Attachment-1-Hepatitis-A-Chapter-Pink-Book.pdf.
[134] *See Meningococcal Disease Surveillance and Trends*, CTRS. FOR DISEASE CONTROL AND PREVENTION (May 9, 2025), https://www.cdc.gov/meningococcal/php/surveillance/index.html.
[135] *See* Ex. 25 (Benjamin Decl.) ¶ 22.
[136] *See id.* ¶¶ 32–33.

has not been released for the February meeting, ACIP members have hinted at potential topics, including downgrading polio and measles vaccines from routine in favor of "freedom of choice" and removing Covid mRNA vaccines from the market.[137] Regardless of topics discussed, however, based on the documented events of this ACIP's prior meetings, Plaintiffs' reasonable fears that future meetings of this ACIP will disseminate further public health misinformation rise above the level of speculation and are sufficient to satisfy the standard for irreparable harm.

Even a modest erosion in vaccination rates could result in immediate increases in preventable illness, morbidity, and death.[138] And crucially, the arbitrary and capricious Non-ACIP Actions and ACIP Actions are negatively affecting trust and immunization rates for ***all*** vaccines, not just the downgraded vaccines.[139] Put simply, "[o]nce these systems fail and preventable disease spreads, no later remedy can restore the lives lost as a result."[140] That kind of threat to human life is a "quintessentially irreparable" harm. *NIH I*, 770 F.Supp.3d at 321 ("The Court is hard pressed to think of a loss more irreparable than the loss of a life . . . . There is no question, there can be no do over and no redress.").

III. The Balance of Equities and the Public Interest Strongly Favor Entry of a Preliminary Injunction.

[137] *See* Apoorva Mandavilli, *Rejecting Decades of Science, Vaccine Panel Chair Says Polio and Other Shots Should be Optional*, N.Y. TIMES, Jan. 23, 2026, https://www.nytimes.com/2026/01/23/health/milhoan-vaccines-optional-polio.html; *see also* End Tribalism in Politics (@EndTribalism), X (Jan. 21, 2026, 5:09 PM), https://x.com/EndTribalism/status/2014098027074449438?s=20. (video of ACIP member Dr. Robert Malone).
[138] *See* Katherine Wu, *Rotavirus Could Come Roaring Back—Very Soon*, THE ATLANTIC, Jan. 5 2026, https://www.theatlantic.com/health/2026/01/childhood-vaccine-schedule-rotavirus-paul-offit/685513/; *see also* Ex. 45 (Jaeger Decl.) ¶¶ 26 ("As vaccination rates begin to decline, herd immunity will erode, at which point outbreaks will occur more rapidly."), 31 ("When vaccines are presented as SCDM rather than routine, parents are more likely to delay or decline. Delays increase the likelihood that future vaccines will also be delayed or missed entirely."); Ex. 27 (Kressly Decl.) ¶¶ 13 ("The Directive removing the COVID-19 vaccine from the routine vaccination recommendations . . . has eroded some patients' faith and trust in all vaccines, causing them to refuse a myriad of routine vaccinations and creating an even more imminent and severe risk of serious illness, hospitalization, and death.").
[139] *See* Ex. 45 (Jaeger Decl.) ¶¶ 13, 26, 31; Ex. 27 (Kressly Decl.) ¶¶ 13, 40; Ex. 41 (Chen Decl.) ¶ 24; Ex. 34 (Racine Decl.) ¶ 20.
[140] *See* Ex. 25 (Benjamin Decl.) ¶ 31-33.

When deciding whether to grant a preliminary injunction, courts must "balance the competing claims of injury and must consider the effect on each party of the granting or withholding of the requested relief." *Winter v. Nat. Res. Def. Council, Inc.*, 129 S.Ct. 365, 367 (2008) (citation modified). Here, both the balance of equities and the public interest overwhelmingly favor Plaintiffs and compel preliminary injunctive relief.

A. The Balance of Hardships Favor Plaintiffs

The balance of hardships overwhelmingly favor Plaintiffs. Absent preliminary injunctive relief, Plaintiffs will continue to suffer immediate, irreparable, and escalating harms caused by Defendants' unlawful vaccine policy actions. Those harms include the diversion of limited clinical and public-health resources from patient care and disease prevention; uncompensated time counseling patients and families confused by abrupt and inadequately explained vaccine recommendations; disruption of established vaccination practices and supply chains; and increased risk that children, pregnant individuals, and immunocompromised patients will forgo timely immunization. These harms are not speculative. They are occurring now and will continue to compound absent judicial intervention. Clinicians and public health organizations are already expending extraordinary time and resources to correct confusion, counter unsupported federal messaging, and mitigate declining vaccination confidence. This time and these resources cannot be recovered and directly detract from the organizations' core mission work of patient care and outbreak preparedness.[141]

[141] *See e.g.* Ex. 25 (Benjamin Decl.) ¶¶ 26, 30-31 ("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 have utilized the evidence-based ACIP framework that the Defendants have abandoned."); Ex. 27 (Kressly Decl.) ¶¶ 26-28, 31; Ex. 28 (O'Shea Decl.) ¶¶ 7-9, 15-16, 18-21 ("Based on the 2026 Schedule Change, our practice was forced to change our operations and develop new protocols to ensure compliance with the new categorization of childhood vaccines. These changes will impact how we see patients, our availability to patients, and ultimately will harm patient uptake of vaccines."); Ex 34 (Racine Decl.) ¶¶ 13-19, 39 ("[A] significant portion of the AAP's efforts involves interpreting government recommendations and translating them into toolkits, guidance documents, and communications for pediatrics and the public . . . due to the confusion that the Vaccine Changes have caused."); Ex.

