

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS,
et al.,

Plaintiffs,

v.

ROBERT F. KENNEDY, JR., in his
official capacity as Secretary of the
Department of Health and Human
Services, et al.,

Defendants.

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

District Judge: Hon. Brian E.
Murphy

**DECLARATION OF RICHARD JAFFE IN SUPPORT OF MOVANTS' MOTION FOR
STAY OF PRELIMINARY INJUNCTION PENDING APPEAL**

1. I am lead counsel for Movants Andrea Shaw, Shanticia Nelson, Dr. Paul Thomas, Dr. Kenneth Stoller, and Children's Health Defense. I submit this declaration in support of Movants' Motion for Stay of Preliminary Injunction Pending Appeal, filed in this Court as directed by the United States Court of Appeals for the First Circuit in its April 9, 2026 order. A true and correct copy of the First Circuit's order is attached as Exhibit 1. I have personal knowledge of the facts stated herein.
2. This declaration presents developments since this Court's March 16, 2026 preliminary injunction order.

Changed Circumstances: The April 1, 2026 Charter Renewal

3. On April 1, 2026, the Secretary of Health and Human Services filed a renewed charter for the Advisory Committee on Immunization Practices pursuant to the mandatory biennial renewal provision of FACA, 5 U.S.C. § 1013(d). The Secretary approved the charter on

March 31, 2026. Notice of the renewal was published in the Federal Register on April 6, 2026. 91 Fed. Reg. 17279 (Apr. 6, 2026). A true and correct copy of the renewed charter is attached as Exhibit 2.

4. The biennial charter renewal is a statutory requirement. Under FACA, advisory committees terminate two years from the date of charter filing unless the charter is renewed. 5 U.S.C. § 1013(d); 41 C.F.R. § 102-3.55. The prior charter's filing date required renewal by April 2026. The Secretary was required to file a renewed charter regardless of this litigation.
5. On April 9, 2026, the United States Court of Appeals for the First Circuit denied Movants' Emergency Motion Under FRAP 8(a)(2)(A)(ii) for Relief Pending Appeal, holding that the motion should be filed in this Court in the first instance. The denial was without prejudice.
6. As of the date of this declaration, no party has filed any motion in this Court presenting the renewed charter as a basis for reconsidering or modifying the March 16, 2026 preliminary injunction. The government has not argued to this Court that the renewed charter addresses the Court's concerns about ACIP member qualifications. Movants present the charter renewal now because no party will.

Key Changes in the Renewed Charter

7. The renewed charter expands the listed fields of expertise for ACIP membership. The prior charter required that 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.”

8. The renewed charter adds the following expertise categories: “medicine, vaccines, immunization practices, immunology, toxicology, pediatric neurodevelopment, epidemiology, data science, statistical analysis, health economics, recovery from serious vaccine injuries, or public health.” Ex. 2 at 4. The renewed charter also adds that members may “have expertise in the use of vaccines or other immunobiologic agents in clinical practice or preventive medicine, have expertise with clinical or laboratory vaccine research, or have expertise in assessment of vaccine safety and efficacy.” Ex. 2 at 4-5.
9. The renewed charter expands ACIP’s scope of activities. It directs ACIP to “provide recommendations regarding revisions and updates to the CDC immunization schedules for children, adolescents, and adults, taking into account emerging diseases, new vaccines, cumulative exposures to vaccines and vaccine components, and changes in disease epidemiology.” Ex. 2 at 2.
10. The renewed charter expands ACIP’s key responsibilities to include: “evaluating the risk/benefit profiles of vaccines based on ongoing surveillance and new research findings; considering analysis of cumulative effects of vaccines and their constituent components; engaging in re-analysis of vaccine safety and efficacy as gaps are identified and new information becomes available; and evaluating the risks and benefits of tailoring immunization practices to maximize benefits and reduce risks and take into account variability in immune response for various populations.” Ex. 2 at 3.

11. The renewed charter directs ACIP to consider “on an ongoing basis the safety, efficacy, and public health impact of new vaccines, as well as novel vaccine platforms such as mRNA vaccines.” Ex. 2 at 3.
12. The renewed charter adds liaison organizations including the Medical Academy of Pediatrics and Special Needs (MAPS), Physicians for Informed Consent (PIC), the Association of American Physicians and Surgeons (AAPS), and the Independent Medical Alliance (IMA). Ex. 2 at 5. These are non-voting liaison representatives, the same category the American Academy of Pediatrics occupies. Each organization’s mission corresponds to specific provisions of the renewed charter.
13. MAPS provides continuing medical education and fellowship training for clinicians treating children with neurodevelopmental disorders, autism spectrum disorders, immune dysfunction, and conditions resulting from vaccine injury. MAPS conferences and fellowship programs are jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC), the same accreditation infrastructure that accredits the American Academy of Pediatrics’ own CME programs. See <https://www.medmaps.org/about-us/>. MAPS’ clinical education mission corresponds to the renewed charter’s expertise categories of “pediatric neurodevelopment” and “recovery from serious vaccine injuries.” Ex. 2 at 4.
1. PIC is a 501(c)(3) nonprofit educational organization that publishes comparative risk-benefit analyses of childhood vaccines and the diseases they target, using peer-reviewed studies and government health statistics. Its 2025 publication, “Vaccines and the Diseases They Target: An Analysis of Vaccine Safety and Epidemiology,” contains over 400

