MAYER | BROWN

Mayer Brown LLP
1999 K Street, NW
Washington, D.C. 20006
United States of America

T: +1 202 263 3000
F: +1 202 263 3300

mayerbrown.com

Andrew J. Pincus
Partner
T: +1 202 263 3220
F: +1 202 263 5220
apincus@mayerbrown.com

Graham White
Counsel
T: +1 212 506 2563
F: +1 212 506 1910
gwhite@mayerbrown.com

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SUBMITTED VIA www.regulations.gov

Cynthia Goss
Deputy Assistant Secretary for Planning and Evaluation
Office of the Secretary
U.S. Department of Health and Human Services
200 Independence Ave SW
Washington, D.C. 20201

Re: Request for Information: Categories Used in Federal Vaccine Recommendations and the Role of Shared Clinical Decision-Making, Docket No. HHS-OS-2026-0332, RIN 0991-ZA62

Dear Deputy Assistant Secretary Goss:

This comment is respectfully submitted on behalf of the American Public Health Association, the Robert Wood Johnson Foundation, the Liberty Health Alliance, the Geiger Gibson Program in Community Health, the Jacobs Institute of Women's Health, and fourteen distinguished health law and policy scholars in response to the Department's Request for Information ("RFI") regarding categories used in federal vaccine recommendations and, in particular, the proper role of shared clinical decision-making in medicine, including with respect to decisions about vaccinations ("SCDM").[1]

These organizations, which are dedicated to protecting and promoting public health, and scholars who have spent decades studying health law, health policy, and the administrative structures that safeguard the public's health, submit these comments to make the simple but foundational point that the long history of America's evidence-based vaccine recommendation system has served Americans well for over 60 years and is at the heart of our Nation's remarkable success in controlling vaccine preventable diseases in the modern era. The Advisory Committee on Immunization Practices ("ACIP") spent decades developing the effective, science-based system for determining the appropriate recommendation categories for vaccines that was in effect in January 2025. That system relied on GRADE ("Grading of Recommendations, Assessment, Development and Evaluation")—an internationally adopted framework for assessing the certainty of evidence and the strength of recommendations in healthcare—and the Evidence-to-

[1] Request for Information: Categories Used in Federal Vaccine Recommendations and the Role of Shared Clinical Decision-Making, 91 Fed. Reg. 54724-01 (Aug. 24, 2026).

Recommendations ("EtR") framework process by which ACIP evaluated the range of factors that were the basis of its recommendations.

Changing that framework, and adopting new categories of recommendations that would serve as the basis of future vaccine recommendations, as the RFI suggests, would bypass both the transparency and the deliberative process of ACIP required by the Federal Advisory Committee Act. It also would violate substantive law, because Congress's express designation of ACIP as the body responsible for vaccine recommendations, in multiple statutes, restricts the Department's authority to alter ACIP's procedural and substantive standards.

Multiplying vaccine recommendation categories would in addition create immense practical problems that would inflict serious harm on America's public health. The arbitrary categories identified in the RFI without context, without accompanying evidence and without a clear communication strategy with medical professionals, the public health system, and the American public will inevitably produce widespread confusion and uncertainty. In the setting of such confusion, the principle of informed decision-making is at risk with the likely result that vaccine doses will be missed and diseases that are vaccine preventable will recur. Altering that system, along the lines of the possible changes identified in the RFI, would thus pose an unacceptable risk of reintroducing diseases that have essentially been eradicated and inflict injuries and death on tens of thousands, or more, Americans—especially infants and children.

INTEREST OF THE COMMENTERS

American Public Health Association ("APHA"). APHA is the oldest and most diverse organization of public health professionals in the world, championing the health of all people and all communities. APHA strengthens the public health profession through advocacy, research, and member engagement.

Robert Wood Johnson Foundation ("RWJF"). RWJF is a leading national philanthropy dedicated to taking bold leaps to transform health in our lifetime. Through funding, convening, advocacy, and evidence-building, RWJF works side-by-side with communities, practitioners, and institutions to get to health equity faster and pave the way to a future where health is no longer a privilege, but a right.

Liberty Health Alliance ("LHA"). Liberty Health Alliance focuses on the impact of public health policies on medically underserved and vulnerable populations and communities. LHA has a special interest in programs and policies that promote access to comprehensive primary health care across the full age spectrum.

The Geiger Gibson Program in Community Health ("GGPCH"). The Geiger Gibson Program in Community Health is the nation's leading academic research and policy center devoted to community health centers and the medically underserved populations and communities they serve.

Jacobs Institute of Women's Health ("JIWH"). The Jacobs Institute of Women's Health at the George Washington University Milken Institute School of Public Health identifies and studies aspects of health care and public health, including legal and policy issues, that affect women's health at different life stages; fosters awareness of and facilitates dialogue around issues that affect women's health; and promotes interdisciplinary research, coordination, and information dissemination.

Law and Policy Scholars. These scholars hold appointments at leading law schools and schools of public health and public policy across the United States. Their collective research and teaching span health law, administrative law, public health law, and health policy. They submit this comment in their individual capacities.[2]

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[2] The scholars are:

Bruce G. Gellin, MD, MPH, Professor of Medicine (Adjunct) at Georgetown University School of Medicine and Deputy Assistant Secretary of Health and Director of HHS' National Vaccine Program Office (2002-2007)

Lynn R. Goldman, MD, MPH, MS, Professor, Environmental and Occupational Health, Milken Institute School of Public Health, George Washington University

Nicole L. Huberfeld, JD, Edward R. Utley Professor of Health Law, Boston University School of Law and School of Public Health

Feygele Jacobs, DrPH, MS, MPH, Director, Geiger Gibson Program in Community Health and Professor, Department of Health Policy and Management, Milken Institute School of Public Health, The George Washington University

Timothy Stoltzfus Jost, JD, Professor Emeritus, Washington and Lee University

Paula Lantz, PhD, James B. Hudak Professor of Health Policy, Gerald R. Ford School of Public Policy, University of Michigan

Jeffrey Levi, PhD, Professor Emeritus, Health Policy and Management, Milken Institute School of Public Health, George Washington University

Anne Markus, PhD, JD, Professor & Chair, Health Policy and Management, Milken Institute School of Public Health, George Washington University

Frances Miller, JD, Professor of Law Emerita, Boston University School of Law

Christopher Robertson, JD, PhD, Neil Pike Scholar in Health and Disability Law, Boston University School of Law

Sara Rosenbaum, JD, Professor Emerita, Health Law and Policy, Milken Institute School of Public Health, George Washington University

William M. Sage, MD, JD, Professor of Law and Medicine, University Distinguished Professor, Texas A&M University - Fort Worth

Joshua M. Sharfstein, MD, Distinguished Professor of the Practice, Johns Hopkins Bloomberg School of Public Health

Laura Stephens, JD, Director and Lecturer, Health Law Program, Boston University School of Law

INTRODUCTION

The public health achievements resulting from the advent and development of a routine vaccination protocol in the United States—particularly well-illustrated by the dramatic benefits from childhood immunization—are among the most significant in the history of medicine. Among children born during the Vaccines for Children era (1994–2023), routine childhood vaccinations prevented an estimated 508 million illnesses, 32 million hospitalizations, and more than 1.1 million deaths, generating approximately $540 billion in direct cost savings and $2.7 trillion in societal savings.[3] For most vaccine-preventable diseases, incidence has declined by 95 percent or more since the introduction of routine vaccination.[4]

The current vaccination schedule actively maintains these benefits. In the 2023–2024 influenza season alone, pediatric flu vaccination prevented an estimated 4.5 million illnesses, 20,000 child hospitalizations, and 266 child deaths.[5] Ninety percent of children who die from influenza are unvaccinated. Declining vaccination contributed to 289 pediatric influenza deaths in the 2024–2025 season—the highest number since national tracking began.[6]

And the benefits of vaccination extend well beyond the individual recipient. Approximately 6.6 percent of the U.S. population—roughly one in fifteen Americans—is immunocompromised and cannot receive certain vaccines or mount a sufficient immune response to them.[7] These individuals, along with infants too young to be vaccinated and elderly persons with waning immunity, depend on high community vaccination rates to maintain population immunity. High vaccination rates accordingly benefit society as a whole, protecting the most vulnerable members of the community and providing an essential step toward the eradication of vaccine-preventable diseases.