By contrast, Defendants will suffer no cognizable hardship from entry of a preliminary injunction. Maintaining the status quo ante would not remove vaccines from the market, restrict access to vaccination, or interfere with routine clinical care. Nor would it prevent Defendants from revisiting vaccine policy through lawful, properly constituted, evidence-based processes. At most, Defendants would be temporarily restrained from implementing actions adopted without adherence to required legal and procedural safeguards. There is no equitable interest in the continued operation of unlawful agency action. *See League of Women Voters of U.S. v. Newby*, 838 F.3d 1, 12 (D.C. Cir. 2016). Because Plaintiffs face immediate and irreparable harm from the continued operation of the Challenged Actions, while Defendants face no equitable hardship from a temporary pause on its unlawful conduct, the balance of hardships tips sharply in Plaintiffs favor.

B. The Public Interest Strongly Supports Preliminary Injunctive Relief

"Courts have consistently held there is a strong public interest in health and safety." *NIH I*, 770 F.Supp.3d at 326 (citing *World Gym, Inc. v. Baker*, 474 F.Supp.3d 426, 434 (D. Mass. 2020)). More critically, there is "no public interest in the perpetuation of unlawful agency action," and a strong public interest "in having governmental agencies abide by the federal laws." *Newby*, 838 F.3d at 12; *see also Neighborhood Ass'n of the Back Bay, Inc. v. Fed. Transit Admin.*, 407 F.Supp.2d 323, 343 (D. Mass. 2005); *Clarke v. Office of Fed. Hous. Enter. Oversight*, 355 F.Supp.2d 56, 66 (D.D.C. 2004) (noting a "substantial public interest" in ensuring that a federal agency "acts within the limits of its authority").

That public interest is directly implicated here. Plaintiffs have demonstrated that the Defendants failure to follow the customary, evidence-based framework for vaccine recommendations has destabilized America's public health infrastructure and forced Plaintiff

36 (Pavia Decl.) ¶¶ 40, 41; Ex. 42 (Pring Decl.) ¶¶ 23–24, 45-46; Ex. 44 (Pavlos Decl) ¶¶ 23, 24, 29, 35-36, 40; Ex. 46 (Srinivas Decl.) ¶¶ 17, 18, 25-26

Organizations, clinician-members, and patients into a state of confusion, uncertainty, and perpetual crisis-response mode.[142] By altering the CDC immunization schedule without ACIP evidence-based review, or through an improperly constituted advisory committee, Defendants have replaced evidence-based recommendations with unexplained departures that have sown confusion and distrust among public health organizations, medical associations, providers, and patients alike.[143] Those disruptions materially increase the risk of outbreaks of vaccine-preventable diseases, including HepB and RSV. Such harms cannot be remedied after the fact.[144] The Defendants here are not preventing public-health harm, they are creating it. Where unlawful government action undermines disease-prevention systems and leaves public health professionals unable to anticipate or contain outbreaks, the public interest weighs decisively in favor of injunctive relief. *See Savino v. Souza*, 459 F.Supp.3d 317, 331–32 (D. Mass. 2020).

The public interest is therefore served by restoring lawful decision-making, preserving reliance on evidence-based immunization frameworks, and preventing further irreparable harm to public health while this case is adjudicated. *See NIH I*, 770 F.Supp.3d at 326. Accordingly, the public interest weighs decisively in favor of preliminary injunctive relief.

IV. CONCLUSION

This Court should grant the relief requested in the Proposed Order attached hereto as Exhibit A.

Dated: January 26, 2026

Respectfully submitted,

By: *James J. Oh*
James J. Oh (*admitted pro hac vice*)

[142] *See* Ex. 25 (Benjamin Decl.) ¶¶ 20–21, 31-32; Ex. 34 (Racine Decl.) ¶¶ 14–15, 40; Ex. 44 (Pavlos Decl.) ¶¶ 16-18, 32-33; Ex. 46 (Srinivas Decl.) ¶¶ 14-28; Ex. 48 (Moser Decl.) ¶ 25.
[143] *See* Ex. 27 (Kressly Decl.) ¶¶ 13, 40; Ex. 41 (Chen Decl.) ¶¶ 22–25; Ex. 31 (Berman Decl.) ¶¶ 16–17.
[144] *See* Ex. 25 (Benjamin Decl.) ¶¶ 22–25; Ex. 28 (O'Shea Decl.) ¶¶ 23-26; Ex. 26 (Lewis Decl.) ¶ 21.

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CERTIFICATE OF SERVICE

I hereby certify that this document was filed and served through the ECF system upon the following parties on this 26th day of January 2026:

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