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

THIRD AMENDED COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

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

INTRODUCTION

1. A great, if not the greatest, achievement of the first Trump Administration was Operation Warp Speed. Announced on May 15, 2020, the goal was to deliver 300 million doses of a safe and effective COVID-19 vaccine by January 2021—a historically rapid timeline. Operation Warp Speed ("OWS") was a partnership between several federal agencies (notably Health and Human Services ("HHS"), the Centers for Disease Control and Prevention ("CDC"), the National Institutes of Health ("NIH"), the Food and Drug Administration ("FDA"), and the Department of Defense), academia, and private companies. The May 15, 2020 announcement of OWS predicted that "President Trump's vision for a vaccine by January 2021 will be one of the greatest scientific and humanitarian accomplishments in history."[1]

2. That was an accurate prediction. The Trump Administration achieved two Covid-19 vaccine authorizations and initiated mass distribution by the end of 2020—marking one of the fastest vaccine development efforts in history. Instead of taking seven years to achieve its successful end point, OWS was able "to successfully evaluate candidate vaccines in approximately 7 months, a breathtaking outcome."[2]

3. Seizing the moment, on or about December 27, 2020, President Trump signed into law 42 U.S.C. § 245(a), which requires the Secretary to "carry out a national, evidence-based campaign ***to increase awareness and knowledge of the safety and effectiveness of vaccines for the prevention and control of diseases, combat misinformation about vaccines, and disseminate scientific and evidence-based vaccine-related information, with the goal of increasing rates of***

[1] *Trump Administration Announces Framework and Leadership for 'Operation Warp Speed,'* DoD (May 15, 2020), https://www.war.gov/News/Releases/Release/Article/2310750/trump-administration-announces-framework-and-leadership-for-operation-warp-speed/.

[2] Michael S. Saag, *Development of COVID-19 Vaccines—An Unanticipated Moon Shot Achieved at Warp Speed*, 6 JAMA NETWORK OPEN, no. 1, 2023, at 1 https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2800713.

vaccination across all ages, as applicable, particularly in communities with low rates of vaccination, ***to reduce and eliminate vaccine-preventable diseases***." (Emphasis added).

4. Since his confirmation as United States Secretary of Health and Human Services, Defendant, Robert F. Kennedy, Jr., ("RFK" or the "Secretary") has deviated from this statutorily-established policy of "increasing rates of vaccination across all ages." He has repeatedly made statements and taken action that demonstrate that the Secretary is pursuing policies that are arbitrary, contrary to law, designed to decrease access to vaccines and rates of vaccination, and to increase vaccine skepticism, hesitancy, or denialism. He cannot change course on a policy that affects the health and safety of every resident of this country without providing the reasonable explanation required by the Administrative Procedure Act.

5. In this Third Amended Complaint, Plaintiffs challenge the following justiciable final agency actions that the Secretary has taken since he has been in office:

i. Designation of the Covid-19 vaccine for children as Shared Clinical Decision Making ("SCDM")

6. On May 27, 2025, the Secretary posted a video on the social media platform X in which he ordered the CDC to remove the recommendation of the Covid-19 vaccine for pregnant women and "healthy" children from CDC Schedules. That same day, the Secretary released a one-page "SECRETARIAL DIRECTIVE ON PEDIATRIC COVID-19 VACCINES FOR CHILDREN LESS THAN 18 YEARS OF AGE AND PREGNANT WOMEN," backdated May 19, 2025 (the "Directive") that repeated the instruction to the CDC that he gave in the video. The Secretary issued the Directive without citing to any evidence, without consulting leadership at the CDC, without consulting with the Advisory Committee on Immunization Practices ("ACIP"), which, since 1964, has been entrusted with the responsibility to make recommendations based on sound science and medical practice as to what immunizations are listed on the CDC's

immunization schedule, and without utilizing the "Evidence to Recommendation" ("EtR") framework that was formally adopted by a unanimous vote of the ACIP in February 2018 during the first Trump Administration.[3] The Secretary must explain this action. Furthermore, although the Secretary instructed the CDC in the May 19 Directive and May 27 video to remove entirely the recommendations that pregnant women and children get the Covid-19 vaccine, the CDC's immunization schedule for children was changed to "Shared Clinical Decision Making" ("SCDM") without notice, explanation, citation to any evidence, or the issuance of any guidance from the CDC as to how to engage in SCDM with the parents of pediatric patients. This too must be explained.

ii. Designation of the Covid-19 vaccine for adults as SCDM

7. The May 19 Directive purportedly instructed the CDC to remove the recommendation that pregnant women receive the Covid-19 vaccine, but left in place the routine recommendation that adults under the age of 65 get Covid boosters. The Secretary's new ACIP, however, voted in September to change the Covid-19 vaccine recommendation for adults from routine to SCDM without following the EtR framework. In announcing this change that adopted the newly-constituted ACIP's recommendations, Defendants, acting through Jim O'Neill, the Acting Director of the CDC ("CDC Director" or "O'Neill"), conflated two distinct concepts. In an October 6 post on X, O'Neill stated: "[i]nformed consent is back. CDC's 2022 blanket recommendation for perpetual COVID-19 boosters deterred health care providers from talking about the risks and benefits of vaccination for the individual patient or parent. That changes today." Informed consent and SCDM are not the same thing. Doctors have always obtained informed

[3] Grace Lee, et al., *Updated Framework for Development of Evidence-Based Recommendations by the Advisory Committee on Immunization Practices*, 67 MORBIDITY & MORTALITY WKLY. REP. 1271 (Nov. 16, 2018), https://pmc.ncbi.nlm.nih.gov/articles/PMC6290811/pdf/mm6745a4.pdf.

consent from patients before performing procedures, including administering a vaccine. In contrast, the CDC's website states that, "[u]nlike routine, catch-up, and risk-based recommendations, shared clinical decision-making vaccinations are individually based and informed by a decision process between the health care provider and the patient or parent/guardian."[4] Moreover, on four occasions before 2025 when the ACIP voted to assign a SCDM designation to a vaccine, the CDC has issued detailed explanation of its underlying rationale and guidance on healthcare providers' engagement in SCDM with patients. That was not done here. This too must be explained.

iii. Reconstitution of the ACIP.

8. The Secretary fired all 17 members of the ACIP on June 9, 2025 for pretextual reasons. He appointed new ACIP members in violation of the Federal Advisory Committee Act's ("FACA") requirements that a federal advisory committee by "fairly balanced" and not "inappropriately influenced" by the appointing official. 5 U.S.C. §§ 5(b)(2) and (3); 41 C.F.R. § 102-3.60(b)(3); *see also Union of Concerned Scientists v. Wheeler*, 954 F.3d 11, 17 (1st Cir. 2020) ("FACA contains no private right of action. The APA, however, generally provides a vehicle for reviewing agency decisions that are alleged to violate federal law."). The current ACIP is not fairly balanced, is not acting independently, and is being inappropriately influenced by the Secretary,[5] as evidenced by the ACIP's discussion and votes at the June and September, 2025 meetings that promoted an anti-vaccine agenda. Further, the Secretary appointed new ACIP members not based on relevant experience or credentials as required by the ACIP Charter,[6] but instead based, upon

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

[5] *See* 41 CFR § 102-3.105(i) (requiring the "agency head" to "[d]evelop procedures to assure that the advice or recommendations of advisory committees will not be inappropriately influenced by the appointing authority or any special interest, but will instead be the result of the advisory committee's independent judgment.").

[6] References herein to the "ACIP Charter" are to the ACIP Charter last filed on April 1, 2024.

information and belief, on whether their views on vaccines align with the Secretary's. Accordingly, the appointments of the current ACIP members are not in accordance with law, were arbitrary and capricious, and must be declared null and void. As a result, the votes taken by the Secretary's reconstituted ACIP that were subsequently adopted by the CDC must be vacated because they were taken by a tainted advisory committee. *See United States v. Trump*, 740 F.Supp.3d 1245, (S.D.Fla. 2024) (dismissing indictment where Special Counsel's appointment violated the law). The Secretary must reconstitute the ACIP in accordance with FACA, federal regulations, and the ACIP Charter.

9. These three final agency actions (collectively hereafter "Final Agency Actions") have not only caused concrete harm to the Plaintiffs, but they also have caused disruption, chaos, and confusion throughout the entire healthcare system.

JURISDICTION AND VENUE

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

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

PARTIES

Plaintiffs

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

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

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

15. Plaintiff, the Infectious Diseases Society of America ("IDSA"), is a professional nonprofit society comprised of over 13,000 members in every state in the country, including practicing clinicians, scientists and researchers in the academic setting, public health officials, hospital epidemiologists, and infectious disease specialists working in a variety of settings nationwide. Many IDSA members are currently providing direct care to infants, children, and pregnant women, in both hospital and outpatient settings. IDSA's mission is to bring together the curiosity, compassion, and knowledge of its members and strengthen the field of infectious diseases, advance science, and advocate for health equity.

16. Plaintiff, the Massachusetts Public Health Association d/b/a Massachusetts Public Health Alliance ("MPHA"), is a nonprofit organization dedicated to advocating for health equity and strong public health systems across the Commonwealth of Massachusetts. MPHA's membership is comprised of both individual and organizational public health leaders, including

members of local public health departments, physicians, nurses, community health center leaders, academic public health professionals, nonprofit executives, and other frontline practitioners.

