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; MARTY MAKARY, in his official capacity as Commissioner of the Food and Drug Administration; FOOD AND DRUG ADMINISTRATION; JAY BHATTACHARYA, in his official capacity as Director of the National Institutes of Health; NATIONAL INSTITUTES OF HEALTH; 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

SECOND AMENDED COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

District Judge: Hon. William G. Young
Magistrate Judge: Hon. M. Page Kelley

Leave to file granted on September 3, 2025

INTRODUCTION

1. This case is about the process and procedure for deciding what vaccines are safe, effective, and should be recommended to the American people so that they can make the best medical decisions for themselves and their families. The questions presented here are (a) whether the Secretary of the United States Department of Health and Human Services ("HHS") may himself unilaterally decide what vaccines are listed on the Centers for Disease Control and Prevention's ("CDC") immunization schedules, and (b) whether the Secretary can ignore, without providing reasoned and reasonable explanation, the process and procedure that HHS has followed for decades to make recommendations on safe and effective use of vaccines to include on CDC immunization schedules for different population groups like pregnant women and children.

2. The entire vaccine ecosystem in this country has come to trust and rely on an evidence-based, scientific, transparent process that began in 1964 with the formation of the Advisory Committee on Immunization Practices ("ACIP"), which sits inside of the CDC. The ACIP has been responsible for making recommendations on what vaccines to include on CDC immunization schedules and how a recommended vaccine can appropriately be administered to different population groups. The ACIP has consistently followed explicit evidence-based methods based on the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach and the Evidence to Recommendations ("EtR") framework. It holds public meetings when discussing a vaccine and when voting on whether and how to safely and effectively use a vaccine.

3. Defendant Robert F. Kennedy, Jr., the Secretary of HHS (the "Secretary"), ignored this process when he made an announcement on May 27, 2025 on the social media platform X that he had ordered the CDC to remove the recommendation of the Covid 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 ordered the CDC to remove the recommendation that children and pregnant women receive the Covid vaccine. He did so without consulting with the ACIP, without following the GRADE approach or EtR framework, and without consulting with the CDC.

4. Indeed, the Secretary issued this Directive in the face of evidence presented by the CDC—only six weeks before he issued the Directive—that pregnant women and healthy children were very much still at risk from Covid. At the April 15, 2025 public meeting of the ACIP, Dr. Lakshmi Panagiotakopoulos, an epidemiologist at the CDC, presented recommendations on use of Covid vaccines for 2025-2026 for different population groups for which there is conclusive evidence of a higher risk of severe illness from the Covid virus. Dr. Panagiotakopoulos noted that pregnant individuals continue to face an increased risk of severe outcomes from contracting Covid.[1] Not only are expectant mothers generally more susceptible to respiratory pathogens like Covid, but infants less than six months old are also at high risk of contracting Covid because they cannot receive the Covid vaccine before six months of age. The way to protect an infant less than six months old from Covid is for the mother to receive the vaccine during pregnancy, which results in the passing of antibodies to the fetus that are protective for months post birth. Dr. Fiona Havers, an epidemiologist at the CDC, also presented findings to the ACIP at the April 15 meeting on the impact of Covid on children in the United States in the past year.[2] "She found that at least 7,000

[1] Lakshmi Panagiotakopoulos, *Use of 2025–2026 COVID-19 Vaccines: Work Group Considerations*, CDC ACIP Meeting (April 15, 2025), https://www.cdc.gov/acip/downloads/slides-2025-04-15-16/05-Panagiotakopoulos-COVID-508.pdf.

[2] Fiona P. Havers, *COVID-19–Associated Hospitalizations—COVID-NET, April 2025 Update*, CDC ACIP Meeting, (April 15, 2025), https://www.cdc.gov/acip/downloads/slides-2025-04-15-16/03-Havers-COVID-508.pdf.

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."[3] Covid vaccination has been shown to reduce the risk of illness and hospitalization due to Covid infection in children; however, the protective effect of the primary vaccine series wanes within approximately six months.[4] Continued protection against severe disease requires immune boosting, either through administration of booster doses or through natural infection. However, while natural infection carries inherent risks, including hospitalization, complications, and the development of long Covid, booster vaccine doses provide protection against both infection risks and the development of long Covid.[5] During the April meeting, Dr. Ruth Link-Gelles discussed vaccine effectiveness, concluding that receipt of the 2024–2025 COVID vaccine conferred additional benefits in populations with both infection-induced and vaccine-induced immunity.[6] No vote on the Covid vaccine was scheduled for the April meeting; rather, evidence and findings were

[3] Paul Offit, *This CDC Resignation Should Scare You*, SUBSTACK (July 8, 2025), https://pauloffit.substack.com/p/this-cdc-resignation-should-scare (emphasis added).

[4] Allison Avrich Ciesla et al., *Effectiveness of Booster Doses of Monovalent mRNA COVID-19 Vaccine Against Symptomatic Severe Acute Respiratory Syndrome Coronavirus 2 Infection in Children, Adolescents, and Adults During Omicron Subvariant BA.2/BA.2.12.1 and BA.4/BA.5 Predominant Periods*, 10 OPEN FORUM INFECTIOUS DISEASES 1, 1 (Apr. 13, 2023), https://academic.oup.com/ofid/article-pdf/10/5/ofad187/50407978/ofad187.pdf; Ruth Link-Gelles, *Updates to COVID-19 vaccine effectiveness (VE) in the U.S.*, at 19 (Sep. 12, 2023), https://www.cdc.gov/acip/downloads/slides-2023-09-12/05-COVID-Link-Gelles-508.pdf; Ruth Link-Gelles, *Effectiveness of Monovalent and Bivalent mRNA Vaccines in Preventing COVID-19–Associated Emergency Department and Urgent Care Encounters Among Children Aged 6 Months–5 Years — VISION Network, United States, July 2022–June 2023*, 72 Morbidity and Mortality Weekly Report 886, 886 (Aug. 18, 2023), https://www.cdc.gov/mmwr/volumes/72/wr/pdfs/mm7233a2-H.pdf.

[5] Anna R. Yousaf, Josephine Mak, and Lisa Gywnn, *COVID-19 Vaccination and Odds of Post-COVID-19 Condition Symptoms in Children Aged 5–17 Years*, 8 JAMA Open Network 1, at 9 (Feb. 24, 2025), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2830556.

[6] Ruth Link-Gelles, *Interim Estimates of 2024-2025 COVID-19 Vaccine Effectiveness*, CDC ACIP Meeting, at 14 (Apr. 15, 2025), https://www.cdc.gov/acip/downloads/slides-2025-04-15-16/04-Link-Gelles-COVID-508.pdf.

presented at the April meeting in anticipation of a vote on recommendations regarding the Covid vaccines for the fall 2025 respiratory virus season and into 2026.

5. Inexplicably, in the face of this uncontroverted evidence, the Secretary posted his video announcement on X six weeks later on May 27, 2025, stating that he "couldn't be more pleased that, as of today, the Covid vaccine for healthy children and healthy pregnant women has been removed from the CDC recommended immunization schedules."[7] In the video, the Secretary falsely claimed that there was a "lack of any clinical data to support the repeat booster strategy in children." Defendants Martin Makary, Commissioner of Food and Drugs ("FDA Commissioner" or "Makary") and Jay Bhattacharya, Director of the National Institutes of Health ("NIH Director" or "Bhattacharya"), were at the Secretary's side in the video. Bhattacharya proclaimed that ending the repeat booster strategy for healthy children was "good science." No one at HHS, including the three officials in the video, have provided any scientific evidence to support the Directive.

6. Dr. Panagiotakopoulos resigned from the CDC on June 3, 2025 because she believed she was "no longer able to help the most vulnerable members" of the U.S. population.[8]

7. Six days later, on June 9, 2025, without any advance notice, the Secretary fired all 17 voting members of the ACIP. Two days later, he replaced them with eight individuals who are either unqualified or who have distributed dis- or misinformation about vaccines.

8. One week later, Dr. Havers resigned from the CDC because she "no longer [had] confidence that these data will be objectively evaluated with appropriate scientific rigor to make evidence-based vaccine policy decisions."[9] She later told the New York Times that: "CDC

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

[8] Julie Steenhuysen, Michael Erman and Dan Levine, *Exclusive: CDC expert resigns from COVID vaccines advisory role, sources say*, REUTERS (June 4, 2025), https://www.reuters.com/business/healthcare-pharmaceuticals/cdc-expert-resigns-covid-vaccines-advisory-role-sources-say-2025-06-03/.