citations and was distributed to every member of Congress, President Trump, and Vice President Vance. See <https://physiciansforinformedconsent.org/silver-booklet/>. PIC's analytical framework, comparing vaccine risk to disease risk for individual diseases, corresponds to the renewed charter's directives on "evaluating the risk/benefit profiles of vaccines based on ongoing surveillance and new research findings" and "re-analysis of vaccine safety and efficacy as gaps are identified." Ex. 2 at 3.¹

2. IMA is a 501(c)(3) nonprofit organization of physicians and scientists that publishes the *Journal of Independent Medicine*, conducts weekly educational webinars, and holds annual conferences on treatment strategies for infectious and chronic disease, including vaccine injury. See <https://imahealth.org/>. IMA's clinical focus on treatment of patients with mRNA vaccine injuries corresponds to the renewed charter's directives on "recovery from serious vaccine injuries" (Ex. 2 at 4) and "considering on an ongoing basis the safety, efficacy, and public health impact of new vaccines, as well as novel vaccine platforms such as mRNA vaccines" (Ex. 2 at 3).
3. AAPS is a national physician organization founded in 1943 that represents physicians in private practice and advocates for physician autonomy and informed consent. See <https://aapsonline.org/>. AAPS' perspective on individualized clinical decision-making corresponds to the renewed charter's directive on "tailoring immunization practices to maximize benefits and reduce risks." Ex. 2 at 3.

The Renewed Charter Addresses the IOM's Recommendations

4. As I stated in my prior declaration (Dkt. 248-4, ¶¶20-22), the Institute of Medicine found in 2002 that no study had compared health outcomes between fully vaccinated and

¹I disclose that I represent *Kory v. Bonta* (E.D. Cal.), presently pending before the Supreme Court concerning physicians' speech to patients.

unvaccinated children, and recommended the CDC conduct retrospective studies using the Vaccine Safety Datalink. The IOM confirmed in 2013 that cumulative-effects studies had never been conducted and that the research was feasible.

5. The prior ACIP charter never directed the committee to consider cumulative effects. The prior ACIP membership did not include the expertise needed to design or evaluate such studies. In the twenty years since the IOM's first recommendation, no Director acted on it.
6. The renewed charter changes both. It directs ACIP to consider "cumulative exposures to vaccines and vaccine components," to engage in "re-analysis of vaccine safety and efficacy as gaps are identified," and to evaluate "variability in immune response for various populations." Ex. 2 at 2-3. It adds expertise categories, including data science, statistical analysis, health economics, toxicology, and pediatric neurodevelopment, that correspond to the disciplines needed to conduct the work the IOM said was overdue. The Secretary is using the chartering authority FACA gives him to direct the advisory committee to do what the IOM recommended twenty years ago.

Under the Renewed Charter, Every Challenged Member Qualifies

7. This Court found that nine of the fifteen ACIP members either lacked vaccine-related expertise (six members) or had only arguably relevant expertise (three members). PI Order at 29-31. At footnote 56, this Court acknowledged that "there may be evidence to demonstrate that each of these individuals have more relevant experience or expertise than what is before the Court at this juncture." This declaration presents that evidence.
8. You do not test a cumulative vaccine schedule with vaccinologists. You test it with the disciplines the IOM said were missing and the renewed charter now requires:

epidemiologists who study population-level outcome variation, risk analysts who build decision-support models, neuroscientists who study developmental outcomes, immunobiologists who understand variability in immune response, and cardiologists who can evaluate the dominant adverse event signal. Each of the nine members this Court found unqualified or arguably qualified satisfies at least one expertise category under the renewed charter.