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

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

19. Plaintiff, Jane Doe 1, is a physician working in a hospital where she puts herself at risk of infectious diseases every day to care for patients and save lives. Jane Doe 1 is also a new mother, having given birth to her first child Baby Doe 1 in October 2025. Although Jane Doe 1 was vaccinated against Covid-19 before becoming pregnant, early in her pregnancy, her doctors advised her to get another dose of the vaccine later in pregnancy to better protect herself and her developing baby from contracting this deadly disease. Pregnancy increases the risk of severe illness and complications from infectious disease, including preterm birth and stillbirth. However,

the Directive created barriers to access to the vaccine, which led her obstetrician to advise her to consider getting an older version of the Covid-19 vaccine earlier in her pregnancy in addition to the 2025–2026 Covid-19 vaccine upon reaching 34 weeks gestation. Accordingly, Jane Doe 1 was forced to decide whether to risk getting an old Covid-19 vaccine early, possibly jeopardizing her access to a 2025–2026 vaccine at the optimal timing in her pregnancy, in order to ensure she could pass at least some immunity to Baby Doe 1 during the pregnancy. This decision weighed on Jane Doe 1, causing her headaches, sleep disturbances, and fatigue which negatively impacted her productivity at work.

20. Plaintiff, Jane Doe 2, is also a new mother, having given birth to her first child Baby Doe 2 in October 2025. Jane Doe 2, who lives in Massachusetts, tried to get the Covid-19 vaccine multiple times after the Secretary's announcement on X, but was refused. Even though Jane Doe 2 had a prescription from her obstetrician after the Directive was issued, a pharmacist refused to give her the vaccine because the pharmacist feared losing her license by giving a vaccine contrary to the CDC immunization schedules. A nurse at her obstetrician's office told her that their office's policy was not to give the vaccine with the change federal guidance regarding pregnant women. Jane Doe 2 subsequently tried at another location to get the Covid-19 vaccine but again was refused because of the Directive. Finally, a chain pharmacy location advised Jane Doe 2 that she could only receive the vaccine if she scheduled an appointment with the pharmacy's "flexible" pharmacist, who would be willing to risk their license to vaccinate her. Even then, the pharmacy required Jane Doe 2 to sign an attestation stating: "If I am receiving a COVID-19 vaccine dose, I attest I am eligible for that dose according to current recommendations from the CDC." When she asked the pharmacist what this meant, he informed her that the CDC's guidelines are unclear, but he "personally chooses to follow the recommendations of OB and pediatric groups." Although

Jane Doe 2 was ultimately successful in obtaining a Covid-19 vaccine during her pregnancy, she and Baby Doe 2 were exposed to Covid-19 over the Fourth of July before she could get vaccinated. The difficulty she faced in getting the Covid-19 vaccine while pregnant and her exposure to Covid-19 exacerbated Jane Doe 2's underlying anxiety and depression, causing her physical injuries including sleep disturbances, and tooth grinding that required a dental intervention. Jane Doe 2 still suffers with the physical manifestations of stress as a result of the uncertainty of being able to get the Covid-19 vaccine while pregnant.

21. Plaintiff, Jane Doe 3 and her two teenage boys live in the Seattle, Washington area. Jane Doe 3 has a Masters in Public Health with a focus on Epidemiology and is immunocompromised. Both of her children are neurodivergent and wanted to get the Covid-19 vaccine before they started school at the end of August, so she made an online appointment for both of them at a nearby location of a national pharmacy. She entered both of her sons' birthdates into the online appointment system and was able to make an appointment for both of them on August 14, 2025. Timmy Doe, who has attention deficit hyperactivity disorder ("ADHD"), anxiety, and a severe needle phobia, had a panic attack the night before his vaccine appointment. When she took her sons to the pharmacy for their vaccine appointments, Timmy Doe had another bout of anxiety. The pharmacist first tried to dissuade her from giving her sons the Covid-19 vaccine because a new Covid-19 vaccine was allegedly coming out in September, to which Jane Doe 3 replied that she did not know that. The pharmacist then asked her why did her sons need the vaccine, and Jane Doe 3 replied that she wanted her children to be protected before school started, and because it takes up to two weeks to obtain the full effect of the Covid-19 vaccine, she wanted them to receive the vaccine now. The pharmacist then took out her phone and started scrolling through something on her screen. The pharmacist then looked up from her phone and

told her that she could not give her sons the Covid-19 vaccine because they were not in the eligible age group. When Jane Doe 3 asked what the eligible age group is, the pharmacist replied either over 60 or 65 is the eligible age group. She was not sure whether it was 60 or over or 65 or over. The pharmacist then ended the conversation by stating that she would not vaccinate her sons because they are not in the eligible age group. Both of her sons were upset that they could not get the Covid-19 vaccine. They were fearful of catching the new Covid-19 strain's "razor-blade throat" themselves and were even more fearful of infecting Jane Doe 3 given her compromised immune system. Jane Doe 3 further demonstrates the harm that the Directive caused. Jane Doe 3 scheduled another appointment for Jimmy Doe and Timmy Doe to be vaccinated on September 12, 2025. Timmy Doe had another panic attack the night before that appointment, which he would not have had but for the first appointment being unsuccessful. The Directive has caused confusion amongst pharmacists; it has prevented those who want to get the Covid-19 vaccine from getting vaccinated, thereby increasing the risk that they and their family members, especially those who are immunocompromised, will get sick with Covid-19; and it has caused fear and anxiety in those who cannot get the vaccine.

Defendants

22. Defendant Robert F. Kennedy, Jr. is the Secretary of the United States Department of Health and Human Services and that agency's highest ranking official. He is charged with the supervision and management of all decisions and actions of that agency. 42 U.S.C. § 300u. He is sued in his official capacity.

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

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

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

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

FACTUAL ALLEGATIONS AND LEGAL BACKGROUND

A. The American Academy Of Pediatrics, The Birth Of The Advisory Committee On Immunization Practices ("ACIP"), And The Vaccination Recommendation Process In The United States

27. For more than 25 years before the ACIP came into existence, the main body that made recommendations on vaccine use in the United States was the AAP's Committee on Infectious Diseases ("COID")—called the Committee on Immunization Procedures at the time of its inception.[7]

28. "By the early 1960s, with the licensure of additional new vaccines (monovalent oral poliovirus vaccine, 1961; trivalent oral poliovirus vaccine, 1963; and measles vaccine, 1963) and increased federal investment of resources in vaccines and immunization programs, it was evident that decision making on use of vaccines required a greater degree of continuity of expert technical advice rather than formation of ad hoc committees to address national immunization policy."[8] Therefore, the Surgeon General established ACIP in March 1964. The committee was "charged with the responsibility of advising the Surgeon General regarding the most effective application in

[7] L. Reed Walton, et al., *The History of the United States Advisory Committee on Immunization Practices (ACIP)*, 33 VACCINE 405 (Jan. 2015), https://pubmed.ncbi.nlm.nih.gov/25446820/.
[8] 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.

public health practice of specific preventive agents which may be applied in communicable disease control."[9] That mission has remained essentially unchanged since the ACIP's inception.[10]

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

30. HHS oversees the process by which vaccines are approved and recommended. To harmonize this process, it has entrusted the FDA and the CDC to support aspects of vaccine review and recommendation relevant to their respective areas of expertise. Since their inception, vaccines have undergone a rigorous and continued safety and efficacy review in the United States. Initially, the FDA reviews applications to market new vaccines and decides whether to license vaccines for use. 42 U.S.C. § 262(2). Following FDA approval, the ACIP, an advisory committee subject to the Federal Advisory Committee Act, 5. U.S.C. §§ 1001, *et seq.*, is charged with developing recommendations for whether and how vaccines are listed on the CDC's immunization schedules (the "Schedules"). The CDC Director has the authority to adopt ACIP recommendations, and, once approved, the CDC publishes all ACIP recommendations on its website and in the Morbidity and Mortality Weekly Report ("MMWR"). 45 C.F.R. § 147.130(a)(1)(ii). Meanwhile, the FDA, the ACIP, and the CDC continue to monitor and review the vaccines on the immunization schedule to ensure they remain up-to-date and comport with emerging peer-reviewed, evidence-based data and studies.

B. The ACIP Is Embedded Into The Federal And State Vaccine Infrastructure

31. For over 60 years, the ACIP has served as a global exemplar of sound prevention policy, providing evidence-based advice and guidance that forms the bedrock of U.S. vaccine

[9] *Id.*
[10] *Id.*

policy. Its recommendations, including the routine immunization schedules for children and adults, are developed through a transparent and rigorous scientific process and are relied upon by clinicians, public health departments, and patients as the "source of truth" for preventing infectious diseases.[11]

32. ACIP recommendations are foundational to U.S. vaccine policy. They form the basis of the official childhood and adult immunization schedules, which are considered the standard of care by clinicians nationwide.