[9] Paul Offit, *This CDC Resignation Should Scare You*, SUBSTACK (July 8, 2025), https://pauloffit.substack.com/p/this-cdc-resignation-should-scare.

processes are being corrupted in a way that I have never seen before. If it isn't stopped, and some of this isn't reversed, like, immediately, a lot of Americans are going to die from vaccine-preventable diseases."[10]

9. In the meantime, the Directive caused direct harm to Plaintiffs Jane Doe 2 and Jane Doe 3 and threatens irreparable harm to Plaintiff Jane Doe 1. Both are pregnant and live or work in Massachusetts. Jane Doe 2 brought a prescription to her local pharmacy for the Covid vaccine that she received from her obstetrician after this issuance of the Directive on May 27. The pharmacist refused to administer the vaccine to her because the pharmacist was afraid of losing her license if she administered a vaccine that the CDC no longer recommended during pregnancy. Jane Doe 2 tried to receive the vaccine at another pharmacy and, again, was refused because of the Directive. While she was ultimately able to receive the vaccine at a third location, the pharmacy required her to sign an attestation asserting that she is eligible to receive the vaccine under the CDC's guidelines, which the pharmacist administering the vaccine to her was unable to confirm. Jane Doe 1 is a physician who works in a Massachusetts hospital where she is exposed to infectious diseases on a daily basis. Jane Doe 1 therefore faces an increased risk of contracting Covid. Now, with the respiratory virus season upon us, she faces the increased imminent risk—as demonstrated by Jane Doe 2—of being unable to get the Covid vaccine because of the Secretary's action.

10. Jane Doe 3 now joins this case because a pharmacist refused to give the Covid vaccine to her two teenage sons on August 14, 2025. Jane Doe 3, who lives in the Seattle, Washington area, made online appointments for her sons to get the Covid vaccine and went to the pharmacy at the appointed times. The pharmacist on duty refused to vaccinate her sons because they ostensibly were not in the eligible age group. When Jane Doe 3 asked what the eligible age

[10] *Id.*

group is, the pharmacist replied either over 60 or 65 is the eligible age group. The pharmacist ended the conversation by reiterating that she would not vaccinate her sons because they are not in the eligible age group. Both of Jane Doe 3's sons were upset that they could not get the Covid vaccine. They are fearful of catching the new Covid strain's "razor-blade throat" themselves and are even more fearful of infecting Jane Doe 3, who has a compromised immune system.

11. The respiratory virus season annually begins in the months of September and October in this country. Presently, schools, health care providers, public health departments, and pharmacists, among others, are gearing up for the public to get flu shots and other vaccines, such as Covid boosters, as the respiratory illness season approaches. The Directive, however, has caused confusion and uncertainty as to whether pregnant individuals and children can—or even should—get the Covid vaccine. The Directive has caused increasing distrust of doctors' advice to their patients to get vaccinated, thus damaging the patient-physician relationship and inhibiting the ability of health care providers to practice according to the standard of care required of them. The solution to the damage that the Directive has caused across the entire vaccine ecosystem is to vacate the Directive and order the Secretary to restore the recommendations that pregnant individuals and children receive the Covid vaccine to the CDC's immunization schedules.

12. Unless the Secretary's baseless and uninformed policy decision is vacated, pregnant women, their fetuses, infants under six months old, and, in fact, all children remain at increased and immediate risk of contracting a preventable disease. This decision immediately exposes these vulnerable populations to a serious illness with potentially irreversible long-term effects and, in some cases, death. This is not a hypothetical concern, but a pressing public health emergency that demands immediate legal action and correction.

13. Pursuant to Federal Rule of Civil Procedure 15(a)(1)(A), Plaintiffs amended as a matter of course their original complaint within 21 days of filing and serving the original complaint on July 7, 2025 to add, *inter alia*, The Massachusetts Chapter of the American Academy of Pediatrics and Jane Doe 2 as Plaintiffs. Plaintiffs now file this Second Amended Complaint to add Jane Doe 3 as a Plaintiff.

JURISDICTION AND VENUE

14. 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.

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

PARTIES

Plaintiffs

16. 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 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.

17. 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.

18. 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.

19. 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.

20. 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.

21. 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.

22. 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.

23. 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 is also more than 20 weeks pregnant. Although she was vaccinated against Covid before becoming pregnant, her doctors have 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 creates barriers to access to the vaccine and has left Jane and her husband overwhelmed with stress and uncertainty. Her worries are not just for herself, but also for the health and safety of her fetus.

24. Plaintiff, Jane Doe 2, is pregnant, lives in Massachusetts, has tried to get the Covid 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 now that federal guidance is not to administer the vaccine to pregnant women. Jane Doe 2 subsequently tried at another location to get the Covid 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."

25. 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 wanted to get the Covid 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. When she took her sons to the pharmacy for their vaccine appointments, the pharmacist first tried to dissuade her from giving her sons the Covid vaccine because a new Covid 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 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 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 vaccine because they are 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 vaccine. They are fearful of catching the new Covid strain's "razor-blade throat" themselves and are even more fearful of infecting Jane Doe 3 given her compromised immune system. Jane Doe 3 further demonstrates the harm that the Directive has caused individuals who want to get the Covid vaccine now. The Directive has caused confusion amongst pharmacists; it has prevented those who want to get the Covid vaccine from getting vaccinated, thereby increasing the risk that they and their family members, especially those who are immunocompromised, will get sick with Covid; and it has caused fear and anxiety in those who cannot get the vaccine.

Defendants

26. 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.

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

28. Defendant Marty Makary is Commissioner of the FDA and is sued in his official capacity.

29. Defendant FDA is an agency that is housed within HHS.

30. Defendant Jay Bhattacharya is Director of the NIH and is sued in his official capacity.

31. Defendant NIH is an agency that is housed within HHS.

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

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

34. 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

35. 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.[11]

36. "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

[11] L. Reed Walton, et al., *The History of the United States Advisory Committee on Immunization Practices (ACIP)*, 33 Vaccine 3, 405–14 (Jan. 2015), https://pubmed.ncbi.nlm.nih.gov/25446820/.

advice rather than formation of ad hoc committees to address national immunization policy."[12] Therefore, the Surgeon General established ACIP in March 1964. The committee was "charged with the responsibility of advising the Surgeon General regarding the most effective application in public health practice of specific preventive agents which may be applied in communicable disease control."[13] That mission has remained essentially unchanged since the ACIP's inception.[14]

37. 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.

38. 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

[12] 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.
[13] *Id.*
[14] *Id.*

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

39. 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 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.[15]

40. 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.

41. 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 and state law, "with nearly 600 statutes and regulations across 49 states, three territories, and Washington, D.C. referencing ACIP recommendations and tying them to essential public health programs and insurance coverage mandates."[16] 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

[15] *See General Committee-Related Information*, Ctrs. for Disease Control & Prevention ("CDC") (Dec. 16, 2024), https://www.cdc.gov/acip/about/index.html.

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

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).

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).[17]

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.[18]

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

[17] "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*, ASPE (May 3, 2024) https://aspe.hhs.gov/reports/ira-elimination-vaccine-cost-sharing-2023

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

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 (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*).

42. Furthermore, ACIP's guidance is foundational to public health functions at the state level, where numerous state laws directly reference and incorporate its recommendations across at least four distinct categories:

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.[19]

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.[20]

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[19] *See Impact of the Advisory Committee on Immunization Practices Recommendations on State Law*, ASTHO (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 11, 1561 (Nov. 2024), https://www.healthaffairs.org/doi/10.1377/hlthaff.2024.00378.

[20] *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.

c. Health Care Worker & Patient Requirements: Many states require that workers in health care facilities be vaccinated according to ACIP recommendations as a condition of employment, and similar requirements can apply to patients in certain residential care settings to prevent outbreaks.[21]

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.

43. 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 built strong reliance interests on ACIP recommendations and the process of evaluating scientific evidence and consultation with experts that underlie those recommendations.

44. The statutory scheme that regulates the vaccine infrastructure in this country demonstrates Congress' repeated policy decision to require that ACIP recommendations, made by a fairly balanced ACIP membership,[22] be the basis for what is included on the CDC's immunization schedules—not the unilateral decision of a single individual. Congress has repeatedly shielded the CDC's immunization schedules from the meddling of politicians and political appointees.