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[3] Fangjun Zhou et al., *Health and Economic Benefits of Routine Childhood Immunizations in the Era of the Vaccines for Children Program—United States, 1994–2023*, 73 MMWR 682 (2024).

[4] U.S. Food & Drug Admin., *Vaccine Safety Questions and Answers*, https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/vaccine-safety-questions-and-answers.

[5] Centers for Disease Control and Prevention ("CDC"), *Estimated Flu Burden Prevented by Vaccination, 2023–2024 Flu Season*, https://archive.cdc.gov/#/details?url=https://www.cdc.gov/flu-burden/php/data-vis/2023-2024.html.

[6] Katie Reinhart et al., *Influenza-Associated Pediatric Deaths—United States, 2024–25 Season*, 74 MMWR 565 (2025).

[7] Melissa L. Martinson & Jessica Lapham, *Prevalence of Immunosuppression Among US Adults*, 331 J. Acad. Medicine 880 (2024), https://perma.cc/6N7Q-4XJD.

The safety of vaccines recommended for routine use rests on rigorous, multi-layered scientific review.[8] Before licensure, vaccines undergo preclinical testing, placebo-controlled randomized clinical trials, and a comprehensive Biologics License Application ("BLA") review by the Food and Drug Administration, which also conducts lot-by-lot testing. After licensure, vaccine safety is continuously tracked through a network of complementary monitoring programs, including the Vaccine Adverse Event Reporting System ("VAERS"), the Vaccine Safety Datalink ("VSD"), the Clinical Immunization Safety Assessment Project ("CISA"), V-safe, and the FDA's Biologics Effectiveness and Safety System ("BEST").[9] In addition, the National Vaccine Injury Compensation Program ("VICP") provides a no-fault mechanism for addressing the rare cases in which a vaccine causes serious injury.

Against this backdrop—a record of extraordinary public health achievement, supported by a robust safety infrastructure—there simply is no basis for the RFI's implicit suggestion that the current recommendation framework produces unsafe results and needs fundamental revision. The Department especially should not generalize the unique and contested experience of COVID-19 vaccination, which unfolded in the midst of an unprecedented national emergency of immense scope, into grounds for changing the template for vaccine policy more broadly and in particular for changing the recommendation structure for childhood vaccines.

Put simply, the current recommendation system, which rests on decades of accumulated scientific evidence and practical experience, has worked and continues to work extremely well to protect Americans against the terrible health effects of diseases that can be prevented, or substantially ameliorated, by vaccines. Indeed, childhood-vaccine confidence remains high, and the overwhelming majority of parents continue to support routine school immunization requirements.

Changing the current recommendation levels, or the science-based standards underlying them, will serve only to create confusion and undermine vaccination rates, producing an increase in deaths and serious injuries, particularly among children. The childhood vaccine safety record reveals absolutely no scientific basis for altering the classification system. The recent, and ongoing, outbreaks of measles around the nation demonstrate that reality.

What the government should do is undertake a broad and affirmative campaign to promote public understanding of and trust in vaccines. Such an effort would help counter the sea of misinformation that has made the task of patient education extremely difficult. A clear embrace of vaccines by the nation's highest public health officials would help doctors and other

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[8] *See* CDC, *How Vaccines Are Developed and Approved for Use* (Aug. 10, 2024), https://www.cdc.gov/vaccines/basics/how-developed-approved.html.

[9] World Health Organization, *Vaccines and Immunization: Vaccine Safety* (Sept. 23, 2025), https://www.who.int/news-room/questions-and-answers/item/vaccines-and-immunization-vaccine-safety.

professionals counsel their patients, and especially parents and caregivers, regarding the benefits of recommended vaccines as well as any scientifically confirmed risks—which is already required for vaccines recommended for routine administration. Communicating broadly and publicly would do much to combat the confusion and disinformation that is reducing vaccine uptake, reintroducing childhood diseases that had been essentially eliminated, and making America a sicker and more vulnerable nation.

I. THE CURRENT RECOMMENDATION FRAMEWORK IS SOUND AND USE OF THE SHARED CLINICAL DECISION-MAKING RECOMMENDATION SHOULD REMAIN LIMITED

A. A "Routine" Recommendation Is Appropriate When The Vaccine Is Safe And Effective For Persons In a Defined Group; Shared Clinical Decision-Making is Warranted Only In Situations Of Clinical Uncertainty

All vaccines—whether routine, targeted to people with certain health risks, or otherwise—require informed consent. To that end, the current ACIP framework provides important science-based information for the patient's decision while at the same time assuring recommendations that are sound, evidence-based, and well suited to the task of guiding vaccination across diverse populations.

A *routine* recommendation is the default that applies when the epidemiology of the vaccine-preventable disease indicates susceptibility of the entire population and the established performance of the vaccine shows that it is safe and effective. The routine recommendation advises vaccination for everyone in a defined age or population group for whom the vaccine is safe and effective, and it is the category under which the overwhelming majority of vaccinations are administered. A *risk-based* recommendation advises vaccination for a subset of the population that shares an identified risk factor—such as occupational exposure, an underlying medical condition, or travel to an area of elevated transmission—rather than for the entire age group. A conversation with a health provider about the benefits and risks of a vaccination in order to ensure informed consent is a standard part of the practice of medicine and should always be encouraged, including with respect to these recommendation categories.

In contrast, *shared clinical decision-making* is not a synonym for the informed consent conversation between a patient and a provider. Rather, it is reserved for the narrow set of vaccines for which the evidence does not support a general recommendation for any defined group, leaving the decision to be made on an individual basis between clinician and patient.

SCDM is not, and was never meant to be, the default vaccination recommendation. The concept of SCDM rests on scholarship regarding clinical uncertainty—in other words, the proper conversation between doctor and patient when the available scientific evidence does not clearly favor one course of action over another. For example, the 1982 report of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral

Research located the need for that collaborative process in situations of genuine uncertainty, emphasizing the importance of disclosing significant uncertainties in treatment information to patients.[10]

The same understanding runs through subsequent medical literature on decisionmaking. In 2001, the Institute of Medicine's landmark report *Crossing the Quality Chasm* reinforced this link between SCDM and clinical uncertainty, concluding that clinicians should determine the most appropriate therapies "on the basis of the strength of the scientific evidence . . . and, *especially where the evidence is equivocal*, shared patient and clinician decisionmaking."[11] The report illustrated the point with examples of genuine "uncertainty associated with different alternatives when applied to the patient's individual circumstances" – *e.g.,* patients with prostate disease choosing among surgery, other treatments, and watchful waiting; menopausal women weighing the risks and benefits of hormone replacement therapy – and emphasized that in such cases, "both are highly individual judgments for which patients need good information to make a decision."[12]

A consistent thread runs through these foundational authorities: **SCDM is meant for clinical situations in which the evidence permits more than one reasonable course of action—situations of genuine *equipoise*. As one group of health scholars observed, "[a] key criterion for the use of this approach is equipoise, meaning that there is no evidence-based best choice of action."[13]**

The paradigmatic examples are clinical decisions like prostate-specific antigen ("PSA") screening for men aged 50 to 69, where a small chance of reducing prostate cancer mortality must be weighed against the risk of false-positive results and overtreatment, or the initiation of statin therapy for adults with borderline cardiovascular risk, where modest prevention benefits must be balanced against the burden and potential side effects of daily medication.[14] In these settings, reasonable clinicians and informed patients may genuinely disagree about the best course, and SCDM provides a structured framework for navigating that uncertainty.