9. **Dr. Hillary Blackburn** (PharmD, MBA) is the first pharmacist ever appointed as a voting member of ACIP. The American Pharmacists Association, the Academy of Managed Care Pharmacy, and the American Society of Health-System Pharmacists, the three leading pharmacy organizations in the country, jointly recommended the addition of a pharmacy professional to ACIP. She has administered hundreds of vaccines and completed national immunization certification. She has 15 years of experience across hospital, community, specialty pharmacy, and health plan settings. She serves as Director of Medication Access and Affordability at AscensionRx and previously served as Chief Pharmacy Officer at the Dispensary of Hope. She is an APhA Fellow. *See ACIP: Who Are the New Members? Introductions in Their Own Words*, Medical Economics (Sept. 18, 2025), <https://www.medicaleconomics.com/view/acip-who-are-the-new-members-introductions-in-their-own-words>; APhA/ASHP Joint Press Release (Sept. 16, 2025), <https://www.pharmacist.com/APhA-Press-Releases/hhs-cdc-announce-first-pharmacist-appointment-to-acip-hillary-f-blackburn-named-voting-member>; CDC ACIP Membership Roster (Mar. 2, 2026), <https://www.cdc.gov/acip/membership/roster.html>. This Court found “no evidence in the record that [she] has any relevant vaccine-related experience or expertise.” PI Order at 29 n.47. Under the renewed charter, Dr. Blackburn satisfies

“medicine,” “public health,” and “health economics” (Ex. 2 at 4), and her expertise in medication access directly serves the charter’s directive on “equitable access to immunizations across communities” (Ex. 2 at 2). Pharmacists administer a substantial share of recommended routine vaccinations in the United States, and APhA has reported that pharmacists administered more recommended routine vaccinations than physicians from 2020 to 2021.

10. **Dr. Evelyn Griffin** (MD) is the Surgeon General for the State of Louisiana. She is board-certified in obstetrics and gynecology, lifestyle medicine, and functional medicine. She has more than 15 years of clinical practice, was among the first robotic-assisted gynecologic surgeons in the United States, and has led efforts to reduce maternal morbidity and mortality. She currently serves as an obstetric hospitalist. See CDC ACIP Membership Roster (Mar. 2, 2026), <https://www.cdc.gov/acip/membership/roster.html>; *HHS and CDC Appoint 5 New ACIP Members*, Contagion Live (Sept. 15, 2025), <https://www.contagionlive.com/view/hhs-and-cdc-appoint-five-new-acip-members-ahead-of-sept-18-to-19-meeting>. This Court found “no evidence in the record that [she] has any relevant vaccine-related experience or expertise.” PI Order at 29 n.48. Under the renewed charter, Dr. Griffin satisfies “medicine” and “public health” (Ex. 2 at 4), and her OB/GYN specialty and maternal health leadership directly serve the charter’s directive on recommendations “for specific populations such as pregnant women” (Ex. 2 at 2).
11. **Dr. Joseph R. Hibbeln** (MD, CAPT USPHS Ret.) is a psychiatrist and neuroscientist who served as Chief of the Section on Nutritional Neurosciences at the National Institutes of Health (NIAAA). He has published more than 250 peer-reviewed scientific papers. His 2007 *Lancet* paper on maternal seafood consumption and childhood neurodevelopmental

outcomes contributed to multiple U.S. agencies reconsidering their dietary guidelines for fish and seafood intake during pregnancy. He has presented to the U.S. National Academy of Sciences, Engineering and Medicine to re-evaluate current U.S. dietary advice. He holds a Benjamin Meeker Distinguished Visiting Professorship at the University of Bristol. He received the USPHS Outstanding Service Medal and three USPHS Crisis Response Awards. See CDC ACIP Membership Roster (Mar. 2, 2026), <https://www.cdc.gov/acip/membership/roster.html>; FAB Research, Dr. Joseph R. Hibbeln Profile, <https://www.fabresearch.org/joseph-hibbeln>; Seafood Nutrition Partnership, Dr. Joseph R. Hibbeln Profile, <https://www.seafoodnutrition.org/profile/joseph-hibbeln/>. See also Joseph R. Hibbeln et al., *Maternal Seafood Consumption in Pregnancy and Neurodevelopmental Outcomes in Childhood (ALSPAC Study): An Observational Cohort Study*, 369 *Lancet* 578 (2007). This Court found “no evidence in the record that [he] has any relevant vaccine-related experience or expertise.” PI Order at 29 n.49. Under the renewed charter, Dr. Hibbeln satisfies “pediatric neurodevelopment” (Ex. 2 at 4), a field now explicitly listed as an expertise category. His career at NIH was devoted to studying how exposures during pregnancy affect neurodevelopmental outcomes in children.