33. ACIP's centrality to the nation's health is not merely a matter of scientific custom but is deeply woven into the fabric of federal law, with at least 13 federal statutes referencing ACIP recommendations and tying them to essential public health programs and insurance coverage mandates."[12] For example:

a. The Affordable Care Act ("ACA"): Section 2713 of the Public Health Service Act provides that a "group health plan and a health insurance issuer … shall not impose any cost sharing requirements for—immunizations that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention," 42 U.S.C. § 300gg-13(a)(2);

b. The Vaccines For Children Program: This federal entitlement program, which provides free vaccines to millions of eligible children, requires that the vaccines provided under this program to be on "the list established (and periodically reviewed and as appropriate revised) by the Advisory Committee on Immunization Practices," 42 U.S.C. § 1396s(e).

[11] *See General Committee-Related Information*, CDC (Dec. 16, 2024), https://www.cdc.gov/acip/about/index.html.
[12] *Impact of the Advisory Committee on Immunization Practices Recommendations on State Law*, ASS'N OF STATE AND TERRITORIAL HEALTH OFF. (June 23, 2025), https://www.astho.org/topic/resource/impact-of-acip-recommendations-on-state-law/.

c. Medicare Part D: This law provides that "with respect to an adult vaccine recommended by the Advisory Committee on Immunization Practices … there shall be no cost-sharing under this section with respect to such vaccine." 42 U.S.C. § 1395w-114(a)(6).[13]

d. Medicaid: The Inflation Reduction Act of 2022 amended the Medicaid and Children's Health Insurance Program (CHIP) statutes to require Medicaid and CHIP coverage and payment without cost sharing beginning October 1, 2023 for FDA approved adult vaccines recommended by the ACIP.[14]

e. The Immigration and Nationality Act: This act provides that any "alien … who seeks admission as an immigrant, or who seeks … the status of an alien lawfully admitted for permanent residence, and who has failed to present documentation of having received vaccination against vaccine-preventable diseases, which shall include at least the following diseases: mumps, measles, rubella, tetanus and diphtheria toxoids, pertussis, influenza type B and hepatitis B, and any other vaccinations against vaccine-preventable diseases recommended by the Advisory Committee on Immunization Practices … is inadmissible." 8 U.S.C. § 1182(a)(1)(A)(ii).

f. Veterans' Benefits: This Act defines "preventive health services" for veterans to include "immunizations against infectious diseases, including each immunization on the recommended adult immunization schedule;" which is defined as "the schedule established

[13] "Effective January 1, 2023, the Inflation Reduction Act (IRA) eliminated cost sharing and deductibles for adult vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) covered under Medicare Part D. In 2023, 10.3 million Medicare Part D enrollees received a recommended vaccine free of charge, which saved enrollees more than $400 million in out-of-pocket costs." Bisma A. Sayed, Yevgeniy Feyman, Kristen L. King, *et al.*, *Inflation Reduction Act Research Series: Medicare Part D Enrollee Vaccine Use After Elimination of Cost Sharing for Recommended Vaccines in 2023*, OFF. OF THE ASSISTANT SEC'Y FOR PLANNING AND EVALUATION (May 3, 2024) https://aspe.hhs.gov/reports/ira-elimination-vaccine-cost-sharing-2023.

[14] *Fact Sheet: Inflation Reduction Act changes to Medicaid & Children's Health Insurance Program (CHIP) Adult Vaccine Coverage*, CMS (June 2023) https://www.medicaid.gov/sites/default/files/2023-06/vaccinations-fact-sheet-06272023.pdf.

(and periodically reviewed and, as appropriate, revised) by the Advisory Committee on Immunization Practices." 38 U.S.C. §§ 1701(7)(G) and (10).

g. TRICARE: in this Department of Defense health insurance program for almost 10 million current and former military members and their dependents, "[b]enefits "routinely are covered for well-child care from birth to under six years of age … [including] [i]mmunizations recommended by the Centers for Disease Control." 32 CFR 199.4(c)(3)(xi)(A)(*2*)(*iv*).

34. Furthermore, ACIP's guidance is foundational to public health functions at the state level, and state law, with nearly 600 statutes and regulations across 49 states, three territories, and Washington, D.C. directly referencing and incorporating its recommendations across at least four distinct categories:[15]

a. State School Entry Immunization Requirements: States universally set vaccine requirements for attendance at daycare, primary, secondary, and higher education institutions, and these legal requirements are frequently tied directly to ACIP recommendations.[16]

b. Provider Legal Scope of Practice: States determine the legal authority for various health professionals, including pharmacists, to administer vaccines, often defining that authority by reference to the ACIP recommendations.[17]

c. Health Care Worker & Patient Requirements: Many states require that workers in health care facilities be vaccinated according to ACIP recommendations as a condition

[15] *Impact of the Advisory Committee on Immunization Practices Recommendations on State Law*, ASS'N OF STATE AND TERRITORIAL HEALTH OFF. (June 23, 2025), https://www.astho.org/topic/resource/impact-of-acip-recommendations-on-state-law/.

[16] *See Impact of the Advisory Committee on Immunization Practices Recommendations on State Law*, ASS'N OF STATE AND TERRITORIAL HEALTH OFF. (June 23, 2025), https://www.astho.org/topic/resource/impact-of-acip-recommendations-on-state-law/; Anna Larson, et al., *School-Entry Vaccine Policies: States' Responses To Federal Recommendations Varied From Swift To Substantially Delayed*, 43 HEALTH AFFAIRS 1561 (Nov. 2024), https://www.healthaffairs.org/doi/10.1377/hlthaff.2024.00378.

[17] *See, e.g.*, Spreeha Choudhury, *Implications for Pharmacies: Navigating Shared Clinical Decision-Making in Vaccination*, PHARMACY TIMES (June 13, 2024), https://www.pharmacytimes.com/view/implications-for-pharmacies-navigating-shared-clinical-decision-making-in-vaccination.

of employment, and similar requirements can apply to patients in certain residential care settings to prevent outbreaks.[18]

d. Insurance Coverage Requirements: Beyond federal mandates, state laws may impose separate requirements on state-regulated private insurers or Medicaid managed care organizations to cover ACIP-recommended vaccines.

35. The statutory scheme that underpins the vaccine infrastructure in this country demonstrates Congress' repeated policy decision to require that appointments to the ACIP be made in good faith, that ACIP membership be fairly balanced, that the ACIP is not inappropriately influenced by the appointing authority. Vaccine policy in this country is not to be made unilaterally by a single individual.

36. The Secretary is prohibited by statute from considering political affiliation when making appointments to the ACIP.

37. Federal and state governments, health care providers, public health officials, pharmacists, insurers—nearly everyone who plays a part in the vaccine infrastructure in this country—have developed strong reliance interests that appointments to the ACIP are made in good faith, without regard to political affiliation, and that the ACIP and its Work Groups work independently without inappropriate influence from political appointees.

C. The Secretary's Actions To Undermine Trust In Vaccines

38. Since his confirmation on February 13, 2025, the Secretary has demonstrated a clear pattern of hostility toward established scientific processes, a disregard for expert guidance, an affinity for placing persons who align with his anti-vaccination views in positions of authority, including members of the ACIP, and a reliance on bias and pretext to further his apparent agenda:

[18] *See State Vaccination Requirements*, CDC (Aug. 6, 2024), https://www.cdc.gov/vaccines/php/requirements-laws/state-vaccination-requirements.html.

to undermine trust in vaccines and reduce the rate of vaccinations in this country. Here are a few examples:

39. A measles outbreak that began in this country earlier this year has spread to 42 states with a total of 1,648 confirmed measles cases as of October 28, 2025, resulting in 171 inpatient hospital admissions, with the largest percentage of those hospitalized (21%) being under five years old. There have been three confirmed deaths from this measles outbreak in 2025.[19] Unfortunately, "[t]he United States surpassed a milestone in reported measles cases, with 2025 now having the most cases since the disease was declared eliminated in the U.S. in 2000 and the most cases in more than three decades."[20] In response to this outbreak, the Secretary has offered, at best, mixed messages about the measles vaccine, even though the CDC's website states that "[m]easles vaccination effectively prevents measles.[21] For example, he stated in a written commentary on March 2, 2025 about the initial measles outbreak that he has "a shared responsibility [with other public health officials] to protect public health … ensuring that accurate information about vaccine safety and efficacy is disseminated … make vaccines readily accessible for all those who want them … [and] [t]he decision to vaccinate is a personal one."[22] In the very next paragraph of his commentary, the Secretary implied that vitamins could prevent measles: "Good nutrition remains a best defense against most chronic and infectious illnesses. Vitamins A, C, and D, and foods rich in vitamins B12, C, and E should be part of a balanced diet." There is no evidence that Vitamins, A, C, D, B12, C, and E are defenses against measles. In fact, the

[19] *Measles Cases and Outbreaks*, CDC (Aug. 6, 2025), https://www.cdc.gov/measles/data-research/index.html.
[20] *U.S. Measles Cases Hit Highest Level Since Declared Eliminated in 2000*, Johns Hopkins Bloomberg School of Public Health, International Vaccine Access Center (July 7, 2025), https://publichealth.jhu.edu/ivac/2025/us-measles-cases-hit-highest-level-since-declared-eliminated-in-2000
[21] *Progress Toward Measles Elimination — Worldwide, 2000–2023* (November 14, 2024), https://www.cdc.gov/mmwr/volumes/73/wr/mm7345a4.htm?
[22] Robert F. Kennedy Jr., *Measles outbreak is call to action for all of us*, FOX NEWS (Mar. 2, 2025), https://www.foxnews.com/opinion/robert-f-kennedy-jr-measles-outbreak-call-action-all-us.

