No. 26-1503

United States Court of Appeals
for the First Circuit

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; MASSACHUSETTS CHAPTER OF THE AMERICAN ACADEMY OF PEDIATRICS; JANE DOE; 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 FOOD & DRUG ADMINISTRATION; JAY BHATTACHARYA, in the official capacities as Director of the National Institutes of Health and as Acting Director of Centers for Disease Control and Prevention; NATIONAL INSTITUTES OF HEALTH; CENTERS FOR DISEASE CONTROL AND PREVENTION; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; KYLE DIAMANTAS, in the official capacity as Acting Commissioner of the Food and Drug Administration, DOES 1-50, Inclusive,
Defendants - Appellants.

On Appeal from the United States District Court
for the District of Massachusetts

BRIEF OF AMICUS CURIAE DEFEND PUBLIC HEALTH IN SUPPORT OF PLAINTIFFS-APPELLEES AND AFFIRMANCE

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rules of Appellate Procedure 26.1, Defend Public Health certifies that it is not a publicly held corporation, it does not have a parent company, and no publicly held corporation owns a 10% or more ownership interest in it.

RULE 29(a)(4)(E) STATEMENT

No party's counsel authored this brief in whole or in part. No party or party's counsel contributed money intended to fund preparing or submitting this brief. No person other than Defend Public Health, its members, or its counsel contributed money intended to fund preparing or submitting this brief.

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I. INTEREST OF AMICUS CURIAE

Amicus Curiae Defend Public Health ("DPH") is an unincorporated nonprofit association with over 12,000 members in more than 40 states, including physicians, nurses, legal scholars, current and former public health officials, and academic scientists working in biomedical and clinical research, epidemiology, and other areas of public health. Notably, DPH members have significant expertise in the following subjects: infectious disease epidemiology; pediatric and adult infectious disease treatment and prevention; the modeling of vaccine effectiveness and impact; vaccine hesitancy; and domestic and international health policy, including but not limited to, immunization practices.

DPH members have also been involved in advising domestic and international institutions on infectious disease and immunization practice and policy matters throughout their professional careers in medicine and public health. DPH was founded in November 2024 to protect America's public health, healthcare, and biomedical research endeavors and promote sound policies and programs in those areas critical to the advancement of the health and well-being of all Americans, including those concerning immunization against infectious diseases.

All parties have consented to the filing of this brief under Federal Rule of Appellate Procedure 29(a)(2).

II. SUMMARY OF THE ARGUMENT

This appeal concerns an advisory committee, but not an ordinary one. For more than 60 years, the Advisory Committee on Immunization Practices ("ACIP") has supplied the expert record on which federal vaccine recommendations ordinarily rested. Its critical value came from having members with extensive, relevant expertise, rigorous conflict-of-interest protections, multidisciplinary workgroups, systematic evidence review, public deliberation, and transparent rationales. These safeguards have enabled ACIP to evaluate changing evidence, distinguish among patient populations, assess rare safety signals, and weigh benefits, risks, feasibility, and public-health consequences.

Yes, the CDC Director retains final authority over CDC's vaccine recommendations. But CDC historically has relied upon the record produced by ACIP's expert process. Departures from ACIP recommendations exist, but they have been exceedingly rare. So, ACIP's expertise and procedures have been critical, and they have served as the foundation for national vaccine recommendations for more than half a century.

Congress has incorporated ACIP recommendations into federal programs governing vaccine purchasing, access, and insurance coverage. States have incorporated ACIP recommendations into hundreds of statutes and regulations. Clinicians and medical organizations have treated the ACIP/CDC schedule as a

common national reference point. Casting aside ACIP's expertise and procedures, therefore, is profoundly consequential to the systems that have been built around the reliability of ACIP's recommendations, and the result is parallel guidance, fragmentation, and conflict among states and medical organizations that already have begun relying on alternative sources.

The Court should evaluate the challenged ACIP reconstitution against this institutional and public health background.