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[10] President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *Making Health Care Decisions: Report* (1982), https://repository.digital.georgetown.edu/handle/10822/559354.

[11] INSTITUTE OF MEDICINE, CROSSING THE QUALITY CHASM: A NEW HEALTH SYSTEM FOR THE 21ST CENTURY 48 (2001).

[12] *Id.* at 70.

[13] Thomas R. Frieden et al., *CDC's Failure to Recommend COVID-19 Vaccination—"Shared Clinical Decision-Making" Is Abdication of Responsibility*, 335 JAMA 113, 113 (2026).

[14] *Id.*

The corollary is equally important: SCDM "is not appropriate when there is clear evidence of a net benefit or harm."[15] A clear net benefit of immunization against measles, mumps, and rubella ("MMR"), for example, precludes application of a shared decision-making standard to MMR vaccination—just as the clear net harm of prescribing antibiotics for a common cold would.[16]

This understanding exposes a critical distinction that the RFI obscures: Informed consent is a baseline legal and ethical duty that attaches to *every* medical intervention—including every vaccination—regardless of its recommendation category.[17] SCDM is not the same as informed consent; rather, it is the process that applies when a clinician, as part of the informed consent process, must communicate information regarding a specific subset of proposed treatments—those treatments whose value to the patient is uncertain. As the AMA's Code of Medical Ethics provides, "informed consent occurs when communication between a patient and physician results in the patient's authorization or agreement to undergo a specific medical intervention."[18] It requires that providers "[p]resent relevant information accurately and sensitively" and "[a]ssess the patient's ability to understand relevant medical information and the implications of treatment alternatives."[19] No vaccine in the United States may lawfully be administered without informed consent, whether the vaccine is recommended routinely, on a risk basis, or through SCDM.[20]

SCDM requires more than informed consent. It is, as one commentator has described it, "informed consent on steroids, honed for the gray areas"—a structured, collaborative process that applies when the scientific evidence leaves a genuine choice among reasonable options.[21] Because the scientific evidence does not point one way or the other, a more detailed exploration of the relevant

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[15] James F. Childress & Marcia Day Childress, *What Does the Evolution from Informed Consent to Shared Decision Making Teach Us About Authority in Health Care?*, 22 AMA J. Ethics E423, E425 (2020); *see also* Dorinde E.M. van der Horst et al., *For Which Decisions Is Shared Decision Making Considered Appropriate? A Systematic Review*, 106 Patient Educ. & Couns. 3 (2023) (concluding that SCDM is appropriate where more than one clinically reasonable option exists).

[16] James L. Bernat & Michael P. McQuillen, *On Shared Decision-Making and Informed Consent*, 11 Neurology: Clinical Practice 93, 93 (2021).

[17] American Medical Association, *Informed Consent, AMA Code of Medical Ethics*, https://code-medical-ethics.ama-assn.org/ethics-opinions/informed-consent.

[18] *Id.*

[19] *Id.*

[20] *See* Jess Steier et al., *Informed Consent is Alive and Well—Despite What You've Been Told*, UnbiasedScience (Nov. 24, 2025).

[21] Eric Boodman, *Is "Shared Decision-Making" Being Hijacked by U.S. Health Officials to Sow Doubt About Vaccines?*, STAT (Jan. 20, 2026), https://www.statnews.com/2026/01/20/shared-decision-making-vaccine-guidance-twists-meaning-of-term/.

factors is required to reach a shared decision. But—to reiterate—that more detailed investigation is warranted only when the scientific evidence leaves a genuine choice.

Limiting SCDM to situations of genuine scientific uncertainty is essential, because the SCDM designation carries significant costs. When ACIP designates a vaccine as SCDM rather than routine, it removes the default recommendation to vaccinate.[22] That removal, in turn, eliminates the administrative framework that makes vaccination efficient and equitable: standing orders, electronic health record prompts, and pharmacy administration protocols—as well as the ability of a clinician to tell a patient that the U.S. government recommends the vaccine for everyone in the specified population.[23]

Under SCDM, by contrast, uncertainty becomes the baseline, and a provider may choose not even to mention the vaccine.[24] SCDM thus does not *enhance* informed consent—as the RFI's Questions 8 through 10 risk doing by treating SCDM as merely a form of patient-centered decision-making rather than a recommendation category that removes the default[25]—it *replaces* a clear, evidence-based recommendation with an explicit signal of uncertainty.

For these reasons, ACIP developed the vaccine-specific SCDM category incrementally and carefully. In 2010, ACIP formally adopted the Grading of Recommendations, Assessment, Development, and Evaluation ("GRADE") system and initially used a "Category A" designation for vaccines recommended for all persons in an age- or risk-based group and a "Category B" designation for those subject to individual clinical decision-making.[26]

In October 2015, ACIP first applied a permissive or individual decision-making framework to meningococcal serogroup B ("MenB") vaccination for healthy adolescents and young adults ages 16 to 23—a population for which the risk of meningococcal serogroup B disease was elevated in

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

[23] *See* Jake Scott, *The Quiet Dismantling: How 'Shared Decision-Making' Weakens Vaccine Policy*, CIDRAP Op-Ed (Jan. 6, 2026) (explaining that removing a routine recommendation strips away standing orders, pharmacy practices, payer rules, nursing home protocols, and outreach infrastructure), https://www.cidrap.umn.edu/childhood-vaccines/cidrap-op-ed-quiet-dismantling-how-shared-decision-making-weakens-vaccine-policy.

[24] CDC, *ACIP Shared Clinical-Decision-Making Recommendations*, *supra* note 22.

[25] *See* RFI, 91 Fed. Reg. at 54728.

[26] Faruque Ahmed et al., *Methods for Developing Evidence-Based Recommendations by the Advisory Committee on Immunization Practices*, 29 Vaccine 9171 (2011).

certain settings (such as universities) but for which the vaccine's population-level impact was uncertain enough to warrant individual clinical judgment rather than a universal default.[27]

In February 2018, ACIP adopted the EtR framework, which was designed to make transparent the multidimensional considerations bridging evidence and policy—including the public health importance of the problem; the magnitude and certainty of benefits and harms as assessed through GRADE; the values and preferences of the affected population; acceptability to stakeholders; feasibility; and resource use—and to yield one of three outcomes: recommend for all, rely on shared clinical decision-making, or make no recommendation.[28] The EtR framework provides a systematic way to translate scientific evidence into policy decisions, and it ensures transparency and consistency in how vaccine recommendations are developed.[29]

In June 2019, ACIP formally adopted the SCDM terminology and first applied it to human papillomavirus ("HPV") vaccination for adults ages 27 to 45 and pneumococcal vaccine 13-valent ("PCV13") for immunocompetent adults age 65 and older—following approximately three years of workgroup deliberation and a full GRADE Evidence-to-Decision analysis that resulted in a closely contested 10-4 vote.[30]

This history demonstrates that SCDM as a vaccine recommendation category was the product of careful, evidence-driven deliberation. Each prior application rested on a documented finding—arrived at through the GRADE and EtR frameworks—that the evidence for a particular vaccine-population combination did not support the default of a universal, "routine" recommendation for the identified category of individuals.