12. **Dr. Kirk Milhoan** (MD, PhD) is a pediatric cardiologist whose PhD is in mechanisms of myocardial inflammation. He is a former U.S. Air Force flight surgeon with two combat tours in Iraq. He co-founded For Hearts and Souls, an international mission organization for children with congenital heart disease, and has coordinated pediatric cardiac care in more than a dozen countries. See CDC ACIP Membership Roster (Mar. 2, 2026), <https://www.cdc.gov/acip/membership/roster.html>; *HHS Announces 5 New ACIP Members*, *Medical Economics* (Sept. 15, 2025),

<https://www.medicaleconomics.com/view/hhs-announces-5-new-acip-members-for-september-meeting>. This Court found “no evidence in the record that Dr. Milhoan has any relevant vaccine-related experience or expertise.” PI Order at 30 n.50. Under the renewed charter, Dr. Milhoan satisfies “medicine” (Ex. 2 at 4) and the charter’s directive on “evaluating the risk/benefit profiles of vaccines based on ongoing surveillance and new research findings” (Ex. 2 at 3). Myocarditis was the dominant adverse event signal from the COVID-19 vaccines and one of the reasons the FDA’s CBER Director determined the risk-benefit standard “is not met” for healthy children. A pediatric cardiologist whose PhD is in myocardial inflammation is the expert who evaluates that signal.

13. **Dr. James Pagano** (MD) is a board-certified emergency medicine physician with more than 40 years of clinical experience across level 1 trauma centers and community hospitals. See CDC ACIP Membership Roster (Mar. 2, 2026), <https://www.cdc.gov/acip/membership/roster.html>; *Meet the New Members of CDC’s Vaccine Advisory Panel*, Advisory.com (June 12, 2025), <https://www.advisory.com/daily-briefing/2025/06/12/acip-members>. This Court found “no evidence in the record that Dr. Pagano has any relevant vaccine-related experience or expertise.” PI Order at 30 n.51. Under the renewed charter, Dr. Pagano satisfies “medicine” and “public health” (Ex. 2 at 4), and the charter’s new inclusion of “recovery from serious vaccine injuries” as an expertise category (Ex. 2 at 4). An emergency physician is the first clinician to encounter acute vaccine adverse events. Four decades of frontline emergency medicine provides perspective on both the diseases vaccines prevent and the injuries they can cause.

14. **Dr. Raymond Pollak** (MD, FACS, FRCS) is a surgeon and transplant immunobiologist who has published more than 120 peer-reviewed works and served as principal investigator on NIH transplant biology grants and drug trials. He previously served as Chief of Liver Transplantation and Director of Multiorgan Transplant Programs at the University of Illinois and has held leadership roles with the United Network for Organ Sharing and the American Society of Transplant Surgeons. See CDC ACIP Membership Roster (Mar. 2, 2026), <https://www.cdc.gov/acip/membership/roster.html>. This Court found “no evidence in the record that Dr. Pollak has any relevant vaccine-related experience or expertise.” PI Order at 30 n.52. Under the renewed charter, Dr. Pollak satisfies “immunology” (Ex. 2 at 4) and the charter’s directive on “evaluating the risks and benefits of tailoring immunization practices to maximize benefits and reduce risks and take into account variability in immune response for various populations” (Ex. 2 at 3). Transplant immunobiology studies how the immune system responds to foreign biological material and why different individuals mount different immune responses. That is the foundational question underlying both vaccine efficacy and vaccine injury.
15. **Dr. Retsef Levi** (PhD) is a Professor of Operations Management at the MIT Sloan School of Management whose career centers on risk analytics and healthcare decision-making models. See CDC ACIP Membership Roster (Mar. 2, 2026), <https://www.cdc.gov/acip/membership/roster.html>. This Court found that, based on his two vaccine-related publications, “Publishing two papers on a topic, while no doubt relevant to ACIP, likely does not rise to the level of ‘expertise’ called for under ACIP governing documents.” PI Order at 30 n.53. Under the renewed charter, Dr. Levi satisfies “data science,” “statistical analysis,” and “health economics” (Ex. 2 at 4), and the

charter’s directives on “considering analysis of cumulative effects of vaccines and their constituent components” and “engaging in re-analysis of vaccine safety and efficacy as gaps are identified” (Ex. 2 at 3). His expertise directly addresses the gap the Institute of Medicine identified in 2002 and 2013 when it recommended cumulative vaccine-effects studies that were never conducted.