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

45. 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

[21] *See State Vaccination Requirements*, CDC (Aug. 6, 2024), https://www.cdc.gov/vaccines/php/requirements-laws/state-vaccination-requirements.html.
[22] *See* 5 U.S.C. § 1004(b)(2) (requiring that federal advisory committees be "fairly balanced").

at HHS, and a reliance on bias and pretext to further his apparent agenda: to undermine trust in vaccines and reduce the rate of vaccinations in this country.

46. Within a week of his confirmation, on February 19, 2025, the Secretary canceled the CDC's "Wild to Mild" influenza vaccination awareness campaign. This campaign was "aimed to inform the public that while getting immunized against the flu doesn't guarantee you won't catch an influenza virus, it can protect you from severe illness, hospitalization, and death."[23] The Secretary's killing of the Wild to Mild campaign came amidst "the worst flu season the nation has seen in nearly 30 years."[24]

47. The next day, February 20, 2025, the Secretary postponed without explanation a meeting of the ACIP that had long been previously scheduled for February 26–28, 2025. The APHA, AAP, and IDSA signed the "Sign-on Letter to Preserve ACIP Meeting" published by the Partnership to Fight Infectious Disease that stated, *inter alia*: "[e]ach ACIP meeting holds tremendous weight and relevance. Infectious diseases are constantly evolving opponents; vaccines are among the best tools for constantly adapting and responding to the latest public health threats. ACIP meetings, which review the latest vaccination data, vote on recommendations, and produce public transparency via a live video stream, three times a year, are the exact activities in which a thoughtful, transparent and well-organized scientific community engages."[25] The ACP issued the following statement regarding the ACIP meeting postponement: "[t]he American College of Physicians is concerned that the postponement of the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) meeting that had been scheduled

[23] Lindsey Leake, *Amid worst U.S. flu season in decades, RFK Jr.–led CDC pulls vaccine campaign*, FORTUNE (Feb. 20, 2025), https://fortune.com/well/article/rfk-jr-cdc-cancels-flu-vaccine-campaign-amid-surge/.
[24] *Id.*
[25] *Sign-on Letter to Robert F. Kennedy Jr., Secretary, U.S. Department of Health and Human Services to Preserve ACIP* Meeting, Partnership to Fight Infectious Disease, (Feb. 20, 2025), https://www.fightinfectiousdisease.org/post/sign-on-letter-to-preserve-acip-meeting.

to take place next week puts our nation's public health at risk. Our country is currently facing the worst epidemic of influenza in several decades, a measles outbreak in Texas, and an ongoing national outbreak of pertussis. The work that the ACIP does in developing evidence-based recommendations about the use of vaccines is critical to helping prevent the spread of these and other vaccine preventable illnesses."[26]

48. On February 26, 2025, the Secretary canceled a meeting of the Vaccines and Related Biological Products Advisory Committee ("VRBPAC") scheduled for March 13, during which the committee was scheduled to make recommendations for the flu strains to be included in the 2025–26 flu shot or nasal spray for the Northern Hemisphere. The VRBPAC typically meets in March to make recommendations based on the flu strains expected to be circulating in the fall and winter. The FDA uses those recommendations to direct vaccine manufacturers on the composition of the shots, which take approximately six months to produce. The IDSA issued the following statement in response to the VRBPAC meeting cancellation:

> Ensuring that all people are protected from the flu must remain a top priority of our nation's health leaders. Cancelling a critically important Food and Drug Administration meeting that is vital to the development of effective flu vaccines for next flu season is irresponsible, ignores science and shows a lack of concern for the protection of the public from this potentially severe disease. This decision — and other federal efforts to undermine well-established science about vaccine safety — puts everyone at risk, especially when we are currently experiencing the worst U.S. flu season in more than a decade.
>
> Cancelling this meeting means vaccine makers may not have the vital information and time they need to produce and distribute targeted vaccines before the next flu season. If the FDA meeting is not immediately rescheduled, many lives that could be saved by vaccination will be lost.[27]

[26] Isaac O. Opole, *Internal Medicine Physicians Call for Prompt Rescheduling of Vaccine Advisory Meeting*, ACP (Feb. 21, 2025), https://www.acponline.org/acp-newsroom/internal-medicine-physicians-call-for-prompt-rescheduling-of-vaccine-advisory-meeting.

[27] Tina Tan, *Statement on the June meeting of the Advisory Committee on Immunization Practices*, IDSA (June 26, 2025), https://www.idsociety.org/news--publications-new/articles/2025/statement-on-the-june-meeting-of-the-advisory-committee-on-immunization-practices/.

49. A measles outbreak that began in a largely unvaccinated community in West Texas earlier this year has spread to 41 states with a total of 1,356 confirmed measles cases as of August 6, 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.[28] In response to this outbreak, the Secretary has offered, at best, mixed messages about the measles vaccine. For example, he stated in a written commentary on March 2, 2025 about the Texas 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."[29] 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 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.[30]

50. The Secretary's misleading statements about the measles outbreak stand in sharp contrast to what his own agency's website states definitively, *i.e.*, that "[t]he best way to protect

[28] *Measles Cases and Outbreaks*, CDC (August 6, 2025), https://www.cdc.gov/measles/data-research/index.html. Curiously, this page of the CDC's website now states that: "[t]he data on this page will not be updated on Wednesday, August 13, 2025. CDC will resume updates as soon as possible."

[29] 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.

[30] David Martin Davies, *West Texas children treated for vitamin A toxicity as medical disinformation spreads alongside measles outbreak*, TEXAS 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 CENTERS (Apr. 7, 2025), https://poisoncenters.org/news-alerts/13484508.

against the measles is to get the measles, mumps, and rubella (MMR) vaccine."[31] The CDC further notes that one dose of the MMR vaccine is 93% effective against measles, and two doses are 97% effective against measles.[32] The CDC's website further states that "[M]ost people who are vaccinated with MMR & MMRV will be protected for life."[33] The Secretary, however, in a CBS news interview, asserted that "we're always going to have the measles, no matter what happens, as the vaccine wanes very quickly."[34]

51. 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."[35]

52. 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.[36] 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,

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[31] *Measles Vaccination*, CDC (Jan. 17, 2025), https://www.cdc.gov/measles/vaccines/index.html.
[32] *Id*.
[33] *Id*.
[34] CBS News, *Watch: RFK Jr.'s first network TV interview as HHS secretary* (YouTube Apr. 9, 2025), https://www.youtube.com/watch?v=o2U0csKvqMY; Steven Ross Johnson and Cecelia Smith-Schoenwalder, *Calling the Shots: Tracking RFK Jr. on Vaccines*, U.S. News & World Report (June 12, 2025), https://www.usnews.com/news/health-news/articles/calling-the-shots-tracking-robert-f-kennedy-jr-s-moves-on-vaccines#recommendation.
[35] 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.
[36] 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.

modernize disease data systems, respond to outbreaks, and provide critical immunization access, outreach, and education—leaving communities more vulnerable to future public health crises."[37]

53. The Secretary also directed the CDC in March to conduct a study of links between vaccines and autism despite multiple studies that all concluded that there was no link between vaccines and autism. The Secretary hired a vaccine skeptic to assist with the study who has long promoted false claims about the connections between immunization and autism and who was disciplined by Maryland regulators for practicing medicine without a license. More than two dozen studies have been performed since the 2000s on whether there is a link between vaccines and autism, and none have found a link.[38]

54. In testimony before Congress on June 24, 2025, the Secretary testified under oath that "there was no science supporting that recommendation," referring to the Covid vaccine for pregnant women. That is untrue. Peer-reviewed studies and research have repeatedly and consistently shown that administration of the Covid vaccine during any trimester of pregnancy lowers hospitalization rates, serious illness, and adverse outcomes from Covid 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 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.

55. 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

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

[38] Lena H. Sun & Fenit Nirappil, *Vaccine skeptic hired to head federal study of immunizations and autism*, THE WASHINGTON POST (Mar. 25, 2025), https://www.msn.com/en-us/health/other/vaccine-skeptic-hired-to-head-federal-study-of-immunizations-and-autism/ar-AA1BEvp0.