III. ARGUMENT

A. The Expertise of ACIP's Members, Its Conflicts of Interest Provisions, and the Processes It Follows Are Critical to Its Ability To Provide Recommendations that Protect the Public's Health.

ACIP's recommendations have carried weight because the committee's work has been supported by three mutually reinforcing safeguards: (1) members with relevant scientific and clinical expertise; (2) rigorous protections against actual and apparent conflicts of interest; and (3) structured, transparent procedures for evaluating the evidence. This comprehensive framework has enabled ACIP to understand complex scientific data, protect the integrity of its Members' judgment, and provide a disciplined review to translate judgment into recommendations tailored to evolving evidence and different patient populations.

1. ACIP Relies on the Expertise of Its Members To Develop Scientifically Sound Recommendations Regarding Vaccinations.

Since its founding by the Surgeon General in 1964, ACIP has provided federal health officials, the states, and the broader public health community with critical, evidence-based recommendations about immunizations.[1] ACIP has been able to fulfill that role due to the extensive and relevant expertise of its members, rigorous conflicts of interest protections, and its reliance on extensive, evidence-based and transparent procedures to develop its recommendations.[2]

Initially, ACIP was composed of eight members, including the Director of the Centers for Disease Control and Prevention (CDC) ("the Director") and experts in public health, pediatrics, epidemiology, immunology, and preventive medicine. *Id.* In 1972, ACIP was designated a federal advisory committee, subjecting its membership to the provisions of the Federal Advisory Committee Act, 5 U.S.C. § 1001 *et seq*. As a "technical experience" advisory committee, it must be comprised of "persons with demonstrated professional or personal qualifications and

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[1] *Kavya Sakar*, *Cong. Rsch. Serv.*, IF 12371, *The Advisory Committee on Immunization Practices (ACIP)* (2025), https://www.congress.gov/crs-product/IF12317?hl=ACIP&s=1&r=1; Jean Clare Smith, Alan R. Hinman, & Larry K. Pickering, *History and Evolution of the Advisory Committee on Immunization Practices – United States, 1964-2014,* 63 Morbidity & Mortality Wkly. Rpt. 955, 955–58 (Oct. 24, 2014), https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6342a5.htm (hereinafter Smith et al., *History and Evolution*).

[2] Jean Clare Smith, *The Structure, Role and Procedures of the US Advisory Committee on Immunization Practices*, 285 Vaccine A68, A70 (2010) (hereinafter Smith, *The Structure, Role and Procedures*).

experience relevant to the functions and tasks to be performed by the committee." 41 C.F.R. 102-3.60(b)(1).

The Charter in effect when Department of Health and Human Services Secretary Robert F. Kennedy Jr. fired all of ACIP's members on June 9, 2025, stated that ACIP "shall consist" of up to nineteen members, who "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 immunobiological 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."[3] ACIP also included at least one consumer representative and several non-voting members from relevant federal health agencies. *Id.* ACIP's experts were supported in their work by CDC's scientific staff, who presented data on disease surveillance and epidemiology. *Id.* ACIP's work was further informed by non-voting liaison representatives from national medical, nursing, and public health organizations.[4]

ACIP's composition and structure allowed its members to analyze and interrogate highly technical and complex data across fields relevant to vaccine

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[3] *Advisory Comm. on Immunization Practices*, *ACIP Charter* (Dec. 3, 2025), https://perma.cc/8W76-JTTS.

[4] L. Reed Walton, Walter A. Orenstein, & Larry K. Pickering, *The History of the United States Advisory Committee on Immunization Practices* (ACIP), 33 Vaccine 405, 412 (2015).

science and policymaking and to make recommendations about the timing and formulation of vaccines for varied subpopulations, such as children under age 1 or adults over age 65. This expertise made ACIP's recommendations valuable to the Director and the many downstream actors that have relied on them over the decades.