16. **Dr. Robert W. Malone** (MD) is a molecular biologist and adjunct professor at Pennington Biomedical Research Center, Louisiana State University, whose early career centered on mRNA vaccine technology. See CDC ACIP Membership Roster (Mar. 2, 2026), <https://www.cdc.gov/acip/membership/roster.html>. This Court found that “Even crediting that experience, the Court cannot conclude that this experience, thirty plus years ago, constitutes the requisite expertise necessary for ACIP today.” PI Order at 30 n.54. Under the renewed charter, Dr. Malone satisfies “vaccines” and “immunology” (Ex. 2 at 4) and the charter’s directive on “considering on an ongoing basis the safety, efficacy, and public health impact of new vaccines, as well as novel vaccine platforms such as mRNA vaccines” (Ex. 2 at 3). The mRNA platform Dr. Malone helped develop is the basis of the COVID-19 vaccines at the center of this litigation.
17. **Dr. Catherine M. Stein** (PhD) is a Professor of Population and Quantitative Health Sciences at Case Western Reserve University. She is an epidemiologist with more than two decades of research experience on tuberculosis and infectious diseases and more than 100 peer-reviewed publications. She has collaborated extensively in genetics, biostatistics, and immunology. See CDC ACIP Membership Roster (Mar. 2, 2026), <https://www.cdc.gov/acip/membership/roster.html>; Case Western Reserve University Faculty Profile, <https://case.edu/medicine/pqhs/about/people/primary-faculty/catherine->

m-stein-phd. This Court found “no evidence in the record that her experience and expertise relate to vaccines, vaccination, vaccine safety, or vaccine policy as to be relevant to ACIP’s function.” PI Order at 30 n.55. Under the renewed charter, Dr. Stein satisfies “epidemiology” (Ex. 2 at 4) and the charter’s directive on “evaluating the risks and benefits of tailoring immunization practices to maximize benefits and reduce risks and take into account variability in immune response for various populations” (Ex. 2 at 3). Her research program on genetic and environmental susceptibility to infectious disease and on variation in host response fits the charter’s epidemiology category and its focus on variability in immune response across populations.

The Government’s Irreconcilable Litigation Positions

18. The government is simultaneously complying with this Court’s preliminary injunction through the charter renewal while opposing Movants’ claims in *Thomas v. Bhattacharya*, No. 1:25-cv-02685-JMC (D.D.C.), where DOJ seeks dismissal of an APA challenge to the childhood vaccine schedule filed by two Movants. The government’s position in this case is to work within this Court’s framework. Movants’ position is that the framework is wrong. The government is defending the renewed charter by filing it; it is not challenging the legal basis for the order that compelled the revision. Those are irreconcilable litigation strategies that confirm the inadequacy of representation Movants have identified since February 2026.
19. On April 15, 2026, the government filed a motion for summary affirmance in the First Circuit seeking to terminate Movants’ appeal of the intervention denial. *Defendants-Appellees’ Motion for Summary Affirmance*, No. 26-1325 (1st Cir. Apr. 15, 2026), ECF No. 00118432357. The government’s motion argues that the district court did not abuse

its discretion in denying intervention because the government “adequately represent[s]” Movants’ interests. At the same time, the government states that “[n]othing in this filing should be misconstrued as agreeing that the district court’s order of preliminary relief was proper or denying that the order is causing irreparable harm to the government” and that “[d]efendants’ time for appealing that order has not yet run.” *Id.* at 2. The government thus acknowledges that the preliminary injunction is causing it irreparable harm, has not decided whether to appeal, has not sought a stay, has not presented the April 1 charter renewal to this Court, and is simultaneously seeking to prevent Movants from challenging the order. The government’s summary affirmance motion does not mention the renewed charter.

The Litigation Cycle Has No Endpoint

20. AAP has filed four amended in less than ten months. The renewed charter adds expertise categories and liaison organizations that AAP has publicly opposed. Based on AAP’s litigation pattern, AAP might well challenge the renewed charter, the expanded expertise categories, and the new liaison organizations in another amended complain, followed by another motion for preliminary injunction. This Court’s framework would allow for judicial evaluation of the Secretary’s charter every two years, because FACA requires biennial renewal. 5 U.S.C. § 1013(d). There is no endpoint to this cycle and no judicially manageable standard for evaluating whether the Secretary defined the right expertise categories for his own advisory committee.
21. I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on April 20, 2026.

/s/ Richard Jaffe

Richard Jaffe

EXHIBIT 1

Order of the United States Court of Appeals
for the First Circuit
No. 26-1325
Entered April 9, 2026

EXHIBIT 1

United States Court of Appeals For the First Circuit

No. 26-1325

AMERICAN ACADEMY OF PEDIATRICS; AMERICAN COLLEGE OF PHYSICIANS, INC.; AMERICAN PUBLIC HEALTH ASSOCIATION; INFECTIOUS DISEASES SOCIETY OF AMERICA; SOCIETY FOR MATERNAL-FETAL MEDICINE; JANE DOE; MASSACHUSETTS PUBLIC HEALTH ASSOCIATION, d/b/a Massachusetts Public Health Alliance; MASSACHUSETTS CHAPTER OF THE AMERICAN ACADEMY OF PEDIATRICS, INC.; JANE DOE 2; JANE DOE 3,

Plaintiffs - Appellees,

v.