Secretary's endorsement of Vitamin A as a preventative against measles has resulted in children being hospitalized for Vitamin A toxicity that caused abnormal liver function.[23] In late March, senior leaders at the CDC ordered staff not to release their experts' assessment that found the risk of catching measles is increased in areas near outbreaks where vaccination rates are lagging. The report would have emphasized the importance of vaccinating people against the measles that, by that time, had spread to 19 states. A CDC spokesperson said in a written statement that the agency decided against releasing the assessment "because it does not say anything that the public does not already know."[24]

40. On March 25, 2025, the Secretary announced the immediate rescission of approximately $11 billion in public health funds that states and localities were relying on to support core immunization infrastructure.[25] As one state's department of health noted: "sudden loss of federal funding threatens Colorado's ability to track Covid trends and other emerging diseases, modernize disease data systems, respond to outbreaks, and provide critical immunization access, outreach, and education—leaving communities more vulnerable to future public health crises."[26]

41. In testimony before Congress on June 24, 2025, the Secretary incorrectly that "there was no science supporting that recommendation," referring to the Covid-19 vaccine for pregnant women. That is untrue. Peer-reviewed studies and research have repeatedly and consistently shown that administration of the Covid-19 vaccine during any trimester of pregnancy lowers

[23] David Martin Davies, *West Texas children treated for vitamin A toxicity as medical disinformation spreads alongside measles outbreak*, TEX. PUBLIC RADIO (Mar. 27, 2025), https://www.tpr.org/public-health/2025-03-27/west-texas-children-treated-for-vitamin-a-toxicity-as-medical-disinformation-spreads-alongside-measles-outbreak; Shauna Devitt, *Poison Centers Observe Increased Vitamin A Exposures in Children During Measles Outbreak*, AMERICA'S POISON CTR. (Apr. 7, 2025), https://poisoncenters.org/news-alerts/13484508.

[24] Patricia Callahan, *The CDC Buried a Measles Forecast That Stressed the Need for Vaccinations*, PROPUBLICA (March 28, 2025, 4:35 PM), https://www.propublica.org/article/measles-vaccine-rfk-cdc-report.

[25] Brandy Zadrozny, *CDC Is Pulling Back $11B in COVID Funding Sent to Health Departments Across the U.S.*, NBC NEWS (March 25, 2025, 12:18 PM), https://www.nbcnews.com/health/health-news/cdc-pulling-back-11b-covid-funding-sent-health-departments-us-rcna198006.

[26] *Id*. (quoting Kristina Iodice, communications director for Colorado's Department of Public Health and Environment).

hospitalization rates, serious illness, and adverse outcomes from Covid-19 infections in pregnant people and infants. A recently published meta-analysis includes 67 studies with over 1.8 million women evaluated and noted no effect of Covid-19 vaccination on miscarriage or preterm birth prior to 37 weeks. In addition, vaccinated pregnant women and their infants had reduced odds of Covid-related hospital admission.

42. On August 5, 2025, HHS issued a press release announcing "the beginning of a coordinated wind-down of its mRNA vaccine development activities under the Biomedical Advanced Research Development Authority (BARDA), including the cancellation and de-scoping of various contracts and solicitations." The press release quotes the Secretary as follows: "'We reviewed the science, listened to the experts, and acted … BARDA is terminating 22 mRNA vaccine development investments because the show these vaccines fail to protect effectively against upper respiratory infections like COVID and flu." The termination of these "investments" amounts to the cancellation of $500 million in federal funding for mRNA research. An infectious disease physician reviewed the evidence that the Secretary cited in the press release, a 181-page document to which the press release linked.[27] The cited evidence "doesn't support ending mRNA vaccine development. It makes the case for expanding it."[28] The document cited in the press release is a "bibliography assembled by outside authors … [with the] lead author … a dentist, not an immunologist, virologist, or vaccine expert."[29] One of the cited reviews in the bibliography "directly compares infection with vaccination and concludes vaccination 'is the more favorable

[27] Jake Scott, *Kennedy's case against mRNA vaccines collapses under his own evidence,* STAT (August 13, 2025) https://www.statnews.com/2025/08/13/rfk-jr-mrna-vaccine-research-science-papers-justification-misreading/
[28] *Id*.
[29] *Id*.

option for protection.' Kennedy is literally citing evidence that contradicts his position. … He's citing sources that explicitly support vaccination while claiming they oppose it."[30]

43. On September 29, 2025, the Secretary posted a video on X to rebut a chart titled "How Vaccines Helped All But Eradicate Diseases" that he claimed that Senator Maria Cantwell used to credit vaccines for the dramatic decline in the overall death rate in the U.S. in the 20th Century. As one leading expert in the vaccine field stated, the September 29 video, which conveyed the message that vaccines do not save lives and have had minimal effect, is inaccurate and misleading when compared with *disease-specific epidemiologic evidence*. While the Secretary invoked a true historical fact that many broad gains predated vaccines, he used that fact to support an inaccurate leap that vaccines did not materially reduce deaths *from the diseases they target*.[31] In other words, while *aggregate-level* infectious-disease mortality did fall substantially before some vaccine rollouts, if disease-specific timelines are analyzed, the drop *after* vaccine introduction is dramatic and temporally linked to vaccination. Peer-reviewed articles such as Roush (JAMA 2007)[32] and the CDC's own data show a greater than 90% decline in cases and ~99% declines in deaths for many vaccine-preventable diseases once vaccines were used widely.

44. The position that the Secretary took in his September 29 video is contrary to a CDC article published in the MMWR in 1999 titled "Ten Greatest Public Health Achievements – United States, 1900-1999." At the top of the list of the ten greatest public health achievements in the 20th Century – vaccination:[33]

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[30] *Id.*

[31] Ezekial J. Emanuel, et al., *RFK Jr. says vaccines don't save lives. He's wrong.* STAT (Oct. 10, 2025), https://www.statnews.com/2025/10/10/measles-polio-vaccines-lives-saved-sanitation-nutrition-expert/.

[32] Sandra W. Roush, et al., *Historical Comparisons of Morbidity and Mortality of Vaccine-Preventable Diseases in the United State*s, *298* JAMA 2155 (2007), https://jamanetwork.com/journals/jama/fullarticle/209448.

[33] CDC, *Ten Great Public Health Achievements – United States, 1900-1999*, 48 MORBIDITY & MORTALITY WKLY. REP. 241, 241 (Apr. 2, 1999), https://stacks.cdc.gov/view/cdc/27168.

Ten Great Public Health Achievements — United States, 1900–1999

- Vaccination
- Motor-vehicle safety
- Safer workplaces
- Control of infectious diseases
- Decline in deaths from coronary heart disease and stroke
- Safer and healthier foods
- Healthier mothers and babies
- Family planning
- Fluoridation of drinking water
- Recognition of tobacco use as a health hazard

D. The Secretary's Unlawful Appointments to The ACIP

i. Qualifications for ACIP Membership

45. While 42 U.S.C. § 217a gives the Secretary the authority to "appoint such advisory councils or committees (in addition to those authorized to be established under other provisions of law), for such periods of time, as he deems desirable … for the purpose of advising him in connection with any of his functions," he does not have unbridled discretion in doing so. First, by law, the Secretary is forbidden from considering political affiliation in making appointments to advisory committees. 42 U.S.C. § 217a–1. ("Advisory committees; prohibition of consideration of political affiliations. All appointments to advisory committees established to assist in implementing the Public Health Service Act [42 U.S.C. 201 et seq.] … *shall be made without regard to political affiliation*.").[34] Second, the ACIP Charter provides that "[m]embers shall be selected from authorities who are knowledgeable in the fields of immunization practices and public health, have expertise in the use of vaccines and other immunobiologic agents in clinical practice

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

or preventive medicine, have expertise with clinical or laboratory vaccine research, or have expertise in assessment of vaccine efficacy and safety.[35] Third, by virtue of Congress incorporating ACIP recommendations within at least 13 federal statutes, and the adoption of nearly 600 statutes and regulations across 49 states, three territories, and Washington D.C., policy makers at all levels of government and healthcare providers, among others, have developed a very strong, deep reliance interest in the selection of ACIP members being done in good faith, without regard to political affiliation, based on merit only, which has been an emphasis since day one of the current Administration.[36] How is merit defined in this context? By the ACIP Charter requiring that members "be knowledgeable in the fields of immunization practices and public health, have expertise in the use of vaccines and other immunobiologic agents in clinical practice or preventive medicine, have expertise with clinical or laboratory vaccine research, or have expertise in assessment of vaccine efficacy and safety."[37]

ii. The Secretary Fires The ACIP on June 9, 2025 for Pretextual Reasons

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

47. It did not take long for the Secretary to break his promise. On June 9, 2025, at exactly 4 p.m. Eastern Time, an Opinion Commentary written by the Secretary appeared in the