Yet in September 2025, ACIP voted to move six vaccines—rotavirus, COVID-19, influenza, hepatitis A, hepatitis B, and meningococcal—from routine to SCDM despite no change in the

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[27] ACIP, *Use of Serogroup B Meningococcal Vaccines in Adolescents and Young Adults: Recommendations of the Advisory Committee on Immunization Practices*, 64 MMWR 1171 (2015); *see also* Richard Hughes IV et al., *Vague Vaccine Recommendations May Be Leading to Lack of Provider Clarity, Confusion Over Coverage*, Health Affairs Forefront (May 7, 2019), https://www.healthaffairs.org/content/forefront/vague-vaccine-recommendations-may-leading-lack-provider-clarity-confusion-over-coverage.

[28] Grace Lee et al., *Updated Framework for Development of Evidence-Based Recommendations by the Advisory Committee on Immunization Practices*, 67 MMWR 1271 (2018); RFI, 91 Fed. Reg. at 54725 (describing the EtR framework and its three possible outcomes).

[29] Jose F. Meneses-Echavez et al., *Evidence-to-Decision Frameworks: Enhancing the Quality and Rigour of Guidelines and Recommendations*, 3 Clinical & Pub. Health Guidelines e70078 (2026), https://onlinelibrary.wiley.com/doi/epdf/10.1002/gin2.70078.

[30] Elissa Meites et al., *Human Papillomavirus Vaccination for Adults: Updated Recommendations of the Advisory Committee on Immunization Practices*, 68 MMWR 698 (2019).

underlying scientific evidence.[31] An independent review found that ACIP's policymaking-maturity score fell from 100 percent in April 2025 to 58 percent in September 2025 and identified transparency violations and failures to systematically apply the GRADE and EtR frameworks—standards that are not merely internal ACIP practices, but the very standards Congress incorporated when it designated ACIP as the body responsible for vaccine recommendations.[32] As we explain in Part II, that distinction matters: because those standards define the substance of the authority Congress delegated, a vote that abandons them is not simply unwise policy but a violation of the delegated authority itself. The RFI recounts this history selectively and now proposes to address precisely the multidimensional considerations that ACIP's combined GRADE/EtR process was designed to weigh—but to do so by ignoring the standards and evidentiary rigor that those frameworks require, scientific frameworks that Congress endorsed when it designated ACIP in multiple statutes as the body responsible for vaccine recommendations.

B. There Is No Evidentiary Basis For Reclassifying Routine Vaccines, And Broader Use Of SCDM Or New Categories Would Depress Uptake And Sow Confusion

The RFI rests on the unstated, unmistakable—and wholly false—premise that childhood vaccines currently recommended for routine use may no longer be safe, and that the recommendation framework must therefore be revised to convey greater caution. That premise permeates both the Executive Order the RFI implements and the RFI's own framing of "continuous evaluation of the risk-benefit profile of recommended vaccines."[33] It is unsupported by any evidence the Department has offered.

No new clinical or epidemiological evidence calls into question the safety of any routinely recommended childhood vaccine. Recommendations are made only for vaccines that have already undergone FDA licensure following preclinical testing and placebo-controlled randomized clinical trials, and ACIP recommends a vaccine only after separately weighing how safe and effective it is at specific ages, how serious the vaccine-preventable disease is, and how many people would

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[31] Jennifer Kates & Josh Michaud, *The New Federal Vaccine Schedule for Children: What Changed and What Are the Implications?*, KFF (Jan. 9, 2026), https://www.kff.org/other-health/the-new-federal-vaccine-schedule-what-changed/.

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

[33] *See* Exec. Order No. 14,420, Delivering Gold Standard Childhood Vaccine Recommendations for Americans, 91 Fed. Reg. 53,173 (Aug. 14, 2026); RFI, 91 Fed. Reg. at 54,725 (describing the Executive Order's direction to evaluate "the continuous evaluation of the risk-benefit profile of recommended vaccines").

contract the disease absent vaccination.[34] Once a vaccine is in use, national authorities continuously monitor its safety through complementary surveillance systems and independent expert review of any adverse-event signal.[35] The empirical record produced by this process is one of extraordinary and sustained benefit: among children born during the Vaccines for Children era, routine childhood vaccination is estimated to have prevented approximately 508 million lifetime illnesses, 32 million hospitalizations, and more than 1.1 million deaths.[36]

A framework revision premised on doubts about the safety of routine vaccines—doubts the Department has not substantiated and that the scientific record refutes—would be unjustifiable and irrational. To the extent the RFI's suggested new categories are designed to signal caution about vaccines for which no safety concern has been demonstrated, they would communicate a message that is affirmatively false and would themselves undermine the public trust the RFI purports to protect.

A vaccine should never be recommended as routine where the evidence suggests limited value. But the corollary is equally important: a vaccine should not be downgraded from routine to SCDM—or to any new, lesser category—where the evidence continues to demonstrate substantial, population-wide benefit. There is at present no evidence that any currently routine childhood vaccine should be reclassified. To do so in the absence of such evidence would be arbitrary and capricious and would inflict a devastating injury on pediatric practice.

The empirical record confirms that SCDM depresses vaccine uptake. The MenB vaccine, the paradigmatic SCDM vaccine on the adolescent schedule, achieved coverage of only 29.4 percent, compared with 60.8 percent for meningococcal conjugate vaccine ("MenACWY"), which carries a routine recommendation.[37] A separate analysis found that only 12 percent of eligible adolescents received MenB under SCDM, compared with 61 percent for routine MenACWY.[38] The PCV13

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[34] CDC, *How Vaccines Are Developed and Approved for Use* (Aug. 10, 2024), https://www.cdc.gov/vaccines/basics/how-developed-approved.html.

[35] World Health Organization, *Vaccines and Immunization: Vaccine Safety* (Sept. 23, 2025), https://www.who.int/news-room/questions-and-answers/item/vaccines-and-immunization-vaccine-safety.

[36] Zhou et al., *supra* note 3.

[37] CDC, *Vaccination Coverage Among Adolescents Aged 13-17 Years—National Immunization Survey—Teen, United States, 2022* (Aug. 25, 2023), https://www.cdc.gov/mmwr/volumes/72/wr/mm7234a3.htm.

[38] ROBERT POPOVIAN, ENHANCING ADULT VACCINE UPTAKE—CHALLENGES IN SHARED CLINICAL DECISION MAKING AND RISK BASED RECOMMENDATIONS, GLOBAL HEALTHY LIVING FOUNDATION (Mar. 2025), https://ghlf.org/wp-content/uploads/2025/03/Enhancing-Adult-Vaccine-Uptake-GHLF.pdf.

pneumococcal vaccine saw uptake decline from over 70 percent to under 60 percent after it was moved to SCDM, including among vulnerable and immunocompromised individuals.[39]

The RFI essentially recognizes these deficiencies. It acknowledges that approximately 90 to 95 percent of physicians report that implementing SCDM recommendations requires more time than implementing routine recommendations.[40] Fewer than half of physicians are aware that SCDM vaccines remain covered by insurance without cost-sharing.[41] Electronic health records ("EHR") and immunization forecasting tools display SCDM vaccines inaccurately or incompletely.[42] And most providers agree that the SCDM designation confuses patients.[43] Survey data further confirm that patients are equally confused: an Annenberg Public Policy Center survey found that more than two in five Americans (42 percent) incorrectly believe that "shared decision-making" means it is up to the individual whether to consult a health care provider at all, and only about two-thirds (68 percent) understand that SCDM means reviewing one's medical history with a provider before deciding.[44]

But the RFI completely misunderstands the lesson to be taken from this data. It is not that SCDM can somehow be "fixed" but rather that recommendations other than "routine" necessarily create uncertainty, impose significant burdens on providers, and create confusion for patients—because they by definition provide less clear guidance to providers and patients. That is a reason to apply SCDM only when the science requires it, not a reason to expand the use of SCDM to situations in which the science is not equivocal.