ROBERT F. KENNEDY, JR., in the official capacity as Secretary of the Department of Health and Human Services; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; MARTIN MAKARY, in the official capacity as Commissioner of the Food and Drug Administration; US FOOD & DRUG ADMINISTRATION; JAY BHATTACHARYA, in the official capacity as Director of the National Institutes of Health; NATIONAL INSTITUTES OF HEALTH; JIM O'NEILL, in the official capacity as Acting Director of Centers For Disease Control and Prevention; CENTERS FOR DISEASE CONTROL AND PREVENTION; DOES 1-50, Inclusive,

Defendants,

ANDREA SHAW; SHANTICIA NELSON; DR. PAUL THOMAS; DR. KENNETH STOLLER; CHILDRENS HEALTH DEFENSE,

Movants - Appellants.

Before

Barron, Chief Judge,
Aframe and Dunlap, Circuit Judges.

ORDER OF COURT

Entered: April 9, 2026

Movants-Appellants have filed an "Emergency Motion Under FRAP 8(a)(2)(A)(ii), For Relief Pending Appeal." Per Federal Rule of Appellate Procedure 8(a)(1)(A), such a motion should

be filed in the district court in the first instance. Accordingly, the motion is denied, without prejudice to movants-appellants' pursuit of relief in the district court in the first instance.

By the Court:

Anastasia Dubrovsky, Clerk

cc:

Robert N. Meltzer, Richard Jaffe, Donald Campbell Lockhart, Thomas Pulham, Michael L. Fitzgerald, Isaac Belfer, Douglas C. Dreier, Robert E. Wanerman, Stuart M. Gerson, Elizabeth J. McEvoy, Kathleen Barrett, James J. Oh, Jeremy A. Avila, Richard H. Hughes IV, William Walters, Daniella R. Lee, Gianna Monet Costello, Jose A. Perez, Francisco Maria Negrón, Jr., Molly A. Meegan, Thanithia R. Billings, Meaghan Hannan Davant, Kimberly A. Parker, Mark L. Hanin, Andrew Matthew London, Caroline Lindsay Farrell, Ashley H. Wisneski, Holly E. Peterson, Kevin M. Serafino, David Steven Schumacher, Wendy Ellen Parmet, Heather M. Romero, Julia Caldwell, Andrew J. Pincus, Natasha Harnwell-Davis, Allison Aviki, Graham White, Crystal Paulino, Megan Barbero, Kyle H. Keraga, Sarah Allen, Marilyn J. Icsman

EXHIBIT 2

Charter of the Advisory Committee
on Immunization Practices
Approved March 31, 2026
Filed April 1, 2026

EXHIBIT 2

CHARTER

ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES

Advisory Committee's Official Designation.

Advisory Committee on Immunization Practices (ACIP or Committee).

Authority.

The ACIP was established under Section 222 of the Public Health Service Act (42 U.S.C. §217a), as amended. The Committee is governed by the provisions of the Federal Advisory Committee Act (FACA), Public Law 92-463 (5 U.S.C. § 1001 et seq.), as amended.

The ACIP has been given statutory roles under subsections 1928(c)(2)(B)(i) and 1928(e) of the Social Security Act (42 U.S.C. § 1396s(c)(2)(B)(i) and 1396s(e)) and subsection 2713(a)(2) of the Public Health Service Act (42 U.S.C. § 300gg-13(a)(2)).

Objective and Scope of Activities.

The Secretary, Department of Health and Human Services (HHS), and by delegation the Director, Centers for Disease Control and Prevention (CDC), are authorized under Section 311 and Section 317 of the Public Health Service Act, [42 U.S.C. §243 and 42 U.S.C. §247b], as amended, to assist states and their political subdivisions in the prevention and control of communicable diseases; to advise the states on matters relating to the preservation and improvement of the public's health; and to make grants to states and, in consultation with the state health authorities, to agencies and political subdivisions of states to assist in meeting the costs of communicable disease control programs.

Vaccines have played an important role in public health around the globe. The Advisory Committee on Immunization Practices (ACIP) provides recommendations to the CDC Director on the use of vaccines and immunization program strategies to inform individuals, clinicians, and broader public health efforts. This committee convenes scientific and medical experts to provide recommendations based on the best available evidence of vaccine risks and benefits, and efficacy.

ACIP shall provide advice and guidance to the CDC Director regarding use of vaccines and related agents for effective control of vaccine-preventable diseases and/or decreased symptomatology in the civilian population of the United States and gaps in vaccine safety research including adverse effects following vaccination. Recommendations made by ACIP are initially reviewed by the CDC Director, and if adopted, become official CDC/HHS recommendations, and may be published in the *Morbidity and Mortality Weekly Report (MMWR)*. The CDC Director informs the HHS Secretary, and Assistant Secretary for Health, of immunization recommendations provided by the Committee. Upon the licensure or authorization of any vaccine or any new indication for a vaccine, the Committee shall, as appropriate, consider the use of the vaccine at its next regularly scheduled meeting. If the Committee does not make a recommendation at the Committee's first regularly scheduled meeting, the Committee shall provide an update on the status of such for the Committee's review.