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 data 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.[39] The cited evidence "doesn't support ending mRNA vaccine development. It makes the case for expanding it."[40] 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."[41] One of the cited reviews in the bibliography "directly compares infection with vaccination and concludes vaccination 'is the more favorable 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."[42]

56. 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

[39] 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/
[40] *Id*.
[41] *Id*.
[42] *Id.*

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 desires their protection from COVID-19 to have access to the vaccine."[43] In a tweet later that day, the Secretary stated that "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."[44]

57. The Secretary has also placed into positions of authority throughout HHS individuals who are unlikely to challenge his views on vaccines or stand in the way of his agenda. FDA Commissioner Makary was confirmed on March 25, 2025. He previously made headlines for his comments during the pandemic, including advocating for looking at natural immunity, questioning the requirement for booster shots in younger people, and opposing vaccine mandates.[45]

58. NIH Director Bhattacharya, who also was confirmed on March 25, 2025, was an author in 2020 of the "Great Barrington Declaration" that advocated for "herd immunity" through natural infection—*i.e.*, allow the disease to spread through the "healthy" population while somehow isolating the elderly and other vulnerable populations.[46] There is no precedent in history for advocating for the uncontrolled spread of an infectious disease to control an epidemic.[47] Upon information and belief, Bhattacharya has never practiced medicine and never did a residency. His research has focused on the economics of health care.

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[43] 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.
[44] Robert F. Kennedy, Jr. (@SecKennedy), X (Aug. 19, 2025, 5:17 PM), https://x.com/SecKennedy/status/1957914911415153107.
[45] Jordan King, *Everything Marty Makary Has Said About Vaccines*, Newsweek (Mar. 26, 2025), https://www.newsweek.com/dr-marty-makary-fda-vaccines-health-2050757.
[46] Bruce Werness, *Debunking Heard Immunity: A Review of We Want Them Infected*, GLOBAL AUTOIMMUNE INST. (Dec. 16, 2024), https://www.autoimmuneinstitute.org/articles/debunking-herd-immunity-a-review-of-we-want-them-infected/.
[47] *Id.*

59. Even more recently, on or about August 12, 2025, NIH Director Bhattacharya authored an op-ed in the Washington Post[48] where he defended Kennedy's recent announcement that the federal government would end its $500 million commitment in funding mRNA vaccine research—a technology that has been critical to the fields of immunology and vaccine development. NIH Director Bhattacharya stated that while "promising," mRNA vaccines simply failed to earn the public trust for use in response to public health emergencies. Upon information and belief, the evidence Kennedy and/or NIH Director Bhattacharya reviewed, if any, did not support ending this research, and the decision to cease this funding will have a markedly negative impact on vaccine trust, development, and availability.

60. On or about March 28, 2025, the Secretary forced out Peter Marks, MD, PhD, as Director, Center for Biologics Evaluation and Research ("CBER").[49] CBER is situated within the FDA and is responsible for reviewing applications for new biological products, like vaccines, "by evaluating scientific and clinical data submitted by manufacturers to determine whether the product meets CBER's standards for approval."[50] In his resignation letter, Marks wrote: "[u]ndermining confidence in well-established vaccines that have met the high standards for quality, safety, and effectiveness that have been in place for decades at FDA is irresponsible, detrimental to public health, and a clear danger to our nation's health, safety, and security."[51] He further wrote that: "I was willing to work to address the Secretary's concerns regarding vaccine

[48] Jay Bhattacharya, *Why the NIH is Pivoting Away from mRNA Vaccines*, THE WASHINGTON POST (Aug. 12, 2025), https://www.washingtonpost.com/opinions/2025/08/12/nih-mrna-vaccines-jay-bhattacharya/

[49] Berkeley Lovelace, Jr., *FDA's Top Vaccine Scientist is Out, Citing Kennedy's 'Minsinformation and Lies*,' NBC NEWS (Mar. 28, 2025), https://www.nbcnews.com/health/health-news/fdas-top-vaccine-scientist-dr-peter-marks-rcna198682.

[50] *About CBER*, U.S. FOOD AND DRUG ADMIN. ("FDA") (May 13, 2025), https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/about-cber.

[51] *Letter from Peter Marks, Dir., Ctr. for Biologics Evaluation and Research, U.S. Food and Drug Admin., to Sara Brenner, Acting Comm'r of Food and Drugs*, FDA (Mar. 28, 2025), https://s3.documentcloud.org/documents/25873243/peter-marks-resignation-letter.pdf (informing of his resignation).

safety and transparency by hearing from the public and implementing a variety of different public meetings and engagements with the National Academy of Sciences, Engineering, and Medicine. However, ***it has become clear that truth and transparency are not desired by the Secretary, but rather he wishes subservient confirmation of his misinformation and lies.***"[52]

61. Marks was replaced by Dr. Vinay Prasad, a critic of vaccine mandates, mask mandates, and booster shots,[53] who was named the head of CBER on May 7, 2025. On May 16, 2025, Prasad issued "A Center Director Decisional Memo" that overruled the recommendation from FDA's vaccine staff members to approve for licensure a new protein-based Covid vaccine for all individuals 12 and older.[54] On May 30, 2025, Prasad issued a "Center Director Override Memo" that overrode FDA vaccine staff members' recommendation to license the next generation of mRNA vaccines.[55]

62. A curious hire at the FDA was Dr. Tracy Beth Høeg ("Høeg"). Høeg was hired as a "special assistant" at the FDA on or about April 2, 2025. Shortly thereafter, Høeg was involved in delaying approval of the protein-based vaccine that was the subject of Prasad's Center Director Decisional Memo of May 16.[56] Høeg is a former sports medicine doctor whose Board certification is in Physical Medicine and Rehabilitation who also has promoted incorrect information and

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

[53] *Dr. Vinay Prasad to Head FDA, Biologics Division,* VACCINE ADVISOR (May 20, 2025), https://www.vaccineadvisor.com/news/dr-vinay-prasad-to-head-fda-vaccine-biologics-division/.

[54] Vinayak Prasad, Director, Ctr. for Biologics Evaluation and Research, *Center Director Decisional Memo* (May 16, 2025), https://static01.nyt.com/newsgraphics/documenttools/24b944c1a77fbed7/209038df-full.pdf regarding CBER's decision on the submission of Nuvaxovid (COVID-19 Vaccine, Adjuvanted)).

[55] Christina Jewett, *Top F.D.A. Official Overrode Scientists on Covid Shots,* NEW YORK TIMES (July 2, 2025), https://www.nytimes.com/2025/07/02/health/fda-covid-vaccines.html.

[56] 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/.

misinterpreted data about vaccines.[57] Despite this, Høeg was named to be FDA's liaison to the ACIP prior to the April 2025 meeting.

D. The Secretary's Stacking Of The ACIP

63. In addition to hiring individuals opposed to settled science, the Secretary completely overhauled the membership of the ACIP for pretextual reasons.

64. On June 9, 2025, at exactly 4 p.m. Eastern Time, an Opinion Commentary written by the Secretary appeared in the online version of the *Wall Street Journal*. In the column, the Secretary announced he was "totally reconstituting the Advisory Committee for Immunization Practices (ACIP)" and "retiring the 17 current members of the committee."[58]

65. 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.

66. The Secretary fired the ACIP members, although he promised Senator Bill Cassidy, whose vote was critical to his confirmation, that he would "maintain the Centers for Disease Control and Preventions Advisory Committee on Immunization Practices without changes."[59]

67. 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,"

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[57] *Id.*
[58] 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.
[59] 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.

had "become little more than a rubber stamp for any vaccine," and, by innuendo and implication, accused them of being "corrupt" and "directly work[ing] for the vaccine industry." None of these accusations are remotely true. He also justified the terminations by referencing reports from 1997, 2000, and 2009 on the ACIP, years in which none of the 17 terminated members were on the ACIP.

68. The AAP, the ACP, the APHA, the IDSA, and many other public health stakeholders condemned the terminations.[60]

69. Two days after the terminations, on June 11, 2025, the Secretary announced the appointment of eight new members to the ACIP. Only one of the eight met the qualifications for ACIP membership articulated in the ACIP Charter.[61]

70. Four of the new members have no discernible expertise in vaccines, infectious diseases, or immunology.

71. Four of the new members have pronounced anti-vaccine views, including the new Chair of the ACIP, who was a co-author with Bhattacharya of the Great Barrington Declaration that promoted "natural immunity" over public health measures, opposed vaccination in children against Covid, as well as masking, lockdowns, and vaccine mandates, and who lost positions at Brigham and Women's Hospital and Harvard after refusing to get vaccinated. Another new ACIP member is a current staff member at the National Vaccine Information Center, whose mission "is dedicated to preventing vaccine injuries and deaths." Another new ACIP member is a professor of operations management who said on May 25, 2025: "[t]hat these vaccines [are] still recommended

[60] Susan Kressly, MD, FAAP, *AAP Statement on Changes to Advisory Committee on Immunization Practices*, AAP (June 9, 2025), https://www.aap.org/en/news-room/news-releases/aap/2025/aap-statement-on-changes-to-advisory-committee-on-immunization-practices/.