[35] *ACIP Charter*, CDC, at 4 (Apr. 1, 2024), https://www.cdc the traditional American values of hard work, excellence, and individual achievement .gov/acip/about/acip-charter.html.
[36] *See* Exec. Order No. 14,173, 90 Fed. Reg. 8633 (Jan. 21, 2025) (extolling "the traditional American values of hard work, excellence, and individual achievement," and "the importance of individual merit, aptitude, hard work, and determination.").
[37] *See also* 41 CFR § 102-3.60(b)(3)(i) ("Advisory committees requiring technical expertise should include persons with demonstrated professional or personal qualifications and experience relevant to the functions and tasks to be performed by the committee.").
[38] KFF Health News, *Sen. Cassidy Says RFK Jr. Promised Key Vaccine Safety Commitments*, at 2:02. YOUTUBE (Feb. 4, 2025), https://www.youtube.com/watch?v=QrJcBtkfwvo.

online version of the *Wall Street Journal*. In the column, the Secretary announced he was "totally reconstituting the Advisory Committee for Immunization Practices (ACIP)" and "retiring the 17 current members of the committee."[39]

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

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

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

50. The Secretary's "persistent conflicts of interest" justification was pretextual. First, he justified the terminations by referencing reports from 1997, 2000, and 2009 on ACIP conflicts of interest, years in which none of the 17 terminated members were on the ACIP. Second, "research from the USC Schaeffer Center for Health Policy & Economics finds that reported conflicts on that Centers for Disease Control and Prevention panel had been *at historic lows* for years before Kennedy's abrupt dismissal. Furthermore, *the type of conflict typically considered the most concerning—income from vaccine makers—had been virtually eliminated among members*

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

of the CDC panel, known as the Advisory Committee on Immunization Practices (ACIP)."[40] "Since 2016, an average of 6.2% of ACIP members and 1.9% of VRBAC members have reported a financial conflict of interest at any given meeting. During that time, *less than 1% of reported conflicts on both committees were related to personal income from vaccine makers*, which includes consulting fees, stock, royalties or ownership."[41] Third, the Secretary has failed to fulfill his promise to release both the Confidential Financial Disclosure Report (for Special Government Employees) and the OGE Form 450s[42] for those he has appointed to the ACIP. Shortly before the Secretary's new ACIP met in June of this year, an HHS spokesperson stated: "[b]efore starting work on ACIP, the new members' ethics agreements *will be made public*. Every ACIP member will be vetted in accordance with their ethics agreement before they are permitted to participate in each meeting agenda item," and further, that "both the ethics agreement and the OGE 450s will be disclosed."[43] Nothing has been disclosed, even though new ACIP member Robert W. Malone, MD, posted on X on June 12, 2025, that "i have already completed three months of ethics vetting and COI training by the appropriate HHS officials."

51. Fifth, the Secretary has not followed the Advisory Committee on Immunization Practices Policies and Procedures manual that provides: '[u]pon appointment, each voting member

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[40] *Conflicts of Interest on CDC Vaccine Panel Were at Historic Lows Before RFK Jr. Dismissal*, UNIV. OF SOUTHERN CAL. SCHAEFFER CTR. (Aug. 18, 2025), https://schaeffer.usc.edu/research/cdc-acip-vaccine-conflicts-rfk-jr/.

[41] *Id*. (emphasis added).

[42] *See* 5 C.F.R. § 2634.901 Policies of confidential financial disclosure reporting ("High-level officials in the executive branch are required to report certain financial interests publicly to ensure that every citizen can have confidence in the integrity of the Federal Government. It is equally important in order to guarantee the efficient and honest operation of the Government that other, less senior, executive branch employees, whose Government duties involve the exercise of significant discretion in certain sensitive areas, report their financial interests and outside business activities to their employing agencies, to facilitate the review of possible conflicts of interest.").

[43] Isabella Cueto, *HHS backtracks on pledge to disclose new vaccine advisers' conflict of interest*, STAT (July 9, 2025), https://www.statnews.com/2025/07/09/kennedy-conflict-of-interest-radical-transparency-acip-vaccine-experts/#:~:text=WASHINGTON%20%E2%80%94%20The%20Department%20of%20Health,make%20key%20disclosure%20documents%20public.

is required to file an Office of Government Ethics 450 form … and a Confidential Financial Disclosure Report."[44]

52. Sixth, the Secretary, contrary to law, and upon information and belief, required candidates for membership on the ACIP to be a registered Republican or Independent and could not have previously made public criticisms of the President or the Secretary. Good science, good medicine, and this case, however, have nothing to do with politics, political affiliations or for whom someone votes. Viruses are notoriously apolitical. They respect neither borders nor political affiliations.

iii. The Secretary Appointed Current ACIP Members Who Do Not Meet The Qualifications Required By FACA and the ACIP Charter.

53. On June 11, 2025, the Secretary announced the appointment of eight new members to the ACIP. In his announcement of his picks, the Secretary asserted that his selections were "highly credentialed scientists, leading public-health experts, and some of America's most accomplished physicians… committed to evidence-based medicine, gold-standard science, and common sense."[45] On or about September 11, 2025 the Secretary announced four more appointments to the ACIP. The Secretary's stated reasons for appointing the current members of the ACIP were pretextual. The backgrounds and credentials of those whom he selected, with one exception, belie his assertion that he made selections based on merit.

54. The current ACIP members are:

i. Hillary Blackburn, who holds a PharmD from the University of Mississippi and was the Director of Medication Access and Affordability at AscensionRx when

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

appointed to the ACIP. Upon information and belief, she has not published any articles or participated in any studies or performed any research on vaccines, immunizations, or infectious diseases.[46] At the September 2025 ACIP meeting she speculated that the Covid-19 vaccine could be connected to her mother's lung cancer diagnosis.

ii. **Evelyn Griffin**, whom the CDC's website lists as being an Obstetrician and Gynecologist at Baton Rouge General Hospital and states that she is "board-certified in obstetrics and gynecology, lifestyle medicine, and functional medicine. With 15 years of clinical practice, she was among the first robotic-assisted gynecologic surgeons in the U.S. and has led efforts to reduce maternal morbidity and mortality."[47] The Baton Rouge General Hospital lists an **Ewelina Griffin**, MD, Obstetrics & Gynecology, Gynecology, Hospitalist, but provides no information on where she went to medical school or college. Upon information and belief, Evelyn or Ewelina Griffin, assuming that they are the same person, has not engaged in any vaccine-related research, vaccine administration, or worked in a relevant public health policy position. Dr. Griffin spoke at a 2024 Louisiana "Health Freedom Day" event promoting efforts to repeal vaccine mandates, where she was introduced as being harassed for her coronavirus opinions and having lost her job with a health care system for refusing to get a coronavirus vaccine. In her speech, she said physicians "blindly believed" in the coronavirus vaccines because they were taught in medical school that vaccines were harmless. 'When you are faced with this vaccination schedule, you are just taught, "Just memorize it at this point. Trust us, it's safe,"' she said, also adding that 'Big Pharma' influences medical school curriculums."[48]

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[46] Hillary Blackburn has published a book, *see* HILLARY BLACKBURN, HOW PHARMACISTS LEAD: ANSWERS FROM WOMEN WHO ARE LEADING, SUCCEEDING, AND IMPACTING PHARMACY (2020).

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

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

iii. Joseph Hibbeln, MD. The CDC's website describes Hibbeln as a Psychiatrist, Neuroscientist, and former Chief of Section on Nutritional Neurosciences, National Institutes of Health where he led "research on immune regulation, neurodevelopment, and mental health. His work has informed U.S. public health guidelines, particularly in maternal and child health." Upon information and belief, Dr. Hibbeln has not studied, researched, or published on vaccines, immunizations, infectious disease, or epidemiology.

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

v. Retsef Levi, has a PhD in Operations Research from Cornell University and, according to his bio on the Massachusetts Institute of Technology website, has an impressive background in *operations management*. Noticeably absent from his MIT bio, however, is any mention of *vaccines*.[49] The CDC's website, however, states that Dr. Levi is "a leading expert in healthcare analytics, supply chain and manufacturing analytics, risk management, and biologics

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

and *vaccine safety*" and that he has "co-authored studies examining the association between mRNA COVID-19 vaccines and risks of cardiovascular disease, mortality, and adverse pregnancy outcomes.[50] Upon information and belief, Dr. Levi has co-authored only two articles on the association between mRNA COVID-19 vaccines and adverse health outcomes, neither were peer reviewed, and both were published in 2025.[51] Before he co-authored these articles, Levi is on record stating that: "The evidence is mounting and indisputable that mRNA vaccines cause serious harm including death, especially among young people. We have to stop giving them immediately!"[52] Both of Levi's studies were published online by medRxiv, which warns that: "This article is a preprint and has not been peer reviewed. It reports new medical research that has yet to be evaluated and so should *not* be used to guide clinical practice." The publisher further warns that "authors use the medRxiv service to make their manuscripts available as 'preprints' before certification by peer review, allowing other scientists to see, discuss, and comment on the findings immediately. Readers should therefore be aware that articles on medRxiv have not been finalized by authors, *might contain errors, and report information that has not yet been accepted or endorsed in any way by the scientific or medical community*. We also urge journalists and other individuals who report on medical research to the general public to consider this when discussing work that appears on medRxiv preprints and *emphasize it has yet to be evaluated by the medical community and the information presented may be erroneous."*[53] A co-author of one of these