Description of Duties.

The Committee shall provide advice for the control of diseases for which a vaccine is licensed or authorized in the U.S. The guidance will address use of vaccines and may include recommendations for administration of immune globulin preparations and/or antimicrobial therapy shown to be effective in controlling a disease for which a vaccine is available. Guidance for use of unlicensed vaccines may be developed if circumstances warrant and the Committee is directed to develop such guidance by the CDC Director. For each vaccine, the Committee advises on population groups and/or circumstances in which a vaccine or related agent is recommended. The Committee shall also provide recommendations on contraindications and precautions for use of the vaccine and related agents and provides information on recognized adverse events. The Committee also may provide recommendations that address the general use of vaccines and immune globulin preparations as a class of biologic agents, use of specific antibody products for prevention of infectious diseases, and special situations or populations that may warrant modification of the routine recommendations.

The main tasks of the Committee can be organized into review and recommendations, immunization schedules, and public health strategies. ACIP shall review the latest scientific evidence on vaccine safety, efficacy, and effectiveness to make recommendations on the routine use of vaccines, including for specific populations such as pregnant women, elderly, and immunocompromised individuals. Such review may include evaluation of pre- and post-licensure data or if available, clinical trial data for vaccines under an Emergency Use Authorization. ACIP shall provide recommendations regarding revisions and updates to the CDC immunization schedules for children, adolescents, and adults, taking into account emerging diseases, new vaccines, cumulative exposures to vaccines and vaccine components, and changes in disease epidemiology. Furthermore, ACIP shall advise on vaccination strategies that promote optimal vaccine coverage, address health disparities, and ensure equitable access to immunizations across communities.

Committee deliberations on use of vaccines to control disease in the U.S. shall include consideration of disease epidemiology and burden of disease, vaccine risks and benefits, vaccine efficacy and effectiveness, the quality of evidence reviewed, economic analyses, and

implementation issues. The Committee may revise or withdraw their recommendation(s) regarding a particular vaccine as new information on disease epidemiology, vaccine effectiveness or safety, economic considerations, or other data become available.

Key responsibilities in developing committee recommendations can be organized into vaccine recommendations, vaccine safety and monitoring, emerging vaccines and technology, global health practices, and public engagement and transparency as part of ACIP public meetings. ACIP shall be responsible for formulating recommendations for routine vaccination schedules for different age groups and high-risk populations, advising on the use of vaccines in emergency situations (such as during disease outbreaks or public health emergencies), and reviewing immunization practices (including those related to vaccine storage, handling, and administration). ACIP shall also be responsible for reviewing data on vaccine safety and adverse events, providing recommendations to enhance vaccine safety surveillance systems, and advising CDC on gaps in vaccine safety research; evaluating the risk/benefit profiles of vaccines based on ongoing surveillance and new research findings; considering analysis of cumulative effects of vaccines and their constituent components; engaging in re-analysis of vaccine safety and efficacy as gaps are identified and new information becomes available; and evaluating the risks and benefits of tailoring immunization practices to maximize benefits and reduce risks and take into account variability in immune response for various populations. Furthermore, ACIP shall be responsible for considering on an ongoing basis the safety, efficacy, and public health impact of new vaccines, as well as novel vaccine platforms such as mRNA vaccines; and evaluating vaccines for new diseases or variants of concern, ensuring that recommendations adapt to new scientific evidence and evolving disease landscapes. ACIP shall also be responsible for reviewing global initiatives; and reviewing vaccination schedules by other countries and international organizations.

ACIP shall employ a transparent, evidence-driven decision-making process in developing recommendations. The Committee shall review clinical data, listen to expert presentations, and consult with subject matter experts to determine the benefits and risks of vaccines. ACIP decisions shall be based on rigorous scientific analysis and deliberation, with the goal of recommending immunization practices that protect and improve public health in the United States.

In accordance with Section 1928 of the Social Security Act, ACIP also shall establish and periodically review and, as appropriate, revise the list of vaccines for administration to children and adolescents eligible to receive vaccines through the Vaccines for Children Program, along with schedules regarding the appropriate dose and dosing interval, and contraindications to administration of the pediatric vaccines. The Secretary, and as delegated by the CDC Director, shall use the list established by ACIP for the purpose of the purchase, delivery, and administration of pediatric vaccines in the Vaccines for Children Program.