[61] *ACIP Charter*, CDC, at 4 (Apr. 1, 2024), https://www.cdc.gov/acip/about/acip-charter.html ("Members shall be selected from authorities who are knowledgeable in the fields of immunization practices and public health, have expertise in the use of vaccines and other immunobiologic agents in clinical practice or preventive medicine, have expertise with clinical or laboratory vaccine research, or have expertise in assessment of vaccine efficacy and safety.").

in pregnancy is incomprehensible!" Another new ACIP member is a medical doctor who has spoken at anti-vaccine rallies.

72. Thus, two weeks before the next scheduled the ACIP meeting on June 25, 2025, the Secretary stacked the ACIP with unqualified members with histories of taking anti-vaccine positions.

73. None of the new ACIP members were required to follow the rigorous application process to become an ACIP member.[62] Historically, the application process to become a voting ACIP member has taken up to two years.

74. Upon information and belief, to qualify for membership on the new ACIP, a candidate had to be a registered Republican or Independent and could not have previously made public criticisms of the President or the Secretary.

75. The Secretary promised to release the ethics forms that list conflicts of interest for the new ACIP members before the next ACIP meeting scheduled for June 25-26, 2025. An HHS spokesperson stated that, "[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."[63] OGE Form 450 requires disclosure of financial interests related to their committee work. The Secretary has not released the ethics agreement and OGE 450s,[64] even though new ACIP member Robert W. Malone, MD, posted on

[62] *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*, JAMA NETWORK (June 16, 2025), https://jamanetwork.com/journals/jama/article-abstract/2835626.

[63] Isabella Cueto, *HHS backtracks on pledge to disclose new vaccine advisers' conflict of interest*, STAT NEWS (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.

[64] *Conflicts of Interest Disclosures of ACIP Members*, CDC (July 10, 2025), https://www.cdc.gov/acip/disclosures/by-member.html.

X on June 12, 2025, that "i have already completed three months of ethics vetting and COI training by the appropriate HHS officials."[65] Thus, at least since March of this year, the Secretary was planning to replace the ACIP membership with supporters of his views.

76. Concerned with the credentials of the newly-appointed ACIP members, on the eve of the June 25, 2025 meeting, Senator Bill Cassidy, M.D., posted on X the following call for postponement of the June 25 meeting:

> Although the appointees to ACIP have scientific credentials, many do not have significant experience studying microbiology, epidemiology or immunology. In particular, some lack experience studying new technologies such as mRNA vaccines, and may even have a preconceived bias against them. Robust and transparent scientific discussion is important, so long as it is rooted in evidence and understanding. Wednesday's meeting should not proceed with a relatively small panel, and no CDC Director in place to approve the panel's recommendations.[66] The meeting should be delayed until the panel is fully staffed with more robust and balanced representation—as required by law—including those with more direct relevant expertise. Otherwise, ACIP's recommendations could be viewed with skepticism, which will work against the success of this Administration's efforts.[67]

77. The Secretary did not delay the ACIP meeting as Senator Cassidy suggested and the new ACIP met on June 25–26, 2025 in Atlanta.

78. The final agenda for the June 25-26 ACIP meeting was posted on the CDC's website the night before.[68] Based on discussions at the April ACIP meeting, expectations were that a vote on updated Covid vaccines would be scheduled for the June meeting. No such vote was on the June 25–26 final agenda.

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[65] Robert W. Malone, MD (@RWMaloneMD), X (Jun. 12, 2025, 12:36 PM), https://x.com/RWMaloneMD/status/1933216806338244828.

[66] With no CDC Director in place as of the June 25–26 meeting, the decision whether to approve ACIP recommendations falls to the Secretary. *See* 42 C.F.R. § 147.130(a)(1)(ii).

[67] United States Senator Bill Cassidy, MD (@SenBillCassidy), X (Jun. 23, 2025, 3:54 PM), https://x.com/SenBillCassidy/status/1937283186758680766.

[68] *Final Agenda: Meeting of the Advisory Committee on Immunization Practices*, CDC (June 24, 2025), https://www.cdc.gov/acip/downloads/agendas/Final-posted-2025-06-24-508.pdf.

79. A notable item new on the agenda was thimerosal. A presentation and a vote on thimerosal in flu vaccines were scheduled for June 26, 2025, with the presentation to be delivered by Lyn Redwood, a former long-time President of Children's Health Defense,[69] the anti-vaccine organization founded by the Secretary.[70] The Children's Health Defense website credits Redwood as the co-author of "a landmark paper" published in 2000 that linked autism to exposure to mercury.[71] The Secretary appointed Redwood to lead the CDC's Immunization Safety Office on June 25, 2025.[72] Redwood, like the Secretary, has argued for decades that mercury causes autism.[73] However, the CDC website states in big, bold print that: **Vaccines do not cause autism.**[74]

80. The ACIP voted on June 26, 2025 that children, pregnant women, and adults all should "receive seasonal influenza vaccines only in single-dose formulations that are free of thimerosal as a preservative."[75] For decades before becoming Secretary, the Secretary advocated for the removal of thimerosal from vaccines, even though the papers and studies linking thimerosal to autism have been thoroughly debunked.

81. After the June 25–26 meeting, the IDSA released the following statement:

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[69] *Directors & Advisors Emeriti,* CHILD.'S HEALTH DEF., https://childrenshealthdefense.org/about-us/director-emeritus/ (last visited July 5, 2025).

[70] *Id.*; Will McDuffie, Jade Cobern, MD, *RFK Jr. appoints longtime anti-vaccine ally Lyn Redwood to HHS position*, ABC NEWS (June 25, 2025, 4:49 PM), https://abcnews.go.com/US/rfk-jr-appoints-longtime-anti-vaccine-ally-lyn/story?id=123213887.

[71] *Directors & Advisors Emeriti,* CHILD.'S HEALTH DEF., https://childrenshealthdefense.org/about-us/director-emeritus/ (last visited July 5, 2025).

[72] Alexander Tin, *CDC to hire former head of anti-vaccine group founded by RFK Jr.*, CBS NEWS (June 25, 2025, 8:49 PM), https://www.cbsnews.com/news/cdc-vaccine-safety-office-hire-former-head-anti-vaccine-group-founded-rfk-jr/.

[73] Robert F. Kennedy, Jr., *Attack on Mothers*, HUFFINGTON POST (June 19, 2007), https://web.archive.org/web/20070622053901/http:/www.huffingtonpost.com/robert-f-kennedy-jr/attack-on-mothers_b_52894.html

[74] *Autism and Vaccines*, CDC (Dec. 30, 2024), https://www.cdc.gov/vaccine-safety/about/autism.html [https://perma.cc/T6VN-L8WL].

[75] *CDC's Advisory Committee on Immunization Concludes Meeting with Joint Statement*, CDC (June 26, 2025), https://www.cdc.gov/media/releases/2025/2025-cdcs-advisory-committee-on-immunization-concludes-meeting-with-joint-statement.html.

> This week's meeting of the Advisory Committee on Immunization Practices, or ACIP, was politicized, chaotic and not transparent. That kind of process is harmful to the American people.
>
> Agenda items were added last minute, limiting the ability of members to review data. Disclosures about potential conflicts of interest of the newly appointed ACIP members have not been made public.
>
> Re-examining the childhood vaccine schedule and the use of thimerosal are both politically motivated actions that are not based on science. Raising questions without adequate data casts doubt on vaccination, which can further drive down confidence in vaccines. More than any other medications, vaccines are extensively and constantly reviewed and evaluated. Vaccination saves lives.
>
> The American people deserve an objective and transparent review process based on scientific evidence, not political agendas with no basis in facts.[76]

82. On July 31, 2025, an email from acip@cdc.gov was sent to members of ACIP Liaison organizations, which include members of Plaintiffs AAP and ACP, informing them that Liaison organizations were terminated from participating in ACIP workgroups like the Covid-19 Work Group. The ostensible reason given in the email was that "Liaison 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."[77]

[76] Tina Tan, *Statement on the June meeting of the Advisory Committee on Immunization Practices*, IDSA (June 26, 2025), https://www.idsociety.org/news--publications-new/articles/2025/statement-on-the-june-meeting-of-the-advisory-committee-on-immunization-practices/.