The multiple new categories floated in the RFI—"recommended, but not during infancy," "recommended with qualification," and "SCDM with qualification"—would compound rather than resolve these harms. The appropriate response to SCDM's demonstrated limitations is not to expand its use or to invent additional categories of ambiguity, but rather to use SCDM sparingly

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[39] *Id.*

[40] RFI, 91 Fed. Reg. at 54725; *see also* Allison Kempe et al., *Shared Clinical Decision-Making Recommendations for Adult Immunization: What Do Physicians Think?*, 36 J. Gen. Intern. Med. 2283 (2021) (reporting that 90–95% of physicians found SCDM more time-consuming than routine recommendations, only 41–43% knew that SCDM vaccines were insurance-covered, and forecasting software displayed SCDM recommendations inconsistently).

[41] Kempe et al., *supra* note 40, at 2287.

[42] *Id.* at 2288.

[43] *Id.* at 2287.

[44] Annenberg Public Policy Center, *CDC Urges "Shared Decision-Making" on Some Childhood Vaccines; Many Unclear About What That Means*, University of Pennsylvania (Jan. 5, 2026), https://www.annenbergpublicpolicycenter.org/cdc-urges-shared-decision-making-on-some-childhood-vaccines-many-unclear-about-what-that-means/.

where genuine equipoise exists—as ACIP has historically done—and to preserve the routine recommendation for all vaccines where the evidence warrants it.

Finally, a fundamental distinction, sometimes obscured in public discourse and not recognized in the RFI, is the separation of a federal vaccine recommendation from a vaccine mandate. All three current ACIP recommendation categories—routine, risk-based, and SCDM—rest on a foundation of voluntary, informed consent. No federal recommendation compels any individual to receive a vaccine—indeed, the RFI itself concedes both the recommendation/mandate distinction and the historical role of state law in compulsory vaccination.[45]

That distinction is important. As scholars have explained, "[a] recommendation from CDC is not a vaccine mandate, nor does it keep patients from asking questions about vaccines or declining vaccination; all vaccines are given only after informed consent. A recommendation is a statement, based on evidence, that for individuals in the designated group, vaccination's benefits exceed the risks and will reduce the risk of serious illness."[46]

C. Changing Vaccine Recommendation Standards Would Impose The Greatest Burden On Rural And Other Medically Underserved Communities

The RFI ignores the practical burdens that would result from the potential changes in vaccine recommendations that it identifies. They would expand burdens on providers, patients, and parents—multiplying the number of appointments required to obtain vaccine protection against dangerous diseases, and creating uncertainty for both providers and patients about when and whether to administer vaccines. And despite the fact that the Administration has made strengthening rural health care a departmental priority, the heaviest burdens would fall on rural and medically underserved communities where providers are scarce and appointments hard to obtain[47]—and on working parents who would be required to take much more time away from their jobs in order to protect their children against life-threatening diseases.

SCDM imposes substantial burdens on clinical encounters. Unlike a routine recommendation—which can be efficiently implemented through standing orders, vaccine administration protocols, and brief provider affirmation—an SCDM discussion requires the provider to review the individual patient's medical history, explain the evidence for and against vaccination, elicit and discuss the patient's values and concerns, and arrive at a shared decision. Sixty-seven percent of

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[45] RFI, 91 Fed. Reg. at 54726-27 (acknowledging the distinction between federal recommendations and state mandates and describing the historical role of state law in compulsory vaccination).

[46] Frieden et al., *supra* note 13, at 114.

[47] Celli Horsten & Arnav Shah, *The State of Rural Primary Care in the United States*, The Commonwealth Fund (Nov. 7, 2025), https://www.commonwealthfund.org/publications/issue-briefs/2025/nov/state-rural-primary-care-united-states.

providers experiencing SCDM cited lack of time as a primary barrier to implementation.[48] Nearly 20 percent of Texas health providers identified the time commitment as an anticipated barrier to SCDM for HPV vaccination specifically.[49] Providers also report uncompensated counseling time, liability concerns stemming from the absence of a clear default recommendation, and difficulty accessing complete patient medical records—all of which discourage the very conversations SCDM is designed to promote.

The RFI gives no consideration to the consequences of that reality for the nation's most vulnerable children and families. The added time required to convey needlessly complex information will fall hardest in medically underserved communities, where families already face limited access, lower health literacy, and competing priorities.[50] Community health centers are the front-line safety net for these families and, as the federal government's own data show, already face overwhelming demand and declining insurance coverage among their patients as a result of changes championed by the administration.[51] Thus, government data analyzed by the Geiger Gibson Program show that health centers served 9,365,906 children in 2025—456,739 under age one, 1,867,199 ages one to four, and 7,041,968 ages five to seventeen—meaning that roughly one in eight U.S. children depends on a health center for primary care.[52] These are among the poorest children living in shortage areas; imposing an evidence-free, more complicated classification system on their clinicians would require scarce time that simply may not be available, without improving care.

For vaccines with narrow dosing windows, such as rotavirus (which must be initiated by 15 weeks of age and completed by 8 months), fragmenting administration across multiple visits would harm

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[48] Popovian, *supra* note 38 (reporting that 67% of providers experiencing SCDM cited lack of time as a barrier); *see also* Frieden et al., *supra* note 13, at 114.

[49] *See* Manali Desai et al., *Healthcare Professionals' Awareness of and Barriers to Shared-Clinical-Decision-Making for HPV Vaccination Among Adults 27-45 Years*, 21 Hum. Vaccin. Immunother. 2560061 (2025).

[50] *See* Centers for Medicare & Medicaid Services, *CMS Roundup, Guidance on Coverage of Immunizations* (Feb. 2024) (documenting disparities in vaccination rates by race, ethnicity, gender, geography, and socioeconomic status and noting that Medicaid/CHIP vaccination rates declined for all vaccines except influenza during the COVID-19 period), https://www.cms.gov/newsroom/cms-roundup/cms-roundup-feb-23-2024.

[51] Leighton Ku et al., *Public Insurance Funding Helped Sustain Community Health Centers in 2025, But Health Centers Are at High Risk in 2026 and 2027*, Geiger Gibson Program (Aug. 2026), https://geigergibson.publichealth.gwu.edu/76-public-insurance-funding-helped-sustain-community-health-centers-2025-health-centers-are-high.

[52] Geiger Gibson Program, *Analysis of Government Data on Children Served by Health Centers* (2025) (on file with commenters).

the families least able to return for follow-up.[53] SCDM assumes reliable access to a clinician with time for in-depth discussion and continuity of care to revisit decisions. Yet more than 100 million Americans lack a consistent primary care provider, and clinic workflow, staff turnover, and heavy workloads already impede the extended discussions SCDM requires.[54] Layering SCDM complexity onto the settings where it is unjustified by the underlying scientific evidence worsens access without any justification.