2. ACIP Members Are Subject to Rigorous Conflict of Interest Safeguards.

Expertise alone, however, is not enough. ACIP serves as a trusted national reference point only because the committee also protects its deliberations from conflicts and applies disciplined procedures to its assessment of the evidence. Before June 2025, all ACIP member candidates underwent "careful screening for potential conflicts of interest."[5] Candidates with specific-vaccine related interests, such as employment of a family member by a vaccine manufacturer, were not considered for the committee. *Id.* Similarly, candidates who advised or consulted manufacturers were asked to resign from those roles and refrain from receiving travel reimbursement or honoraria from manufacturers. *Id.*

ACIP members were also required to file annual confidential financial reports with the Office of Government Ethics and publicly disclose all vaccine-related interests and work, including participation in clinical trials. *Id.* Members had to declare any conflicts, real or apparent, at the start of each "work group" meeting. *Id.*

[5] Smith, *The Structure, Role and Procedures*, at A70.

Members with a conflict were required to recuse themselves from conversations and votes on products related to their conflict and "recuse from voting on other products from that manufacturer, and on vaccines of other companies that directly compete with the product for which they have a conflict of interest." *Id.*

3. ACIP's Expertise Was Enhanced by Rigorous Processes Designed To Ensure a Thorough and Consistent Evaluation of the Scientific Evidence.

The expertise and independence of ACIP's members enabled it to employ a scientifically rigorous, transparent, and highly technical process that ensured its recommendations were based on the best available scientific evidence and protected the public's health.

Vaccine recommendations would typically go through a rigorous, years-long process.[6] Work groups were "established to review and analyze data regarding specific pathogens, diseases, vaccine interventions, and their efficacy and safety outcomes."[7] These work groups included ACIP members and other subject matter experts. *Id.* CDC aided the work groups by performing a systematic Grading of Recommendations Assessment Development and Evaluation (GRADE) analysis of the data. (*Id.* 2–3). The analysis was based on factors such as study design, bias, and

[6] Smith et al., *History and Evolution*, at 957.

[7] Edwin J. Asturias et al., *Science for Vaccine Policy: Independent Review of the September 2025 ACIP Process, Deliberations and Votes*, 67 Vaccine 127876, at 2 (2025) (hereinafter Asturias et al., *Science for Vaccine Policy*).

result consistency.[8] ACIP also separately utilized the Evidence to Decision (EtD) framework to enable evidence to be used in a structured and transparent way and to consider the magnitude of the desirable and undesirable effects of a vaccine, the certainty of the evidence of these effects, and how much affected individuals value the outcomes.[9]

4. The Expertise of ACIP's Members Has Played a Critical Role in Protecting the Public from Infectious Diseases and Vaccine-Related Injuries.

Together, expertise, conflict safeguards, and disciplined review have enabled ACIP to assess vaccine risks and benefits to develop carefully formulated recommendations that have protected the public from both vaccine-related risks and vaccine-preventable diseases. RotaShield and human papillomavirus (HPV) vaccines illustrate two distinct and important ACIP functions, including the rapid response to emerging safety signals and incremental refinement of recommendations as evidence develops.

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[8] Manya Prasad, *Introduction to the GRADE Tool for Rating Certainty in Evidence Recommendations, 25* Clin. Epidemiology & Glob. Health 1, 1–5 (2024), https://tinyurl.com/578dpv46.