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

E. The Process To Recommend Covid Vaccines Prior To The Directive

83. The ACIP first voted on recommending a Covid vaccine on December 12, 2020. On that day, the ACIP voted 11-0, with three abstentions, to recommend the Pfizer-BioNTech Covid vaccine for persons 16 years of age and older in the United States under the FDA's grant of an Emergency Use Authorization. Before that vote, a Covid-19 Work Group of the ACIP followed the GRADE (Grading of Recommendations, Assessment, Development and Evaluation) approach for developing evidence-based recommendations.[78] "The GRADE approach provides a framework for assessing the certainty (i.e., quality of confidence) of the evidence and moving from evidence to decision making (i.e., recommendations)."[79] The Covid-19 Work Group has consisted of voting members of the ACIP, medical doctors, epidemiologists, a professor of microbiology and immunology, a medical officer for a state Department of Public Health, vaccine researchers, leaders of vaccine trials, and an infectious disease researcher.

84. The Covid-19 Work Group also utilized the Evidence-to-Recommendations ("EtR") framework, which is used to "describe information for consideration in making recommendations move from evidence to decisions, and to provide transparency around the impact of these factors on deliberations when considering a recommendation." The EtR framework is informed by GRADE. There are seven domains in the EtR framework that the Covid-19 Work Group considered and evaluated: (1) the problem; (2) benefits and harms; (3) values; (4) acceptability; (5) resource use; (6) equity; and (7) feasibility.[80]

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[78] Julia W. Gargano, *Grading of Recommendations, Assessment, Development, and Evaluation (GRADE): Pfizer BioNTech COVID-19 Vaccine*, CDC ACIP Meeting (December 11, 2020), https://stacks.cdc.gov/view/cdc/105432.
[79] *ACIP Grade Handbook for Developing for Evidence-based Recommendations, Chapter 1: Introduction*, CDC (Apr. 22, 2024), https://www.cdc.gov/acip-grade-handbook/hcp/chapter-1-introduction/index.html.
[80] *ACIP Evidence to Recommendations Framework*, CDC https://www.cdc.gov/acip/media/pdfs/2024/09/ACIP-Evidence-to-Recommendations-Framework-cdc.pdf (last visited July 22, 2025); *ACIP Evidence to Recommendation User's Guide*, CDC (Oct. 1, 2020), https://www.cdc.gov/acip/media/pdfs/2024/09/ACIP-EtR-Users-Guide_October-1-2020.pdf.

85. Since the ACIP's first meeting to discuss a Covid vaccine in June 2020, the ACIP has met in public meetings 42 times to vote on 32 Covid 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 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 vaccines.

86. Thus, even during the height of the pandemic, the FDA, the CDC, and the ACIP consistently adhered to this established vaccine approval-and-recommendation process.

F. The Arbitrariness and Capriciousness of the Directive

87. The foregoing provides the backdrop and context for the Directive.

88. Curiously, in the video announcement posted on X on May 27, 2025, Defendant Makary (FDA Commissioner) flanks him on his right and Defendant Bhattacharya (NIH Director) on his left:

89. No representative of the CDC or ACIP appears in the video, even though CDC and ACIP, not the FDA or NIH, have responsibility for making recommendations as to which vaccines are added to or removed from the CDC's immunization schedules.

90. This announcement came as a surprise to officials at the CDC, who five hours after the video was posted on X, received the Directive.[81] CDC staff were confused that the Directive was dated May 19, eight days prior.[82]

91. Just a week before this video appeared on X, and a day after the Directive is dated, FDA Commissioner Makary published an article that he co-authored with Prasad dated May 20, 2025, in The New England Journal of Medicine stating that "pregnancy and recent pregnancy" are factors which "increase a person's risk of severe COVID-19."[83] The first note to the article states that "[t]he views expressed in this article represent the policy position of the Food and Drug Administration." 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.'"[84]

92. 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. Instead, on May 29, 2025, the CDC downgraded the recommendation to a "shared clinical

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[81] Lena H. Sun, *CDC blindsided as RFK Jr. changes covid-19 vaccine recommendations*, THE WASHINGTON POST (May 28, 2025), https://www.washingtonpost.com/health/2025/05/28/vaccines-cdc-rfk-jr-covid/.
[82] *Id.*
[83] Vinay Prasad & Martin Makary, *An Evidence-Based Approach to Covid-19 Vaccination*, 392 THE NEW ENGLAND J. MED. 2484, 2485, fig. 2 (2025).
[84] 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/.

decision-making" ("SCDM") recommendation from routine.[85] A "routine" recommendation is not a requirement that a child get the Covid vaccine; rather, it is an unqualified recommendation.

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

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

95. The Secretary did not consult with the CDC about the Directive.[86] 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 vaccines for 2025-2026 for different population groups for which there is conclusive evidence of a higher risk of severe illness from the Covid virus. Dr. Panagiotakopoulos noted that pregnant individuals continued to face an increased risk of severe outcomes from contracting Covid. Not only does a Covid vaccine protect the mother, but it also protects infants less than six months of age because infants less than six months old cannot receive the Covid vaccine, but the mother can protect the infant by passing antibodies to the fetus from a Covid vaccine administered during pregnancy. Dr. Fiona Havers, also an epidemiologist at the CDC, presented findings at the April 25, 2025 ACIP meeting on the impact of Covid on children in the United States in the past year. "She found that at least 7,000 children were hospitalized with Covid. About 20 percent of those hospitalized were admitted to the intensive care unit, *half were previously healthy*, virtually none had been vaccinated, and *152 had died, most less than 4 years of age*. The conclusion was clear; all children in the United States,

[85] *Child and Adolescent Immunization Schedule by Age*, CDC (July 2, 2025), https://www.cdc.gov/vaccines/hcp/imz-schedules/child-adolescent-age.html.
[86] Lena H. Sun, *CDC blindsided as RFK Jr. changes covid-19 vaccine recommendations*, WASHINGTON POST (May 28, 2025), https://www.washingtonpost.com/health/2025/05/28/vaccines-cdc-rfk-jr-covid/.

whether they were previously healthy or not, should receive the primary series of Covid vaccines."[87]

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

97. 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."[88]

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

99. In fact, less than a month after the announcement on X, CDC employees presented evidence at the June 25 ACIP meeting that contradicted the Directive with respect to both pregnant individuals and children.[89]

G. Injury To The Plaintiffs

100. Plaintiff Jane Doe 1 is a physician who works in a hospital where she is exposed to infectious diseases every day. She is currently pregnant and was shocked to learn of the Directive. The Directive has and will make it more difficult for her to get a Covid vaccine while she is pregnant, which in turn will endanger her fetus.

101. Plaintiff Jane Doe 2 is a pregnant individual residing in Massachusetts who received a prescription for the Covid vaccine after the Directive was issued, took it to a local

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[87] Paul Offit, *This CDC Resignation Should Scare You*, SUBSTACK (July 8, 2025), https://pauloffit.substack.com/p/this-cdc-resignation-should-scare (emphasis added).

[88] 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.

[89] Adam MacNeil, *Current Epidemiology of COVID-19*, CDC ACIP Meeting, at 22 (June 25, 2025), https://www.cdc.gov/acip/downloads/slides-2025-06-25-26/02-MacNeil-COVID-508.pdf (presented by Dr. Adam MacNeil); Sarah Meyer, *Update on CDC's COVID-19 Vaccine Safety Monitoring*, CDC ACIP Meeting, at 24 (June 25, 2025), https://www.cdc.gov/acip/downloads/slides-2025-06-25-26/04-Meyer-COVID-508.pdf.

pharmacy, but the pharmacist refused to give the vaccine because the pharmacist was concerned she would lose her license if she gave a vaccine that was no longer on the CDC's immunization schedule.[90] She reported this refusal to her doctor's office, who told her that the office would no longer prescribe the Covid vaccine during pregnancy with the change in CDC guidance. She nonetheless tried again at a different location but was again refused the vaccine because of the Directive. Finally, a chain pharmacy location advised Jane Doe 2 that "this is the first time a recommendation did not come from the [ACIP] and, therefore, this is a 'grey area,'" and she would need to schedule her vaccination when a "flexible" pharmacist "who would be willing to risk their license to vaccinate" her was available. Even then, the pharmacy required Jane Doe 2 to attest that: "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 "flexible" pharmacist what this meant, he advised that the CDC's guidelines are unclear, but he "personally chooses to follow the recommendations of OB and pediatric groups."