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[50] *ACIP Membership Roster*, CDC (Sept. 16, 2025), https://www.cdc.gov/acip/membership/roster.html#cdc_generic_section_5-evelyn-griffin-m-d (emphasis added).
[51] Retsef Levi, et al., *Twelve-Month All-Cause Mortality after Initial COVID-19 Vaccination with Pfizer-BioNTech or mRNA-1273 among Adults Living in Florida*, MEDRXIV (Apr. 29, 2025), https://www.medrxiv.org/content/10.1101/2025.04.25.25326460v1; Josh Guetzkow, et al., *Observed-to-Expected Fetal Losses Following mRNA COVID-19 Vaccination in Early Pregnancy*, MEDRXIV (June 20, 2025), https://www.medrxiv.org/content/10.1101/2025.06.18.25329352v1.full-text.
[52] Retsef Levi (@RetsefL), X (Jan. 30, 2025, 1:28 AM), https://x.com/RetsefL/status/1619945525670981632.
[53] *Frequently Asked Questions (FAQ)*, MEDRXIV, https://www.medrxiv.org/about/FAQ#unrefereed (last visited Nov. 4, 2025) (emphasis added).

articles was Dr. Joseph Lapado, the current Surgeon General of the State of Florida, who has vowed to eliminate all vaccine mandates in the State of Florida and has compared vaccine mandates to slavery.[54] On the other article, a co-author was Tracy Beth Høeg, a surprise hire as a "special assistant" at the FDA in April 2025, who is a former sports medicine doctor who has promoted incorrect information and misinterpreted data about vaccines. [55][56]

vi. **Robert W. Malone** has an MS in Biology from UC San Diego, an MD from Northwestern University, did one year of post-doctoral work at Harvard University, and was involved in early research on mRNA technology in the 1980s and 1990s. Malone claimed to be the inventor of mRNA vaccines, but "[w]hile he was involved in some early research into the technology, his role in its creation was minimal at best", according to half a dozen Covid experts and researchers, including three who worked closely with Dr. Malone.[57] Malone spread so much misinformation and disinformation about the COVID-19 vaccine that he was permanently suspended from Twitter for repeated violations of Twitter's COVID-19 misinformation policy.[58] Malone claimed on The Joe Rogan Experience podcast in late 2021 that "mass formation psychosis" was developing in American society in its reaction to COVID-19 just as during the rise of Nazi Germany[59] and has spoken at anti-vaccine rallies.[60]

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[54] Kayla Epstein, *The Florida surgeon general who likens vaccine mandates to slavery*, BBC NEWS (Sept. 4, 2025) https://www.bbc.com/news/articles/c62q41qm9pvo.
[55] Sarah Karlin-Smith, *'Highly Problematic': Acting FDA Commissioner Paused Planned OK Of Novavax Shot*, CITELINE (Apr. 4, 2025), https://insights.citeline.com/pink-sheet/agency-leadership/us-fda/highly-problematic-acting-fda-commissioner-paused-planned-ok-of-novavax-shot-GUT6LR4X6ZALRMMZAEXYZHY36Y/.
[56] *Id.*
[57] Davey Alba, *The Latest Covid Misinformation Star Says He Invited the Vaccines*, NEW YORK TIMES (Apr. 3, 2022), https://www.nytimes.com/2022/04/03/technology/robert-malone-covid.html.
[58] Sophie Mellor, *Science Vs podcast takes on the Joe Rogan Experience and others, vowing to fact-check what Spotify won't*, FORTUNE (Feb. 1, 2022), https://fortune.com/2022/02/01/science-vs-podcast-drops-show-focus-fact-checking-joe-rogan-experience-spotify-slap-in-the-face/.
[59] Timothy Bella, *A vaccine scientist's discredited claims have bolstered a movement of misinformation*, THE WASH. POST (Jan. 24, 2022), https://www.washingtonpost.com/health/2022/01/24/robert-malone-vaccine-misinformation-rogan-mandates/.
[60] *Id.*

vii. **Cody Meissner** is "a Professor of Pediatrics at the Geisel School of Medicine at Dartmouth and a nationally recognized expert in pediatric infectious disease epidemiology, vaccine development, and immunization safety. He previously served as Chief of the Division of Pediatric Infectious Disease at Tufts-New England Medical Center and on the CDC's Advisory Committee on Immunization Practices and the FDA's Vaccine and Related Biologic Products Advisory Committee."[61]

viii. **Kirk Milhoan** has an MD from Jefferson Medical College and a Ph.D. in the mechanisms of myocardial inflammation from University of California, San Diego. He is a Senior Fellow at the Independent Medical Alliance, which advocates for mRNA-based Covid-19 vaccines to be withdrawn from the market.[62]

ix. **James Pagano**, according to the CDC's website, "is a board-certified emergency medicine physician with more than 40 years of clinical experience. He has worked in diverse emergency settings, from Level 1 trauma centers to small community hospitals, caring for patients across all age groups including infants, pregnant women, and the elderly. Dr. Pagano has served on multiple hospital committees, including utilization review, critical care, and medical executive boards."[63] He has no discernable expertise in vaccines or immunology.

x. **Vicky Pebsworth**, who has a Ph.D in Health Services Organization and Policy from University of Michigan, is currently the Director of Research & Patient Safety at the National Vaccine Information Center, a known anti-vaccine organization and has "'probably been anti-vax longer than RFK has.'"[64]

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[61] *ACIP Membership Roster*, CDC (Sept. 16, 2025), https://www.cdc.gov/acip/membership/roster.html.
[62] Stephanie Armour, *mRNA Vaccines, Once a Trump Boast, Now Face Attacks from Some in GOP*, KFF HEALTH NEWS (Mar. 10, 2025), https://kffhealthnews.org/news/article/mrna-vaccines-trump-boast-under-gop-attacks-legislation/
[63] *ACIP Membership Roster*, CDC (Sept. 16, 2025), https://www.cdc.gov/acip/membership/roster.html.
[64] *Nurse on new CDC Vaccine Panel said to have been 'anti-vax longer than RFK,'* The Guardian (July 5, 2025) https://www.theguardian.com/us-news/2025/jul/05/vicky-pebsworth-vaccine-experts-rfk-jr

xi. **Catherine Stein**, who has a Ph.D. in Epidemiology and Biostatistics from Case Western Reserve University, is a "COVID-19 truther" who claimed that Covid-19 was "not the scary killer the media and government portray it to be," and claimed that Ohio's Department of Health was misconstruing the data.[65] Stein has ties to Health Freedom Ohio, which is linked to Children's Health Defense, the anti-vaccine organization founded by the Secretary.[66] Dr. Stein has testified in support of different versions of legislation written to allow lawmakers to vote down public health orders. She has spoken in support of the bills alongside affiliates of Health Freedom Ohio and the Ohio Advocates for Medical Freedom, another anti-vaccine group. Dr. Stein also testified in support of a "Truth in Covid Statistics" bill, which essentially would force the Ohio Department of Health to publish certain data points about Covid-19 — most of which the department already publishes. She also has spread misinformation equating Covid-19 disease severity with influenza.

xii. **Raymond Pollack** is the Chief of Liver Transplantation and Director of Multiorgan Transplant Programs at the University of Illinois and has held leadership roles with the United Network for Organ Sharing and the American Society of Transplant Surgeons. His experience with vaccines and infectious disease appears limited to non-existent.

55. Eight of the current ACIP members have stated views on vaccines that align with the Secretary's. Three lack the relevant experience and credentials required by the ACIP Charter. Only one has legitimate credentials and expertise of comparable merit to the ACIP members who were fired on June 9.

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

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

56. None of the new ACIP members were required to follow the rigorous application process to become an ACIP member.[67] Historically, the application process to become a voting ACIP member has taken up to two years.

57. On July 31, 2025, an email from acip@cdc.gov was sent to members of ACIP Liaison organizations, which include members of Plaintiffs AAP and ACP, informing them that Liaison organizations were terminated from participating in ACIP workgroups like the Covid-19 Work Group. The pretextual reason given in the email was that "[l]iaison organizations are special interest groups and therefore are expected to have a 'bias' based on their constituency and/or population they represent. It is important that the ACIP Workgroup activities remain free of influence from any special interest groups so ACIP workgroups will no longer include Liaison organizations." While Liaison members do not vote at ACIP public meetings on vaccine recommendations, they have "historically done important work undertaking detailed evidence reviews of the safety and effectiveness of vaccines that helps to inform the group's votes."[68]

58. The ACIP Charter, however, states that: "There also ***shall*** be non-voting liaison representatives from … American Academy of Pediatrics; … the American College of Physicians; … Infectious Diseases Society of America; …" The Secretary's termination of liaison representatives from participation in ACIP work groups violates the ACIP Charter.