[9] *Id.*; Gordon H. Guyatt et al., *GRADE: An Emerging Consensus on Rating Quality of Evidence and Strength of Recommendations*, 226 BMJ 924, 924 (2008).

a. RotaShield

Rotavirus causes substantial childhood diarrheal illness in the United States and significant mortality worldwide.[10] In the late 1990s, when the first vaccine to prevent it, tetravalent rhesus human reassortant rotavirus vaccine (RRV-TV)—commercially known as RotaShield—was undergoing clinical trials, rotavirus was estimated to cause 2.7 million symptomatic infections, 600,000 physician visits, and around 60,000 hospitalizations and 20 to 60 deaths annually in the United States.[11]

Years before U.S. Food and Drug Administration (FDA) licensure, an ACIP work group with relevant vaccine-safety and infectious-disease expertise reviewed RotaShield's safety and efficacy data. *Id.* at 284. Although clinical trials showed substantial efficacy, they also revealed a possible association with intussusception, a rare and potentially life-threatening condition. The difference observed in the trials was small and not statistically significant, but ACIP nonetheless recommended

[10] Roger I. Glass et al., *Introduction: Rotavirus – from Basic Research to A Vaccine,* 174 J. Infec. Diseases S1, S1 (1996) https://doi.org/10.1093/infdis/174.Supplement_1.S1; Umesh D. Parashar et al., *Global Illness and Deaths Caused by Rotavirus Disease in Children.* 9 Emerg. Infect. Dis 565, 565–66 (2003).

[11] Jason L. Schwartz, *The First Rotavirus Vaccine and the Politics of Acceptable Risk,* 90 Milbank Q. 278, 281 (2012) (hereinafter Schwartz, *The First Rotavirus Vaccine*).

specific post-licensure surveillance for intussusception when it recommended the vaccine in 1999.[12]

After wider use, reports of intussusception appeared in the Vaccine Adverse Events Reporting System, CDC's passive surveillance system. CDC investigated a possible causal link, and at its October 1999 meeting, ACIP considered evidence from multiple observational study designs, applying members' expertise in pathology, infectious-disease epidemiology, causal inference, and biostatistics to assess the biological plausibility, timing, and magnitude of the risk.[13]

ACIP ultimately concluded that RotaShield increased the risk of intussusception and that, in the United States, the vaccine's benefits did not outweigh that risk. It also recognized that the balance could differ in settings where rotavirus mortality was substantially higher.[14]

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[12] *Rotavirus Vaccine (RotaShield) and Intussusception*, Ctrs. For Disease Control & Prevention (Apr. 22, 2011), https://archive.cdc.gov/www_cdc_gov/vaccines/vpd-vac/rotavirus/vac-rotashield-historical.htm#intussusception; Asturias et al., *Science for Vaccine Policy*, at 2, 5.

[13] *Ctrs. for Disease Control & Prevention, Advisory Comm. on Immunization Practices*, *Records of the Meeting Held on October 20-22, 1999*, https://stacks.cdc.gov/view/cdc/76562.

[14] Schwartz, *The First Rotavirus Vaccine*, at 288–90; J. Iskander et al., *Suspension of Rotavirus Vaccine After Reports of Intussusception – United States, 1999,* 53 Morb. Mort. Weekly Rep. 786, 786 (2004).

ACIP's expertise and process thus allowed it to identify a rare safety signal, evaluate it based on multiple sources of evidence, and reach a nuanced, population-specific judgment that safeguarded the health of American infants.

b. Human papillomavirus (HPV) vaccine

HPV posed a different challenge for ACIP. HPV is common, has over 150 types, and some types can cause cancer,[15] but the appropriate recommendation depended on evolving evidence for the age- and sex-specific disease burden and the immunogenicity and cost-effectiveness of different vaccines and schedules.

Before the first HPV vaccine was licensed in 2006, an ACIP workgroup met regularly to review the data from the clinical trials. The details of their process and analysis are critical:

> The Advisory Committee on Immunization Practices (ACIP) HPV vaccine workgroup first met in February 2004 to begin reviewing data related to the quadrivalent HPV vaccine. The workgroup held monthly teleconferences and meetings three times a year to review published and unpublished data from the HPV vaccine clinical trials, including data on safety, immunogenicity, and efficacy. Data on epidemiology and natural history of HPV, vaccine acceptability, and sexual behavior in the United States also were reviewed. Several economic and cost effectiveness analyses were considered. Presentations on these topics were made to ACIP during meetings in June 2005, October 2005, and February 2006. Recommendation options were developed and discussed by the ACIP HPV vaccine workgroup. When evidence was lacking, the recommendations incorporated expert opinion of the workgroup members. Options

[15] Lauri E. Markowitz et al., *Human Papillomavirus Vaccination: Recommendations of the Advisory Committee on Immunization Practices (ACIP),* 63 Morb. Mort. Weekly Rep. 1, 1–3 (2014), https://www.cdc.gov/mmwr/pdf/rr/rr6305.pdf.