102. Plaintiff Jane Doe 3, who is immunocompromised, is now faced with heightened risk of contracting Covid because a pharmacist refused to administer the Covid vaccine to her two teenage sons on August 14, 2025. The pharmacist refused to give the vaccine to the teenagers because they were not in the approved age group of being over 60 or 65. The teenage sons know that their mother is immunocompromised and want to get the Covid vaccine before they go back to school at the end of this month to protect their mother from them bringing home the virus from school. Plus, they themselves are fearful of getting sick from the Covid virus when they return to school. Their fear is not unfounded, since, as of August 26, 2025, Covid-19 infections were

[90] *See* Mass. Dep't of Pub. Health, Policy 2023-02: Vaccine Administration, at 1 (Sep. 7, 2023), https://www.mass.gov/doc/2023-02-vaccine-administration-pdf/download ("Qualified pharmacy personnel are authorized to administer routine vaccines which are FDA-approved or authorized vaccines that have been recommended for routine use by the Advisory Committee on Immunization Practices . . . .").

"growing or likely growing in 31 states, declining or likely declining in 4 states, and not changing in 12 states," according to the CDC.[91] Washington state, according to the CDC, is experiencing growing or likely growing rates of Covid infections.[92]

103. The Directive has adversely affected the physician-patient relationship because, *inter alia*, it has injected mistrust, misinformation, uncertainty, and confusion into that relationship, putting physicians in the conflicting position of either advising patients on what they believe is the proper standard of care or adhering to inconsistent federal guidance. The Directive will also result in decreased rates of vaccination, increased rates of transmission, long-lasting illness, and ultimately deaths among pregnant women, their fetuses, and all children – deaths that could have been prevented.

104. 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 vaccine for the child, who was eligible for the VFC program. Dr. Hopkins, however, was unable to order the Covid 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 Directive, Dr. Hopkins has been required to spend more time counseling patients regarding the safety of the Covid vaccine for pregnant persons and children. He estimates that he has had discussions with at least 20–25 patients in the last six weeks regarding the effectiveness

[91] *Current Epidemic Trends (Based on R_t) for States*, CDC (Aug. 15, 2025) https://www.cdc.gov/cfa-modeling-and-forecasting/rt-estimates/index.html
[92] *Id.*

of the Covid vaccines and recommending a booster shot. Approximately half of the patients he sees in a given day require counseling on Covid vaccines. In those discussions, Dr. Hopkins has counseled patients that, based on the evidence, the Covid vaccine is safe and beneficial for children and pregnant women. 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 vaccine for their child. His relationship with these patients has deteriorated as a result of the Secretary's May 19, 2025 Directive.

105. Dr. Susan J. Kressly is the current President of the AAP. She has learned from AAP members that, because of the May 19 Directive, AAP members are experiencing great frustration and new barriers in effectively counseling patients and their families regarding the Covid 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 May 19 Directive. That Directive has caused physician members to spend more time counseling patients regarding the effectiveness of the Covid vaccines, which adds up to time and resources diverted 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 prior to the issuance of the Directive in November 2024. The Directive has 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 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.

106. AAP member Dr. Mary Doherty-O'Shea Galluci is a pediatrician and owns two practices in Michigan. She is experiencing an uptick in vaccine hesitancy after the Directive was issued. Parents are now questioning Dr. Galluci whether they should vaccinate their children against Covid, or worse, whether they can. Parents are now distressed and unsure about Covid 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 complications, and the only way to protect their infants is through maternal vaccination and early-life immunization. Covid infection in infants can be severe or fatal. Denying or delaying access to the Covid vaccine in this population is medically dangerous and ethically indefensible. The May 19 Directive is 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 vaccine for children has put a chilling effect on her practice. Shared decision-making implies that the Covid vaccine is optional or suspect, making it harder to hold Covid 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 vaccine due to the conflicting directives and recommendations from HHS, which further discourages vaccination. Access to Covid vaccines is reduced as a result of the May 19 Directive. In short, the May 19 Directive is 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.

107. Dr. Jason Goldman is the current President of the ACP and owns his own internal medicine practice in Florida. Since Covid vaccines were first approved for pregnant patients, physician members of ACP have been recommending and administering the Covid vaccine to pregnant patients. This routine administration of the vaccine to pregnant women has become the standard of care for physician members of the ACP. ACP physician members have informed Dr. Goldman that the Directive has placed them in a conflict situation with their patients. When a pregnant patient has requested a Covid vaccine, some ACP member physicians have turned patients away because administering the Covid vaccine is contrary to both the Directive and the CDC's Adult Immunization Schedule, which could lead to licensure problems for the physician. ACP physicians who now administer the Covid vaccine face financial harm because some insurers do not cover vaccines that are not on the CDC immunization schedules. ACP members are placed in the untenable position of either complying with a directive from the government's top health official or not providing their patients with the standard of care that they believe they should be providing to their patients.

108. Dr. Georges C. Benjamin is the current Executive Director of the APHA. He has discovered that, since the Directive, APHA members across the country are faced with an untenable conflict between counseling patients and their communities on what the CDC recommends, and the optimal standard of care that members have been following since the Covid vaccines were approved. Members are either forced to provide inferior care to pregnant women and children that increases the risk of preventable illness, hospitalization and death, or risk losing their medical license or professional certifications. For public health administrators, this creates a professional conflict between the standard of public health practice required to control a disease outbreak in their community and the non-evidence-based Directive. Moreover, the Directive has frustrated the

ability of clinicians and other public health members to consult with individuals and their families or advise those communities regarding the effectiveness of the Covid vaccine at preventing serious illness and death, thus compromising APHA members' ability to practice consistent with their standard of care. Because the Directive has increased vaccine hesitancy and diminished trust in sound medical advice, APHA members are required to spend more time correcting misinformation with individuals and families regarding the effectiveness of the Covid vaccines, which diverts time and resources away from other important health care or public health duties.

109. 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 an infection by vaccine-preventable illnesses by operating an immunization clinic which offers several immunizations including immunizations against Covid-19 through its Columbus Public Health Vaccine Preventable Diseases Clinic and Program (the "CPH Clinic"). The Directive frustrates the purpose and mission of Columbus Public Health because the CPH Clinic staff can no longer advise pregnant women to receive a Covid-19 immunization, which is completely at odds with the mission, vision, and values of Columbus Public Health and the standards it holds itself to. Furthermore, CPH Clinic has been able to purchase vaccines at a discount that is available when included in the Vaccines for Children program, as determined by the ACIP. The Secretary's Directive prevents the CPH Clinic from purchasing discounted Covid-19 vaccines. Despite having offered the Covid-19 immunization for several years, decisions such as the Directive that have increased the cost and/or removed eligible groups from the recommendation have resulted in CPH Clinic ceasing the stocking of all Covid-19 vaccines. This

negatively affects Columbus Public Health's ability to serve all residents. The Secretary's Directive is an existential threat to Columbus Public Health.

110. 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 vaccine, which has become the standard of care for IDSA physician members and which IDSA has adopted into its guidelines. The Directive, however, places IDSA members into a conflict situation between following a federal recommendation for Covid vaccination that is no longer evidence-based versus following the optimal standard of care that IDSA physician members have been following since the vaccines were approved. Because of the Directive, IDSA members are now encountering parents who are expressing increasing concern and confusion about whether their infants and children should get the Covid vaccine even though IDSA members continue to recommend the vaccine for children and pregnant women in the face of the Directive. This conflict is destroying the trust that is the cornerstone of the physician-patient relationship.

111. 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 that the standard of care in his practice is to recommend the Covid vaccine 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 Directive has placed him in an impossible position because it contradicts the standard of care for pediatricians. His patients have already suffered harm from confusion

about the vaccine, canceled vaccine appointments, and an erosion of trust between him and his patients' families, which is damaging to his practice. He believes that his ability to protect his youngest, most vulnerable patients, is under direct assault.

112. 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 disincentivizes physicians from recommending Covid vaccines for pregnant individuals and children ages 6 months through 17 years and creates uncertainty about eligibility for this vaccination as well as patient access to those vaccines. She has advised patients of child-bearing age and one patient who was planning a pregnancy to receive the vaccine. Dr. LaRocque has witnessed the Secretary's Directive creating cost and logistical barriers for children and pregnant women to receive the vaccination. Her recommendation for healthy children and pregnant women to receive the vaccination is based on her professional assessment of the standard or care, but it may require some patients to choose between paying for daily necessities and paying for the vaccine, which creates an ethical challenge for her clinical practice. 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 and experience severe symptoms, including death, if there are barriers to vaccinating pregnant individuals and children between the ages of six months and 17 years, such as the Secretary's Directive. The Directive is disrupting her practice and compromising her ability to provide the highest level of care to her patients.