Health equity demands that the Department consider who bears the cost of reduced uptake: communities of color, immigrant communities, rural populations, and families living in poverty are the same populations that already bear a disproportionate burden of vaccine-preventable disease.[55] American Indian and Alaska Native children have hepatitis B infection rates approximately twice as high as non-Hispanic white children, and Asian and Pacific Islander children account for nearly half of all hepatitis B infections in the United States.[56] Vaccination disparities by race, ethnicity, and socioeconomic status are already well documented; SCDM's additional burdens would predictably widen those disparities by making vaccination harder to access in precisely the communities that need it most.[57]

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[53] CDC, *Rotavirus Vaccination* (July 19, 2024) (describing the dosing window: first dose by 15 weeks of age, series completed by 8 months), https://www.cdc.gov/rotavirus/vaccines/index.html; *see also* World Health Organization, *Rotavirus vaccines: WHO position paper—July 2021*, 96 Wkly. Epidemiological Rec. 301 (2021) (recommending that "rotavirus vaccines should be included in all national immunization programmes").

[54] Elisabeth Rosenthal, *The Shrinking Number of Primary Care Physicians Is Reaching a Tipping Point*, KFF Health News (Sept. 8, 2023) (reporting that more than 100 million Americans lack a consistent primary care provider), https://kffhealthnews.org/health-industry/lack-of-primary-care-tipping-point/.

[55] *See* Ranee Seither et al., *Coverage with Selected Vaccines and Exemption Rates Among Children in Kindergarten—United States, 2023–24 School Year*, 73 MMWR 925 (2024) (documenting vaccination coverage disparities).

[56] CDC, Epidemiology and Prevention of Vaccine-Preventable Diseases (Pink Book), Chapter 10: Hepatitis B (May 9, 2024) (reporting elevated hepatitis B infection rates among American Indian/Alaska Native and Asian/Pacific Islander populations), https://www.cdc.gov/pinkbook/hcp/table-of-contents/chapter-10-hepatitis-b.html; *see also* Thi T. Hang Pham et al., *Gaps in Prenatal Hepatitis B Screening and Management of HBsAg-Positive Pregnant Persons in the U.S., 2015–2020*, 65 Am. J. Prev. Med. 52 (2023).

[57] *See* CMS, *supra* note 50 (documenting that adult vaccine uptake among certain racial and ethnic groups is generally lower compared with non-Hispanic white populations, even after adjusting for socioeconomic factors); *see also* MACPAC, VACCINE ACCESS FOR ADULTS ENROLLED IN MEDICAID 32-33 (2022) (documenting vaccination rate disparities by race and ethnicity among Medicaid beneficiaries), https://www.macpac.gov/wp-content/uploads/2022/03/Chapter-2-Vaccine-Access-for-Adults-Enrolled-in-Medicaid.pdf.

D. The Unique COVID-19 Experience Provides No Basis For Revising Long-Successful Vaccine Policy

It would be a profound error to generalize the unique experience of the COVID-19 pandemic—and the revolutionary if occasionally uneven rollout of novel mRNA vaccines developed at unprecedented speed—into a rationale for destabilizing clinical practice for vaccines that have decades of demonstrated safety and enormous, well-documented population-level benefit. COVID-19 was a once-in-a-century global health emergency that demanded extraordinary measures and that inevitably tested public trust in ways that a normal vaccine recommendation process does not. The appropriate lessons from that experience are narrow and context-specific; they should not be extrapolated to the childhood immunization schedule.

The evidence, moreover, does not support the premise that childhood-vaccine confidence has collapsed. To the contrary, recent research shows that public confidence in childhood vaccines remains high. A Washington Post–KFF survey found that more than 80 percent of parents support routine childhood vaccination requirements for school attendance, including for measles and polio.[58] A Pew Research Center study found that a majority of the public (63 percent) expressed high confidence that childhood vaccines are effective at preventing illness.[59] And a peer-reviewed survey found no evidence that the public widely believes childhood vaccines are overused.[60]

Of the vaccines that have been moved to SCDM or are under discussion in the RFI, only the COVID-19 vaccine is genuinely new. Influenza vaccination for children has been routine since 2006; hepatitis B vaccination has been part of the childhood schedule since 1991. These vaccines have accumulated decades of safety and efficacy data. The controversy surrounding COVID-19 vaccine authorization and distribution—however legitimate the questions it raised—cannot be extrapolated to these long-established vaccines without doing violence to the evidence.

Even with respect to COVID-19 itself, applying SCDM to high-benefit groups was the wrong call. As scholars have explained, CDC's failure to provide an unambiguous, strong recommendation for COVID-19 vaccination of high-risk individuals was an "abdication of responsibility" that "misinforms and does not support informed decision-making."[61] SCDM may be appropriate where

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[58] Washington Post–KFF Survey (2025), https://files.kff.org/attachment/topline-kff-washington-post-survey-of-parents.pdf.

[59] Eileen Yam et al., *Public Confidence in Childhood Vaccines*, Pew Research Center (Nov. 18, 2025), https://www.pewresearch.org/science/2025/11/18/how-do-americans-view-childhood-vaccines-vaccine-research-and-policy/.

[60] Amanda Eiden et al., *Public Attitudes Toward Vaccination,* 53 Vaccine 127053 (2025) (finding no evidence of widespread public belief that vaccines are overused).

[61] Frieden et al., *supra* note 13, at 113–14.

genuine equipoise exists, but applying it to populations at high risk of severe illness or death from a vaccine-preventable disease is not shared decision-making—it is indecision presented as policy.

II. THE DEPARTMENT LACKS AUTHORITY TO RECLASSIFY VACCINES OUTSIDE THE ACIP PROCESS OR TO JETTISON ACIP'S SCIENTIFIC STANDARDS, AND ANY SUCH ACTION WOULD BE UNLAWFUL

A. Statutory Authority Over Vaccine Classification Rests with ACIP, Not the Secretary or the Task Force—and That Authority Is Bound By the Evidence-Based Standards That Congress Incorporated

To the extent the RFI is intended to lay the groundwork for the Secretary or the Task Force on Safer Childhood Vaccines—rather than ACIP, through its established evidence-based process—to revise recommendation categories or reclassify individual vaccines, that course of action would exceed the Department's statutory authority. Recommendations advanced by a body other than ACIP would have no legal effect under the framework Congress has established.

The Task Force's enabling statute demonstrates the Task Force's limited responsibilities. 42 U.S.C. § 300aa-27 charges the Task Force with a single mission: to "promote the development of childhood vaccines that result in fewer and less serious adverse reactions" and to improve licensing, manufacturing, testing, surveillance and research "in order to reduce the risk of adverse reactions to vaccines."[62] The Task Force's role is therefore to recommend to the Secretary how to implement those safety-focused requirements in connection with vaccine development—not to classify vaccines approved for use, assign recommendation categories, or determine which populations should receive which vaccines. That authority rests with ACIP.

That is confirmed by the fact that, across a broad range of federal statutes, Congress has repeatedly and specifically designated ACIP as the originating authority for vaccine recommendations. The Affordable Care Act requires coverage for immunizations with "a recommendation from [ACIP]."[63] Medicare Part D prohibits cost-sharing on vaccines "recommended by [ACIP]."[64] Medicaid covers vaccines "recommended by [ACIP]."[65] Veterans' benefits are tied to ACIP's recommended immunization schedule.[66] The Vaccines for Children Program provides, in

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[62] *See* 42 U.S.C. § 300aa-27(a).

[63] 42 U.S.C. § 300gg-13(a)(2) (Affordable Care Act: coverage for "immunizations that have in effect a recommendation from [ACIP]").

[64] 42 U.S.C. §§ 1395w-102(b)(8), (c)(8) (Medicare Part D: zero-cost-sharing for "adult vaccine[s] recommended by [ACIP]").