> being considered by the workgroup were presented to ACIP in February 2006. The final recommendations were presented to ACIP at the June 2006 ACIP meeting. After discussions, minor modifications were made and the recommendations were approved at the June 2006 meeting. Modifications were made to the ACIP statement during the subsequent review process at CDC to update and clarify wording in the document.[16]

In 2006, ACIP first recommended HPV vaccination for females ages 9 to 26. *Id.* at 2. Then, as evidence of substantial disease burden and cost-effectiveness in other populations developed, ACIP extended its recommendations for routine vaccination to boys and young men, while later recommending shared clinical decision-making rather than routine vaccination for adults ages 27 to 45.[17] Such nuanced, population-specific recommendations were possible only because multidisciplinary experts conducted a careful and robust review of evolving scientific evidence with respect to HPV. Over time, as the recommendations were refined and the schedule simplified to a two-dose regimen, virologists and immunologists adjudicated the impact of fewer doses on different strains of the virus and the attendant immunogenicity, and health economists evaluated the cost-

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[16] Lauri E. Markowitz et al., *Quadrivalent Human Papillomavirus Vaccine: Recommendations of the Advisory Committee on Immunization Practices,* 56 Morb. Mort. Weekly Report 1, 2–3 (2007) https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5602a1.htm.

[17] *Id.*; Eileen F. Dunne, *Recommendations on the Use of Quadrivalent Human Papillomavirus Vaccine in Males — Advisory Committee on Immunization Practices (ACIP), 2011,* 60 Mort. Morb. Weekly Rep. 1705, 1705–08 (2011), https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6050a3.htm.

effectiveness of routine vaccination for different populations—with all recommendations requiring multidisciplinary judgment of the evidence.

B. The CDC Director Has Historically Relied on ACIP Expertise and Accepted Recommendations.

The value of ACIP's expert process is reflected in the Director's reliance on its recommendations. Although the Director has final authority over CDC's vaccine recommendations, Directors historically accepted ACIP's expert-based recommendations almost without exception. Before the events at issue in this litigation, the Secretary had not displaced the process.

In ACIP's over fifty years of existence, there have been only two known cases where the Director rejected ACIP recommendations. The first related to the smallpox vaccine in 2002, which was being discussed in response to concerns about bioterrorism. ACIP recommended that the vaccine be administered only to volunteer response team members, around 500,000 people. Viewing the threat of bioterrorism as more grave, the Director adopted a program that covered "up to 10 million health care workers and emergency responders." *Id.*

The second case was from 2021, when ACIP voted 9 to 6 against recommending COVID-19 boosters for high-risk workers aged 18 to 64, and the Director included those boosters. *Id.* Explaining her decision, Director Dr. Rochelle Walensky emphasized the split vote in ACIP and the equivocal nature of those who voted against, saying that it "was not about no. It was more about 'not yet,'" and

emphasizing that FDA's advisory committee previously went the other way.[18] Thus, her decision to reject ACIP's recommendation acknowledged and indeed drew upon the expertise of its members and others in the scientific community. *Id.*

More often, the Director concurred whether ACIP recommended for or against broader use. As one of many examples, in October 2012, ACIP considered meningococcal vaccination for infants and recommended it only for infants at high risk, given the "low burden of disease . . . and low proportion[s] of meningococcal disease."[19] The Director adopted that decision after ACIP considered extensive data over multiple meetings. *Id.*

C. Congress, States, and Medical Organizations Have Built Legal and Practical Systems Around ACIP Recommendations.

The pattern of reliance does not end with the CDC. Congress, states, and medical organizations have built legal and practical systems around ACIP's recommendations. Indeed, broad-based, national reliance is the practical consequence of ACIP's expertise and transparent processes.