113. 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. She believes that the Secretary's May 19 Directive is a life-threatening recommendation that irreparably harms MPHA members by frustrating the work they do to support maternal and child health, vaccine delivery, and pandemic response in Massachusetts. The Secretary's Directive harms MPHA members across the Commonwealth by forcing them into an ethical dilemma: choosing between either providing evidence-based, medically sound recommendations for pregnant patients and children that advance good public health or conforming with what HHS now sets as the standard of care for Covid vaccines, undermining its members' independent medical judgment, and critically weakening the public health infrastructure its members rely on to perform their jobs.

114. 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"). She attests that the Secretary's May 19 Directive has harmed SMFM's 6,500 physician-members who provide direct patient care to high-risk pregnant patients in hospital and outpatient settings nationwide. The Directive has frustrated SMFM's members' ability to effectively counsel patients regarding the effectiveness of the Covid vaccine at preventing serious illness, and the Directive is compromising the standard of care. Since the Directive, SMFM members have reported that pharmacies are denying pregnant patients access to Covid vaccines, citing perceived legal risks or confusion caused by the Directive. SMFM members also report that the Directive harms their practices by undermining and eroding the physician-patient relationship and requires SMFM members to divert resources to addressing confusion about the Covid vaccine that the Directive created.

115. SMFM member Dr. Caroline Rouse is a board-certified maternal-fetal specialist in Indiana who treats high-risk pregnant patients. The Directive has had harmful effects on her

practice because it has disrupted vaccination schedules for her patients and caused dangerous confusion for her clinical practice. She has been placed in the conflict situation of either following the Directive or following the established standard of care to recommend and provide the Covid vaccine to pregnant patients. Her clinical judgment is now in direct conflict with federal guidance. 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 Directive. In short, the Directive is endangering the health and lives of her patients and their fetus as well as undermining the trust and confidence upon which the physician-patient relationship is built. The Directive is disrupting her practice and compromising her ability to provide the highest level of care to her patients.

116. The Directive has 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 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.[93]

117. 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 choose between following HHS's recommendations or following the standard of care that requires recommendation of the Covid vaccine for women; either choice exposes him to professional liability.

CAUSES OF ACTION

COUNT I

Violation of the Administrative Procedure Act – Arbitrary & Capricious

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

119. The Directive constitutes a final agency action subject to the Administrative Procedure Act ("APA").

120. 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[.]" 5 U.S.C. § 706(2)(A).

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

121. 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).

122. The Directive is an arbitrary and capricious final agency action. Substantial evidence supports a finding of arbitrariness and capriciousness, including, but not limited to, the following:

a. five days before issuing the Directive, the Secretary testified under oath before Congress that "my opinions about vaccines are irrelevant" and that "I don't think people should be taking medical advice from me," thus admitting that he is unqualified to issue the Directive;

b. the Directive contradicts the article published seven days before and co-authored by Defendant Makary that states "the policy position of the Food and Drug Administration"[94] that "[p]regnancy and recent pregnancy were underlying medical conditions that increased a person's risk of severe COVID-19." The Secretary has provided no explanation for why he overruled his FDA Commissioner, and the FDA Commissioner has provided no explanation why he supports the Directive even though it contradicts the FDA's policy position that he announced just a week before;

c. the Secretary failed to explain what prompted him to issue the Directive when he did. The Directive states in the first paragraph that HHS "continually considers and

[94] Vinay Prasad and Martin A. Makary, *An Evidence-Based Approach to Covid-19 Vaccination*, 392 NEW ENGLAND J. MED. 2484–86 (May 20, 2025), https://www.nejm.org/doi/full/10.1056/NEJMsb2506929.

evaluates available science and evidence related to … approved or authorized vaccines," but he failed to identify the available science or evidence that prompted him to make his announcement on X on May 27, 2025;

d. the Directive states that the Secretary based his decision with regard to children ages six months to 17 years "on review of the recommendation of the FDA and National Institutes of Health," but he did not identify the recommendation or recommendations or the evidence on which that recommendation or recommendations were based;

e. the Directive states that the Secretary's decision with regard to pregnant women was based "on a review of the recommendation of the FDA," but he does not explain what recommendation of the FDA he based the Directive on or the evidence supporting that recommendation; nor does he explain when or how "the lack of high-quality data demonstrating safety of the mRNA vaccines during pregnancy" came to his attention to prompt him to issue the Directive;

f. the Secretary failed to explain why he ignored and bypassed without explanation the longstanding, well-accepted, science- and evidence-based ACIP process for developing recommendations for the CDC immunization schedules that stakeholders across the country have relied upon for years;

g. the Secretary failed to explain why he consulted with the FDA Commissioner and the NIH Director and had them by his side when he made his May 27 announcement on X, where neither of them have responsibility for making recommendations for the CDC immunization schedules;

h. the Secretary failed to explain why he did not consult with any voting member of the ACIP or anyone on the Covid-19 Work Group;

i. the Secretary failed to explain why he rejected the data, reports, and peer-reviewed studies that form the foundation of the ACIP and ACIP Work Group recommendations that the Directive rescinded;

j. the Secretary failed to explain why he issued the Directive after irrefutable evidence was presented at the April 2025 ACIP meeting that pregnant women and healthy children continue to face grave risk from Covid;

k. the Secretary has failed to explain why he issued the Directive in contravention of the numerous federal and state laws that incorporate reliance on ACIP recommendations—not the unilateral decisions of political appointees—such as which vaccines are to be covered by insurance or entitlement programs, which vaccines are required of aliens for entry into the country, or which vaccines are required for school entry.

l. the Secretary failed to explain whether he considered the impact that his sudden, unilateral Directive would have on the standard of care that applies to physicians who are members of the AAP, the ACP, the APHA, the IDSA, the SMFM, and many other physician organizations and associations around the country;

123. The Secretary issued the Directive in contravention of the overwhelming weight of science and clinical expertise.

124. Neither the Secretary, nor the FDA Commissioner, nor the NIH Director have cited any credible evidence, data, or peer-reviewed studies that support the Directive.

125. The Directive was issued without the reasoned or rational explanation that is required by the APA.

126. The reasons stated in the Directive are contrived and pretextual.

127. Pursuant to 5 U.S.C. § 706 and 28 U.S.C. § 2201, Plaintiffs are entitled to a declaration that the Directive violates the APA because it is arbitrary and capricious.

128. The Directive has injured all of the Plaintiffs in this action.

129. Plaintiffs are also entitled to vacatur of the Directive and a preliminary and permanent injunction ordering the Secretary to reinstate to the CDC immunization schedules the routine recommendations that pregnant women and children ages six months to 17 years be vaccinated against Covid.

COUNT II

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

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

131. 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).

132. The Directive constitutes a final agency action subject to the APA.

133. Over the decades, Congress has authorized and ratified a process that vests responsibility and authority in the ACIP to make recommendations for the vaccines to include on CDC's immunization schedules. By making a unilateral decision to change the CDC immunization schedules without following the ACIP recommendation process, the Secretary rewrites these statutes. Congress has never vested authority to decide what vaccines are recommended on CDC immunization schedules in the Secretary of Health and Human Services.

134. The Directive is also 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." The Directive is directly contrary to this law, signed by then President Donald Trump on December 27, 2020.

135. The Directive has injured all the Plaintiffs in this action.

136. Pursuant to 5 U.S.C. § 706 and 28 U.S.C. § 2201, Plaintiffs are entitled to a declaration that the Directive is contrary to law and in violation of the APA.

137. Plaintiffs are also entitled to vacatur of the Directive and a preliminary and permanent injunction ordering the Secretary to reinstate the Covid vaccine recommendations for pregnant women and children ages six months to 17 years to the CDC immunization schedules.

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. Grant preliminary and permanent injunctive relief ordering the restoration of the Covid vaccine recommendations for pregnant women and healthy children ages six months to 17 years to the CDC immunization schedules posted on its website;

3. Grant preliminary and permanent injunctive relief barring Defendants from enforcing, publicizing, or otherwise encouraging any person or court to follow or to defer to the

challenged Directive dated May 19, 2025 on Pediatric Covid Vaccines for Children Less Than 18 Years of Age and Pregnant Women.

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

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

Dated: September 3, 2025

Respectfully submitted,

By: *James J. Oh*

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CERTIFICATE OF SERVICE

I hereby certify that this document was filed through the ECF system and served upon the following parties by via email on this 3rd day of September, 2025:

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

Marty Makary, in his official capacity as Commissioner of the Food and Drug Administration

Jay Bhattacharya, in his official capacity as Director of the National Institutes of Health

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

c/o Leah Belaire Foley, US Attorney
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/s/ James J. Oh
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