E. The Process To Recommend Covid-19 and Other Vaccines Prior To The Current ACIP

59. In 2010, the ACIP adopted the "GRADE" framework—Grading of Recommendations, Assessment, Development, and Evaluation—for assessing the quality of

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

[68] Brenda Goodman, *HHS further constrains certain vaccine advisors to the CDC, limiting their input in evidence reviews,* CNN (Aug. 1, 2025), https://www.cnn.com/2025/08/01/health/hhs-liaison-acip-vaccine-advisers-cdc.

evidence and developing evidence-based recommendations. Since then, an assessment of the quality of available evidence using GRADE has been an integral part of ACIP recommendation development.

60. In 2018, the ACIP by unanimous vote adopted the Evidence to Recommendation ("EtR") framework to improve transparency in evidence-based decision-making and to better evaluate policy implications across select domains, including public health, benefits and harms, feasibility, use of resources, and equity. The ACIP Evidence to Recommendation User's Guide explains that 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. The purpose of 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."[69]

61. Since the ACIP's first meeting to discuss a Covid-19 vaccine in June 2020, the ACIP has met in public meetings 42 times to vote on 32 Covid-19 vaccine recommendations. Before each of these public meetings, the Covid-19 Work Group spent hours deliberating and analyzing the data, evidence, science, and peer-reviewed studies on the effectiveness and safety of the vaccine. Before every ACIP vote on a Covid-19 vaccine, the Covid-19 Work Group followed the EtR framework to arrive at a recommendation to the ACIP on whether and how to recommend the use of Covid-19 vaccines. The current ACIP has provided no indication that its members understand the EtR framework, let alone that the committee followed the EtR framework with respect to any vote it took on the Covid-19 vaccine or, for that matter, on anything else.

[69] ACIP Evidence to Recommendation User's Guide, CDC, at 3 (Oct. 1, 2020), https://www.cdc.gov/acip/media/pdfs/2024/09/ACIP-EtR-Users-Guide_October-1-2020.pdf.

F. The Arbitrariness and Capriciousness of the Final Agency Actions Challenged Here

i. The Designation of the Covid-19 Vaccine for Children as SCDM

62. The announcement that the Secretary made on May 27 instructing the CDC to remove the Covid-19 vaccine recommendation for pregnant women and children came as a surprise to officials at the CDC, who five hours after the video was posted on X, received the written May 19 Directive for the first time.[70]

63. Just a week before this video appeared on X, and a day after the Directive is dated, FDA Commissioner Marty Makary published an article dated May 20, 2025 in The New England Journal of Medicine that he co-authored with Vinay Prasad, the Director of the Center for Biologics Evaluation and Research in the FDA, stating that "pregnancy and recent pregnancy" are factors which "increase a person's risk of severe COVID-19."[71] 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.'"[72]

64. The CDC's immunization schedules were changed the same day as the May 27 announcement. Although the Directive ordered the CDC "to remove Covid-19 vaccines from the recommended Child and Adolescent Immunization Schedule by Age," the CDC, however, strangely did not entirely remove the recommendation that children be routinely vaccinated against Covid-19. Instead, on May 29, 2025, the CDC downgraded the designation to SCDM.[73]

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

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[70] Lena H. Sun, *CDC blindsided as RFK Jr. changes covid-19 vaccine recommendations*, THE WASH. POST (May 28, 2025), https://www.washingtonpost.com/health/2025/05/28/vaccines-cdc-rfk-jr-covid/.
[71] Vinay Prasad & Martin Makary, *An Evidence-Based Approach to Covid-19 Vaccination*, 392 THE NEW ENGLAND J. MED. 2484, 2485, fig. 2 (2025), https://www.nejm.org/doi/full/10.1056/NEJMsb2506929.
[72] 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/.
[73] *Child and Adolescent Immunization Schedule by Age*, CDC (July 2, 2025), https://www.cdc.gov/vaccines/hcp/imz-schedules/child-adolescent-age.html.

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

67. The Secretary did not consult with the CDC about the Directive.[74] In fact, at the April 15, 2025 open meeting of the ACIP, Dr. Lakshmi Panagiotakopoulos, an epidemiologist at the CDC, presented recommendations on use of Covid-19 vaccines for 2025-2026 for different population groups for which there is conclusive evidence of a higher risk of severe illness from the Covid-19 virus. Dr. Panagiotakopoulos noted that pregnant individuals continued to face an increased risk of severe outcomes from contracting Covid-19. Not only does a Covid-19 vaccine protect the mother, but it also protects infants less than six months of age because infants less than six months old cannot receive the Covid-19 vaccine, but the mother can protect the infant by passing antibodies to the fetus from a Covid-19 vaccine administered during pregnancy. Dr. Fiona Havers, also an epidemiologist at the CDC, presented findings at the April 25, 2025 ACIP meeting on the impact of Covid-19 on children in the United States in the past year. "She found that at least 7,000 children were hospitalized with Covid. About 20 percent of those hospitalized were admitted to the intensive care unit, *half were previously healthy*, virtually none had been vaccinated, and *152 had died, most less than 4 years of age*. The conclusion was clear; all children in the United States, whether they were previously healthy or not, should receive the primary series of Covid vaccines."[75]

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

[74] Lena H. Sun, *CDC blindsided as RFK Jr. changes covid-19 vaccine recommendations*, THE WASH. POST (May 28, 2025), https://www.washingtonpost.com/health/2025/05/28/vaccines-cdc-rfk-jr-covid/.
[75] Paul Offit, *This CDC Resignation Should Scare You*, SUBSTACK (July 8, 2025), https://pauloffit.substack.com/p/this-cdc-resignation-should-scare (emphasis added).

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

70. The Secretary signed the Directive only five days after he testified before Congress that: "what I would say is my opinions about vaccines are irrelevant," and "I don't think people should be taking medical advice from me."[76]

71. The Directive is contrary to the wealth of data and peer-reviewed studies that demonstrate the safety and efficacy of Covid-19 vaccines for children and pregnant women.

72. On August 27, 2025, Susan Monarez, Ph.D., was fired from her position of Director of the CDC. That same day, three top-ranking officials at the CDC resigned in protest, including Dr. Demetre Daskalakis, the Director of the National Center for Immunization and Respiratory Diseases at the CDC. In his resignation letter that he posted on X that night, Dr. Daskalakis stated: "[t]he recent change in the adult and children's immunization schedule threaten the lives of the youngest Americans and pregnant people. The data analyses that supported this decision have never been shared with CDC despite my respectful requests to HHS and other leadership."[77] Upon information and belief, the reference to that change in the adult and children's immunization schedule is a reference to the changes that the Secretary announced in his May 27 video.

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[76] Cecelia Smith-Schoenwalder, *RFK Jr. Gets Grilled on Capitol Hill: 4 Takeaways*, U.S. NEWS (May 14, 2025), https://www.usnews.com/news/health-news/articles/2025-05-14/rfk-jr-defends-trumps-budget-plan-addresses-vaccines-on-capitol-hill.

[77] *See* Michael Melgar, et al., *Use of Respiratory Syncytial Virus Vaccines in Older Adults: Recommendations of the Advisory Committee on Immunization Practices – United States, 2023*, 72 MORBIDITY & MORTALITY WKLY. REP. 793, 797-8 (July 21, 2023), https://www.cdc.gov/mmwr/volumes/72/wr/pdfs/mm7229a4-H.pdf; Miwako Kobayashi, et al., *Pneumococcal Vaccine for Adults Aged ≥19 Years: Recommendations of the Advisory Committee on Immunization Practices, United States, 2023*, 72 MORBIDITY & MORTALITY WKLY. REP. 1, 25 (Sept. 8, 2023); Sarah A. Mbaeyi, et al., *Meningococcal Vaccination: Recommendations of the Advisory Committee on Immunization Practices, United States, 2020*, 69 MORBIDITY & MORTALITY WKLY. REP. 1, 21; Elissa Meites, et al., *Human Papillomavirus Vaccination for Adults: Updated Recommendations of the Advisory Committee on Immunization Practices,* 68 MORBIDITY & MORTALITY WKLY. REP. 698, 700 (Aug. 16, 2019).

ii. The Designation of the Covid-19 Vaccine for Adults as SCDM

73. The ACIP did not apply GRADE criteria or follow the EtR framework prior to voting to change the CDC's immunization schedule in September, 2025 to designate the Covid-19 vaccine as SCDM.

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

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

iii. The Reconstitution of the ACIP

76. The reconstituted ACIP that met in September 2025 was composed of individuals with limited or no experience as practitioners or policy makers for vaccine delivery, and they lacked experience in critical disciplines including vaccinology, public health science, infectious diseases, epidemiology, vaccine program implementation, and health care economic analysis.

77. In addition, the removal of longstanding professional organization liaisons from ACIP work groups deprived the committee of relevant subject matter expertise and professional experience with providers who administer vaccines.

78. The reconstituted ACIP failed to post its agenda in the Federal Register prior to the established deadline for advance notice, and then made unannounced changes to that agenda.

79. The reconstituted ACIP further failed to disclose relevant information including presentation slides, vote language for consideration, and disclosure of voting members' real or potential conflicts of interest.

80. At the September ACIP meeting, a new Covid Work Group presented information that contained material inaccuracies, including an allegation that the Covid-19 vaccine resulted in "DNA contamination". Moreover, non-experts were allowed to present unvetted information that lacked indicia of high scientific rigor or contained anecdotal statements.