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[18] Helen Branswell & Gideon Gil, *CDC Director Defends Decision to Overrule Expert Panel on Covid Booster Shots for Health and Other Frontline Workers,* StatNews (Oct 7, 2021), https://www.statnews.com/2021/10/07/cdc-director-defends-decision-to-overrule-expert-panel-on-covid-booster-shots-for-health-workers/.

[19] Lorry Rubin et al., *Infant Meningococcal Vaccination: Advisory Committee on Immunization Practices (ACIP) Recommendations and Rationale,* 62 Morb. Mort. Weekly Rep. 52, 53 (2013), https://stacks.cdc.gov/view/cdc/29165.

Congress does not merely receive ACIP's advice but has attached federal purchasing and access requirements to its recommendations. In 1993, for example, Congress directed the Secretary to cover the "list established (and periodically reviewed and as appropriate revised) by the Advisory Committee on Immunization Practices" in the Vaccines for Children Program, § 13631(e), Omnibus Budget Reconciliation Act of 1993, 42 U.S.C. § 1396s(e), which provides vaccines for eligible children (over 50% of all children).[20] Similarly, Congress has relied on ACIP's recommendations in the context of health-insurance coverage and liability protections. The Affordable Care Act requires private insurers to cover ACIP-recommended vaccinations. *See* 42 U.S.C. § 300gg-13. Additionally, Medicaid defines "medical assistance" to include ACIP-recommended vaccines. *See* 42 U.S.C. § 1396d(a)(13)(B). And the Inflation Reduction Act of 2022 ties coverage under Medicare Part D, Medicaid, and the Children's Health Insurance Program to ACIP's recommendations.[21] Because federal purchasing and insurance coverage are tied to ACIP recommendations, the reliability of the expert process producing the

[20] Madeleine R. Valier, et al., Vital Signs: *Trends and Disparities in Childhood Vaccination Coverage by Vaccines for Children Program Eligibility – National Immunization Survey-Child, United States, 2012-2022*, 73 Morb. Mort. Weekly Rep. 722 (Aug. 22, 2024), https://pmc.ncbi.nlm.nih.gov/articles/PMC11349383/.

[21] *See Evelyne P. Baumrucker et al.*, *Cong. Rsch. Serv.*, CRS Rpt. 47396, *Health Care Provisions of the Budget Reconciliation Measure P.L. 117-169* (2023), https://www.congress.gov/crs-product/R47396.

recommendations has become indispensable from the operation of the framework that Congress created.[22]

States have likewise relied on ACIP's recommendations with respect to vaccines. According to the Association of State and Territorial Health Officials, "nearly 600 statutes and regulations across 49 states, three territories, and Washington, D.C.," reference ACIP.[23] Many states tie their rules governing who may administer vaccines to ACIP's recommendations.[24] For example, Maine permits pharmacists to administer vaccines to adults when those vaccines are "recommended by the United States Centers for Disease Control and Prevention Advisory Committee on Immunization Practices."[25] Many states also linked childhood-vaccine recommendations and mandates to ACIP's recommendations.[26]

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[22] The federal statutes discussed herein that incorporate ACIP recommendations are illustrative examples. DPH respectfully refers the Court to the Appellees' brief for additional examples. *See* Appellee Br. at 11–12.

[23] *Impact of the Advisory Committee on Immunization Practices Recommendations on State Law*, Association of State and Territorial Health Official (June 23, 2025), https://www.astho.org/topic/resource/impact-of-acip-recommendations-on-state-law/.