[65] 42 U.S.C. §§ 1396a(a)(10)(A), 1396d(a)(13)(B) (Medicaid: coverage for vaccines "approved" and "recommended by [ACIP]").

[66] 38 U.S.C. § 1701(9)(G), (10) (veterans' benefits: immunizations on "the recommended adult immunization schedule" established by ACIP).

mandatory terms, that the Secretary "shall use . . . the list established . . . by [ACIP]."[67] Immigration law conditions admission on receipt of ACIP-recommended vaccines.[68] And the 21st Century Cures Act further incorporates ACIP recommendations into the regulatory framework.[69]

Federal law thus establishes a two-step process for vaccine recommendations. First, ACIP—the statutorily designated expert advisory committee—develops and votes on a recommendation through the GRADE and EtR frameworks described above. Second, the Director of the Centers for Disease Control and Prevention, acting by delegation from the Secretary, decides whether to adopt the recommendation. A recommendation is "in effect" for purposes of federal law only after both steps have been completed.[70] The Director's role is to adopt or to decline to adopt an ACIP recommendation; it is not to originate a recommendation independently. Neither the Secretary nor any substitute committee—including the Task Force on Safer Childhood Vaccines—may originate vaccine recommendations outside the ACIP process.

Read as a coherent scheme as the law requires,[71] these provisions foreclose any interpretation that would allow the CDC Director or the Secretary to originate or modify vaccine recommendations outside the ACIP process. Congress made a deliberate structural choice: ACIP recommends; the CDC Director adopts; and the recommendation, once in effect, triggers a cascade of coverage, eligibility, and regulatory consequences across federal law. The Department may not circumvent that structure.

This structural choice also defines the outer limit of HHS's authority. In designating ACIP as the originating body for vaccine recommendations, Congress withheld from the Secretary, the CDC Director, and any substitute committee the power to redesign the recommendation framework itself; and its repeated designation of ACIP reflects a deliberate legislative choice that forecloses recommendations originating outside that process.[72] Indeed, in defending the parallel ACA

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[67] 42 U.S.C. § 1396s(e) (VFC: the Secretary "shall use . . . the list established . . . by [ACIP]").

[68] 8 U.S.C. § 1182(a)(1)(A)(ii) (immigration: immunization requirements linked to ACIP-recommended vaccines).

[69] 21 U.S.C. § 360bbb-4 note (21st Century Cures Act: incorporating ACIP recommendations into the regulatory framework).

[70] 45 C.F.R. § 147.130(a)(1)(ii) ("[A] recommendation from [ACIP] . . . is considered in effect after it has been adopted by the Director of the [CDC].").

[71] *See Mellouli v. Lynch*, 575 U.S. 798 (2015) (requiring that related statutes be read as a coherent regulatory scheme); *FDA v. Brown & Williamson Tobacco Corp*., 529 U.S. 120, 133 (2000) ("[T]he meaning of one statute may be affected by other Acts, particularly where Congress has spoken subsequently and more specifically to the topic at hand.").

[72] *See* Br. for Cross-Resp. in Opp. 4–5, 13–14, *Braidwood Mgmt., Inc. v. Becerra*, No. 24-475; 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 (2014).

provision against a nondelegation challenge, the government itself argued that Congress's incorporation of ACIP's "past administrative practice" supplied the intelligible principle that saved the statute, because the text does not specify substantive standards for the recommendations.[73] Congress's endorsement of ACIP's long-established procedural and substantive standards thus bars the Department from adopting a new substantive framework that deviates from the one Congress incorporated.[74] This limitation applies to ACIP as well as to the Secretary. Because Congress incorporated ACIP's substantive standards, those standards constrain any exercise of the recommendation power—including by ACIP itself. A recommendation issued without applying them is not a lawful product of the process Congress established.

In sum, ACIP is not an ordinary advisory committee whose expertise may be discarded at the Executive's pleasure or whose process may be dramatically restructured at will; it is a unique expert body whose work Congress made the linchpin of federal immunization law.[75] And so to recategorize vaccines or invent new recommendation categories outside that process would exceed, rather than exercise, the authority Congress delegated.

The Supreme Court's recent decision in *Kennedy v. Braidwood Management, Inc.* reinforces this structural analysis.[76] *Braidwood* involved the U.S. Preventive Services Task Force ("USPSTF"), an advisory body that operates as a separate, parallel element of the ACA's preventive-services mandate. Just as Section 300gg-13(a)(2) requires health plans to cover immunizations with an ACIP recommendation "in effect," Section 300gg-13(a)(1) requires plans to cover preventive services that have an "A" or "B" rating from USPSTF.[77] The two provisions operate identically:

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[73] *See Braidwood,* Br. for Cross-Resp. in Opp. 13–16.

[74] ACIP has followed a rigorous and data-driven recommendation process since its creation in 1964, which it has developed and refined over decades. *See* Smith et al., *supra* note 72, at 955. It formalized that methodology by adopting the GRADE framework in 2010 and the EtR framework – a refinement built upon GRADE – in 2018. *See* Ahmed et al., *supra* note 26, at 9171.

[75] Lee et al., *supra* note 28, at 1271. Congress legislated against the backdrop of this established, evidence-based process: when it conditioned federal insurance-coverage and regulatory obligations on an ACIP recommendation, it "point[ed] to a recommendation process that already existed prior to the passage of the ACA," as the government itself argued in defending the parallel ACA provision against a nondelegation challenge. Def.'s Response to Pls.' Mot. for Summary Judgment at 51, ECF No. 64, *Kelley v. Becerra*, 4:20-cv-00283-O (N.D. Tex. Jan. 28, 2022). Later enactments, including the 21st Century Cures Act of 2016, postdate ACIP's formal adoption of GRADE and thus incorporate that methodology directly. *See supra* note 69. Consistent with this design, ACIP may refine its analytic tools while maintaining fidelity to its core evidentiary principles but may not dramatically depart from them.

[76] *Kennedy v. Braidwood Mgmt., Inc*., 606 U.S. 748 (2025).

[77] 42 U.S.C. § 300gg-13(a)(1).

An expert advisory committee issues a recommendation, a principal officer reviews and adopts (or declines to adopt) it, and only then does the recommendation trigger a coverage mandate. Indeed, the Court cited ACIP as an example of how such advisory-committee processes operate, confirming the structural parallel between USPSTF and ACIP.[78]

Braidwood addressed an Appointments Clause challenge—the plaintiffs argued that USPSTF members are "principal Officers" who must be appointed by the President and confirmed by the Senate, as opposed to "inferior Officers" who may be appointed by department heads.[79] The distinction turns largely on whether the officer is "directed and supervised" by a principal officer. *See Edmond v. United States*, 520 U.S. 651, 663 (1997). The *Braidwood* plaintiffs contended that USPSTF recommendations triggered coverage mandates affecting private parties, and USPSTF members therefore exercised significant executive authority without adequate supervision, making them principal officers.

The Court rejected that challenge, holding that USPSTF members are inferior officers because the HHS Secretary (a principal officer) retains sufficient supervisory authority over their work.[80] Most relevant here, the Court rejected the argument that to comply with the Appointments Clause it was necessary to construe the ACA to provide that the HHS Secretary could circumvent USPSTF and initiate a preventive services recommendation himself.[81] Given Congress's parallel treatment of the USPSTF and ACIP, that reasoning forecloses interpreting the statutes and regulations relating to ACIP to allow the Secretary, the CDC, or the Task Force to circumvent ACIP by originating recommendations outside the advisory-committee process.