81. Prior to the September ACIP meeting, upon information and belief, the Covid Work Group that presented at that meeting did not conduct a systematic literature review, did not solicit input from medical organizations prior to the meeting, and did not apply the GRADE criteria or the EtR framework. Moreover, information regarding rare side effects were given disproportionate attention or taken out of context, such as the risk of myocarditis. In addition, claims regarding mRNA were scientifically inaccurate and lacked biological plausibility.

82. Although the committee discussed potential harms associated with the Covid-19 vaccine, it failed to address the vaccine's benefits in a balanced manner.

G. Injury To The Plaintiffs (and to Public Health)

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

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

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

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

86. Because the Plaintiff medical and public health organizations ("Plaintiff Organizations") do not trust the Secretary or his reconstituted ACIP,[78] the Plaintiff Organizations

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

have had to divert resources to develop new infrastructures, processes, and guidance to fulfill their mission to their members.[79] For example, on August 19, 2025, the AAP "published an independent evidence-based immunization schedule for children and adolescents in the wake of federal officials undermining the rigorous scientific process for making recommendations. … The biggest difference between the AAP and CDC schedules is around COVID-19 vaccination. The CDC no longer recommends routine vaccination for healthy children, although children can get vaccinated after a conversation with their doctor. In contrast, the AAP recommends all young children ages 6-23 months get vaccinated as well as children ages 2-18 years in certain risk groups. It also calls for children whose parent or guardian desire protection from COVID-19 to have access to the vaccine."[80] The same day that the AAP published its own immunization schedule, the Secretary made the following threat: "AAP today released its own list of corporate-friendly vaccine recommendations. … AAP should also be candid with doctors and hospitals that recommendations that diverge from the CDC's official list are not shielded from liability under the 1986 Vaccine Injury Act."[81]

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

> SMFM recommends that all people who are considering pregnancy, pregnant, recently pregnant, or breastfeeding receive vaccination against COVID-19. Surveillance data collected since the beginning of the COVID-19 pandemic, which started in 2020, clearly demonstrates the safety and efficacy of mRNA vaccines in pregnancy.
>
> All physicians and other health care partners, along with health insurers, should continue recommending COVID-19 vaccination to pregnant patients. Maternal immunization is proven to protect patients and their infants against severe illness and death from infectious diseases.[82]

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

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

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

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

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

105. James Lewis, M.D., M.P.H., is a board-certified physician in internal medicine, infectious diseases, and preventative medicine. In addition to his role as an adjunct professor at the University of Washinton's Division of Allergy and Infectious Diseases. Dr. Lewis also serves as the Health Officer for the Snohomish County Health Department in the State of Washington. He is also a member of APHA. Like the other physicians mentioned here, the Secretary's action have concretely harmed Dr. Lewis. Because of the Directive, Dr. Lewis now reallocates his time to projects that otherwise would not be necessary. These include efforts to change local and state laws and Snohomish County policies that tie vaccine recommendations to ACIP and CDC

guidance. Dr. Lewis and his colleagues undertake this work because he can no longer trust in the integrity or judgment of the new ACIP, its recommendations, or CDC guidance.

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

107. David A. Wheeler, M.D., is a practicing physician in Northern Virginia with an emphasis in infectious diseases and internal medicine. He is a fellow of the ACP and the IDSA. Since the designation of the Covid-19 vaccine as SCDM for adults under 65, Dr. Wheeler has seen

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

CAUSES OF ACTION

COUNT I

Violation of the Administrative Procedure Act – Arbitrary & Capricious

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

109. The Final Agency Actions are subject to review under the Administrative Procedure Act ("APA").

110. The APA authorizes courts to "hold unlawful and set aside agency action, findings, and conclusions found to be" "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law or that are taken "without observance of procedure required by law[.]" 5 U.S.C. § 706(2)(A).

111. An agency action is arbitrary and capricious if the agency has "relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of

agency expertise." *Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co*., 463 U.S. 29, 43 (1983).

112. The designation of the Covid-19 vaccine as SCDM for adults and children were arbitrary and capricious final agency actions. The firing of the ACIP on June 9 and appointment of the new ACIP members were based on pretextual reasons and were arbitrary and capricious final agency action.

113. Pursuant to 5 U.S.C. § 706 and 28 U.S.C. § 2201, Plaintiffs are entitled to a declaration that these actions violate the APA because they were arbitrary and capricious.

114. The Final Agency Actions have injured all of the Plaintiffs in this action.

115. Plaintiffs are also entitled to vacatur of the SCDM designations of the Covid-19 vaccine on the CDC's immunization schedules and a permanent injunction ordering the Secretary to reinstate to the CDC immunization schedules the routine recommendations that children and adults get the Covid-19 vaccine.

116. The appointments of the current ACIP members must be vacated and a permanent injunction granted ordering the Secretary to reconstitute the ACIP in accordance with law and the ACIP Charter.

COUNT II

Violation of the Administrative Procedure Act – Not In Accordance With Law

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

118. Under the APA, a court must "hold unlawful and set aside agency action, findings, and conclusions found to be … not in accordance with law; … [or] without observance of procedure required by law; …" 5 U.S.C. § 706(2)(A), (D).

119. The Final Agency Actions are subject to review under the APA.

120. Over the decades, Congress has authorized and ratified a process that vests responsibility and authority in an ACIP that has been constituted in good faith and in accordance with law to make recommendations for the vaccines to include on CDC's immunization schedules. The Secretary's reconstitution of the ACIP was not in accordance with law and were without observance of procedure required by law. The votes that the new ACIP took this year are, therefore, null and void and cannot be relied upon or promoted by any component of the Department of Health and Human Services.

121. The Secretary and the imbalanced, inappropriately influenced ACIP have acted contrary to 42 U.S.C. § 245(a) that requires the Secretary to "carry out a national, evidence-based campaign to increase awareness and knowledge of the safety and effectiveness of vaccines for the prevention and control of diseases, combat misinformation about vaccines, and disseminate scientific and evidence-based vaccine-related information, with the goal of increasing rates of vaccination across all ages, as applicable, particularly in communities with low rates of vaccination, to reduce and eliminate vaccine-preventable diseases."

122. The current ACIP is tainted, and its votes and recommendations have injured all the Plaintiffs in this action.

123. The Secretary's appointments to the ACIP, the majority of whom align with his views on vaccines, have caused Plaintiff Organizations to lose faith and trust in the ACIP and has caused the Plaintiff Organizations to divert resources to combat the misinformation and disinformation coming out of the reconstituted ACIP.

124. Pursuant to 5 U.S.C. § 706 and 28 U.S.C. § 2201, Plaintiffs are entitled to a declaration that the agency actions challenged here are contrary to law and in violation of the APA.

125. Plaintiffs are entitled to vacatur of the SCDM designations of the Covid-19 vaccine and a permanent injunction ordering the Secretary to reinstate the Covid-19 vaccine recommendations for adults (including pregnant women) and children to the CDC immunization schedules.

126. Plaintiffs are entitled to vacatur of the appointments of the current ACIP and an injunction ordering the Secretary to reconstitute the ACIP in accordance with law and the ACIP Charter.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment against Defendants for each of the causes of action raised herein. Plaintiffs respectfully request that this Court enter judgment in their favor and that the Court:

1. Declare unlawful and set aside the Directive as arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law under the APA;

2. Declare unlawful and set aside the changes to the CDC adult immunization schedules that designated the Covid-19 vaccine as "Shared Clinical Decision Making" for everyone under the age of 65;

3. Grant permanent injunctive relief ordering the restoration of the Covid-19 vaccine as a "recommended vaccination" on the CDC's immunization schedules for adults under the age of 65, pregnant women, and children six months to 17 years;

4. Declare that the Secretary's appointments of the current members on the ACIP were arbitrary and capricious, not in accordance with law, violated the APA, and therefore are null and void;

5. Declare that because Congress has incorporated reliance on ACIP recommendation into at least 13 federal statutes, and because nearly 600 statutes and regulations across 49 states, three territories, and the District of Columbia reference ACIP recommendations,[83] it is in the public interest that the Secretary reconstitute the ACIP with all new members, in good faith, and in compliance with FACA and the ACIP Charter;

6. Grant permanent injunctive relief ordering the Secretary to reconstitute the ACIP, in good faith, and in compliance with FACA and the ACIP Charter within 60 days of this Order;

7. Order the Secretary to submit a status report to the Court within 30 days of this Order on the progress being made on reconstituting the ACIP;

8. Award to Plaintiffs reasonable attorney's fees and costs incurred in pursuing this action; and

9. Grant all such other and further relief as this Court deems just and appropriate.

Dated: November 5, 2025

Respectfully submitted,

By: *James J. Oh*

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[83] *Impact of the Advisory Committee on Immunization Practices Recommendations on State Law*, ASS'N OF STATE AND TERRITORIAL HEALTH OFF. (June 23, 2025), https://www.astho.org/topic/resource/impact-of-acip-recommendations-on-state-law/.

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CERTIFICATE OF SERVICE

I hereby certify that this document was filed through the ECF system and served upon the following parties by via email on this 5th day of November 2025:

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

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

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