Further, under provisions of the Affordable Care Act (Section 2713 of the Public Health Service Act, as amended), immunization recommendations of the Committee that have been adopted by the Director of the Centers for Disease Control and Prevention must be covered by applicable health plans.

Agency or Federal Officer Receiving the Advisory Committee's Advice/Recommendations.

The Committee reports to the CDC Director. The CDC Director informs the HHS Secretary and the Assistant Secretary for Health, HHS, of immunization recommendations provided by the Committee.

Support.

Management and support services shall be provided by the CDC's: Office of the Chief of Staff; National Center for Immunization and Respiratory Diseases; National Center for Emerging and Zoonotic Infectious Diseases; and National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention as instructed by the CDC Director, to support ACIP-related activities.

Estimated Annual Operating Costs and Staff Years.

Estimated annual costs for operating the Committee, including (i) Federal personnel (3) and other Federal internal costs are \$1,080,340; (ii) proposed compensation and travel expense payments for up to 19 members is \$42,750; and (iii) reimbursable costs are \$83,106.

Estimated Number and Frequency of Meetings.

Meetings will be held at the discretion of the ACIP DFO in consultation with the Chair.

Meetings shall be open to the public except as determined otherwise by the CDC Director or other official, to whom the authority has been delegated, in accordance with the Government in the Sunshine Act (5 U.S.C. § 552b(c)) and Section 10(d) of the FACA (5 U.S.C. § 1009(d)). Notice of all meetings shall be given to the public.

Duration.

Continuing.

Termination.

Unless renewed by appropriate action, ACIP will terminate 2 years from the date this charter is filed.

Membership and Designation.

The Committee consists of up to 19 voting members, who are Special Government Employees, including the Chair and Vice Chair.

Members shall be selected from authorities who are knowledgeable in the fields of medicine, vaccines, immunization practices, immunology, toxicology, pediatric neurodevelopment, epidemiology, data science, statistical analysis, health economics, recovery from serious vaccine injuries, or public health; have expertise in the use of vaccines or other immunobiologic agents in

clinical practice or preventive medicine, have expertise with clinical or laboratory vaccine research, or have expertise in assessment of vaccine safety and efficacy. The Committee shall include a person(s) knowledgeable about consumer perspectives and/or social and community aspects of immunization programs. Members shall be deemed Special Government Employees.

The Committee also shall consist of non-voting ex-officio members from the Health Resources and Services Administration, the U.S. Food and Drug Administration, Centers for Medicare and Medicaid Services, National Institutes of Health, Indian Health Service, and the National Vaccine Program at HHS or their designees.

If fewer than a quorum of ACIP members are eligible to vote due to absence or a financial or other conflict of interest, the DFO, or designee, shall have the authority to temporarily designate the ex-officio members as voting members.

There also shall be 33 non-voting liaison representatives from the American Academy of Family Physicians; American Academy of Pediatrics; American Academy of Physician Associates; American College Health Association; American College of Nurse Midwives; American College of Physicians; American Geriatrics Society; America's Health Insurance Plans; American Immunization Registry Association; American Medical Association; American Nurses Association; American Osteopathic Association; American Pharmacists Association; Association of Immunization Managers; Association of American Physicians and Surgeons; Association for Prevention Teaching and Research; Association of State and Territorial Health Officials; Biotechnology Innovation Organization; Council of State and Territorial Epidemiologists; Canadian National Advisory Committee on Immunization; Infectious Diseases Society of America; Independent Medical Alliance; International Society of Travel Medicine; Medical Academy of Pediatrics and Special Needs; National Association of County and City Health Officials; National Association of Pediatric Nurse Practitioners; National Foundation for Infectious Diseases; National Medical Association; Pediatric Infectious Diseases Society; Pharmaceutical Research and Manufacturers of America; Physicians for Informed Consent; Society for Adolescent Health and Medicine; and Society for Healthcare Epidemiology of America. Liaisons shall be deemed representatives.

Members, including the Chair and Vice Chair, shall be selected by the HHS Secretary and shall be invited to serve for overlapping terms of up to four years, except that any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of that term. A member may serve 180 days after the expiration of that member's term if a successor has not taken office.

Subcommittees.

Subcommittees composed of members of the parent committee and other subject matter experts may be established with the approval of the HHS Secretary. The subcommittees must report back to the parent committee and do not provide advice or work products directly to the agency. The Department Committee Management Officer will be notified upon establishment of each subcommittee and will be provided information on its name, membership, function, and estimated frequency of meetings.

Filing Date.

April 1, 2026

APPROVED:

March 31, 2026

Date

A handwritten signature in blue ink, appearing to read "Robert F. Kennedy, Jr.", written over a horizontal line.

Robert F. Kennedy, Jr.