Nor does the Court's recognition of the Secretary's supervisory authority open a different door to the same end. Supervisory authority over who serves on an advisory committee, which of course Congress recognized would be subject to the constraints imposed by the Federal Advisory Committee Act, is not authority to dictate the committee's substantive conclusions, much less to direct recommendations untethered from the standards Congress incorporated. The power to appoint, remove, or supervise ACIP's members is not a power to make standards-free reclassification lawful, because the governing substantive and procedural standards are fixed by statute. So however ACIP is constituted, a recommendation that abandons those standards is unlawful because it violates the authority Congress delegated.

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[78] *Braidwood*, 606 U.S. at 767 n.4 (citing 45 C.F.R. § 147.130(a)(1)(ii)).

[79] U.S. Const. art. II, § 2, cl. 2.

[80] *Braidwood*, 606 U.S. at 773-76.

[81] *Id.* at 777.

B. Any Recategorization Of Vaccine Recommendations or Recommendation Categories Would Be Arbitrary and Capricious and Would Disregard Substantial Reliance Interests

Should the Department proceed from this RFI to actual recategorization of any vaccine, any such action would be subject to review under the Administrative Procedure Act's prohibition on arbitrary and capricious agency action. Under *Motor Vehicle Manufacturers Ass'n v. State Farm*, an agency must "examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made."[82] A change to longstanding vaccine recommendations that lacks a reasoned evidentiary basis—that is not grounded in new clinical or epidemiological evidence warranting reclassification—would fail this standard.

The premise animating the RFI—that recategorizing vaccines or expanding SCDM will restore trust in the immunization system—is itself unsupported by evidence and likely counterproductive. The available polling data, discussed in Section I above, shows that public confidence in childhood vaccines remains high. The Department has offered no evidence that reclassifying routine vaccines would increase rather than decrease trust, and the empirical record on SCDM's uptake effects strongly suggests the opposite: reclassification signals uncertainty, and uncertainty depresses vaccination.[83]

Any recategorization would also disregard the substantial reliance interests of patients, providers, insurers, states, schools, and pharmacists who have structured their practices, coverage arrangements, stocking decisions, and legal obligations around the current routine immunization schedule. Providers rely on standing orders, EHR decision-support tools, and clear recommendations to deliver efficient care.[84] Pharmacists' scope-of-practice authority in many states is tied directly to ACIP's routine recommendation category.[85] Insurers have built coverage

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[82] *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co*., 463 U.S. 29, 43 (1983) (requiring that an agency "examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made").

[83] *See* pages 11-14, *supra*.

[84] Frieden et al., *supra* note 13, at 114.

[85] Ass'n of State & Territorial Health Officials (ASTHO), *Impact of the Advisory Committee on Immunization Practices (ACIP) Recommendations on State Law* (June 23, 2025), https://perma.cc/U5QY-SSPP; *see also* Congressional Research Service, *The Advisory Committee on Immunization Practices (ACIP)* (Sept. 15, 2025), https://www.congress.gov/crs-product/IF12317; (noting state laws reference ACIP recommendations in defining the scope of immunizations certain health care professionals, including pharmacists, are authorized to administer); National Alliance of State Pharmacy Associations, *Pharmacist and Pharmacy Technician Vaccination Authority* (Jan. 3, 2025), https://naspa.us/resource/2024-pharmacist-immunization-authority/.

systems around the ACA's zero-cost-sharing requirement for routinely recommended vaccines.[86] States have integrated the ACIP schedule into school-entry requirements—all fifty states and the District of Columbia require certain vaccinations for school attendance—and into Medicaid, CHIP, and EPSDT coverage determinations that are expressly "based on the types of recommendations made by [ACIP]."[87] And parents have relied on the schedule to make health decisions for their children; the prior vaccine schedule was easy to understand, permitted automatic alerts to prompt vaccines at childhood medical appointments, and ensured that physicians' offices stocked the recommended vaccines.[88]

Recategorization would also carry immediate downstream coverage consequences. Moving a vaccine from routine to some new recommendation category could jeopardize its ACA zero-copay status, narrow its Vaccines for Children eligibility, and reduce Early and Periodic Screening, Diagnostic, and Treatment ("EPSDT") coverage—directly harming the children and families the immunization system is designed to protect.[89]

Under settled principles of administrative law, an agency that reverses a longstanding policy must supply "a reasoned explanation . . . for disregarding facts and circumstances that underlay or were engendered by the prior policy."[90] Here, those facts and circumstances include decades of clinical evidence supporting routine recommendations, an elaborate statutory architecture that keys coverage, eligibility, and scope-of-practice determinations to ACIP's recommendation categories, and the settled expectations of every participant in the immunization system—from the parent who relies on the schedule at a well-child visit to the pharmacist whose authority to vaccinate depends on it. Recategorization without new evidence of changed safety or efficacy would impose concrete, measurable harm on the very populations the immunization framework is designed to protect, while offering in return only the unsupported hope that signaling uncertainty will somehow restore trust. The Department should not proceed down that path.

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[86] *See* 42 U.S.C. § 300gg-13(a)(2) (ACA zero-cost-sharing); 42 U.S.C. §§ 1395w-102(b)(8), (c)(8) (Medicare Part D); 42 U.S.C. §§ 1396a(a)(10)(A), 1396d(a)(13)(B) (Medicaid).

[87] *See* CMS, COVERAGE & PAYMENT OF VACCINE ADMINISTRATION UNDER MEDICAID 5 (Feb. 2024) (Medicaid coverage "based on the types of recommendations made by [ACIP]"), https://perma.cc/Q76Y-594D; Seither et al., *supra* note 55 (documenting state school-entry vaccination requirements).

[88] *See* Kempe et al., *supra* note 40 (reporting that EHR and immunization forecasting tools displayed SCDM recommendations inaccurately or not at all for 38% of providers, while 23% produced no recommendation at all); Scott, *supra* note 23 (explaining that removing vaccines from the routine schedule eliminates standing orders, checklists, and electronic prompts that drive vaccination).

[89] *See, e.g.*, 42 U.S.C. § 300gg-13(a)(2) (ACA zero-cost-sharing); 42 U.S.C. § 1396s(e) (VFC eligibility); 42 U.S.C. §§ 1396a(a)(10)(A), 1396d(a)(13)(B) (EPSDT and Medicaid coverage).

[90] *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515-16 (2009).

CONCLUSION

For the foregoing reasons, APHA, RWJF, LHA, the Geiger Gibson Program in Community Health, the Jacobs Institute of Women's Health, and the health law and policy scholars respectfully urge the Department to:

1. Retain the current three-category framework (routine, risk-based, and shared clinical decision-making) for federal vaccine recommendations.
2. Preserve ACIP's statutory role as the sole originating authority for vaccine recommendations and the evidence-based GRADE and EtR frameworks through which ACIP assigns recommendation categories.
3. Reserve SCDM for the narrow circumstances in which genuine equipoise exists—where the available scientific evidence does not clearly favor routine vaccination for a given population—and refrain from expanding its use to vaccines with well-established safety and efficacy profiles.
4. Decline to adopt new, undefined recommendation categories (such as "recommended, but not during infancy," "recommended with qualification," or "SCDM with qualification") that would fragment clinical practice, confuse providers and patients, and risk undermining coverage requirements.
5. Avoid generalizing the unique and context-specific experience of COVID-19 vaccination to the childhood immunization schedule, which continues to enjoy broad public confidence and which protects millions of children from serious, preventable disease.

The current recommendation framework, administered through ACIP's rigorous and transparent evidence-based process, has produced one of the most significant public health achievements in American history. It should be maintained, not undermined.

Respectfully submitted,

Andrew J. Pincus
Graham White

Mayer Brown LLP