[24] Jennifer Kates et al., *Tracking State Actions on Vaccine Policy and Access*, KFF (Sept. 24, 2025), https://www.kff.org/state-health-policy-data/tracking-state-actions-on-vaccine-policy-and-access/.

[25] 32 M.R.S. § 13831(2) (2026).

[26] *Assessing the Impact of Changes to Federal Vaccine Recommendations on State Immunization Policies*, Johns Hopkins Bloomberg School of Pub. Health (Feb. 25, 2026), https://publichealth.jhu.edu/ivac/2026/assessing-the-impact-of-changes-to-federal-vaccine-recommendations-on-state-immunization-policies.

Thus, for decades, states have been able to coordinate around a common federal reference point. The recent response to ACIP's reconstitution, however, shows what follows when confidence in that reference point erodes. Since Secretary Kennedy dismissed all ACIP members in June 2025 and replaced them with a committee that the district court found included members lacking vaccine or immunization expertise required by the charter, (Dist. Court Order at 30), several states have delinked their policies from ACIP recommendations. As of May 2026, 29 states plus the District of Columbia are relying on sources other than ACIP or CDC for vaccine recommendations,[27] including interstate collaborations such as the Northeast Public Health Collaborative and the West Coast Health Alliance.[28] Medical organizations, including some represented in this litigation, have likewise turned to other sources, such as the Vaccine Integrity Project,[29] citing concerns about

[27] *Reliance on Sources Other Than CDC/ACIP for State Childhood Vaccine Recommendations*, KFF (May 4, 2026), https://www.kff.org/other-health/state-indicator/reliance-on-sources-other-than-cdc-acip-for-state-childhood-vaccine-recommendations/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D.

[28] *About Us*, West Coast Health Alliance, https://doh.wa.gov/about-us/west-coast-health-alliance (last visited July 15, 2026).

[29] Bryant Furlow, *US States and Medical Societies Chart New Paths Forward Amid Turmoil at CDC and ACIP*, Lancet Respir. Med. (Sep. 10, 2025), https://www.medschool.umaryland.edu/media/som/news/news-logos/Lancet-ACIP-turmoil-jdc.pdf.

the reconstituted committee's expertise, conflict procedures, transparency, and departure from GRADE, EtD, and other evidence-based frameworks.[30]

IV. CONCLUSION

For over five decades, ACIP has played a critical role in developing national vaccine recommendations that safeguard the public's health because of its multi-disciplinary expertise, conflict-of-interest safeguards, disciplined evidence review, and transparent deliberation. CDC Directors have accepted ACIP recommendations, and Congress, states, clinicians, and medical organizations have used and relied on the recommendations as a common national reference point. The Secretary's undermining of ACIP's expertise and processes has had immediate and profound consequences to the systems that have been built around the reliability of its recommendations, as states and medical organizations search for alternative sources of vaccine guidance, risking the health of all Americans, especially its children.

[30] *See* J. Loehr et al., *Science for Vaccine Policy: Lack of Transparency, Misinformation, and Poor Decision Processes at the December 2025 ACIP Meeting.* 76 Vaccine 12338 (2026) (conducting a thematic analysis of ACIP's December 2025 meeting and noting lack of transparency and misinformation from ACIP members, and lack of reliability compared to the Vaccine Integrity Project).

Dated: July 23, 2026

Respectfully submitted,

/s/ Lyndsey Stults

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 29(a)(5) because it contains 3,769 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f). This brief complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) because it has been prepared in 14-point Times New Roman, a proportionally spaced typeface with serifs.

/s/ Lyndsey Stults
Lyndsey Stults (Bar #1204580)

CERTIFICATE OF SERVICE

I certify that on July 23, 2026, I electronically filed the foregoing brief with the Clerk of the United States Court of Appeals for the First Circuit by using the appellate CM/ECF system. All participants in the case are registered CM/ECF users and will be served by the appellate CM/ECF system.

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