No. 26-1503

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT

AMERICAN ACADEMY OF PEDIATRICS, *et al.*,
Plaintiffs-Appellees,
v.
ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the U.S. Department of Health and Human Services, *et al.*
Defendants-Appellants.

On Appeal from the United States District Court for the District of Massachusetts, No. 1:25-cv-11916 (Hon. Brian E. Murphy)

BRIEF OF PUBLIC HEALTH AND ADMINISTRATIVE LAW SCHOLARS AS *AMICI CURIAE* IN SUPPORT OF APPELLEES

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INTEREST OF *AMICI CURIAE*

Amici are scholars with extensive expertise in public health and administrative law. That expertise gives them a deep understanding of the issues here, including maternal and child health, the importance of vaccines in advancing patient and public health, the role of the Advisory Committee on Immunization Practices in ensuring that federal standards governing vaccine use and administration are evidence-based, and principles of federal administrative law that govern agency action. *Amici* believe that providing their perspective on the important issues presented here will assist the Court in resolving the case. The *amici* are listed in the appendix to this brief.[1]

INTRODUCTION AND SUMMARY OF ARGUMENT

This lawsuit challenges Defendants' actions making unprecedented changes to a number of vaccine recommendations that, if permitted to take effect, will have serious adverse consequences for public health (the

[1] No counsel for a party authored this brief in whole or in part and no person other than *amici* and their counsel made a monetary contribution to its preparation or submission. All parties have consented to the filing of this brief.

Vaccine Changes). The district court's order staying those actions should be upheld by this Court.

Defendants present standing and justiciability challenges to the district court's determinations regarding the Federal Advisory Committee Act (FACA)—and Defendants purport not to challenge the lower court's decision staying the January 2026 action dramatically altering childhood vaccine recommendations. But a number of Defendants' arguments rest on assumptions regarding the role of the Advisory Committee on Immunization Practices (ACIP) that, if endorsed by this Court, would undermine the district court's ruling staying the January action.

Amici therefore submit this brief to explain that an ACIP recommendation is an essential predicate for action by the Director of the Centers for Disease Control and Prevention (CDC); that ACIP must comply with its own procedures in issuing such recommendations; and that the CDC Director's authority is limited to approving or rejecting an ACIP recommendation. *Amici* also explain why the challenged decisions must be set aside for the independent reason that they are arbitrary and

capricious: Defendants' justifications are irrational and ignored overwhelming evidence of the vaccines' safety and effectiveness.

Vaccines rank among the greatest achievements in American public health: routine childhood vaccinations administered from 1994 to 2023 prevented an estimated 508 million illnesses, 32 million hospitalizations, and over 1.1 million deaths.[2]

Starting in 2025 and culminating in January 2026, Defendants made significant changes to vaccine recommendations. They first downgraded the COVID-19 and Hepatitis B vaccine recommendations from "routine"—which means that the "default decision" is "to vaccinate"—to "shared clinical decision-making" (SCDM), which carries no such presumption, creating significant uncertainty for both doctors and patients.[3] And then, without any input from ACIP, Defendants

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[2] 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 Morbidity and Mortality Weekly Report 682, 682–85, CDC (Aug. 8, 2024), https://perma.cc/L6S3-J7YU; Jeff Goad & Luke Halpern, *Q&A: Expert Warns of Public Health Risks After Childhood Vaccine Schedule Changes*, Pharmacy Times (Jan. 20, 2026), https://perma.cc/QV67-KCN7.

[3] Jake Scott, *CIDRA Op-Ed: Quiet Dismantling: How Shared Decision-Making Weakens Vaccine Policy and Harms Kids* at 6, CIDRAP (Jan. 6, 2026), http://perma.cc/9XGC-XYXZ.

overhauled the Childhood Vaccine Schedule by "reduc[ing] the number of diseases targeted from 17 to 11 and the number of routine vaccines from 13 to 7," dropping the "routine" recommendations, substituting SCDM recommendations for six vaccines, and cutting the HPV vaccine regimen to a single dose.[4]

These changes are unlawful several times over. Federal law creates a two-step process—ACIP issues recommendations regarding vaccines, and the CDC Director's role is limited to approving or rejecting those recommendations. Indeed, Congress has repeatedly designated ACIP, not the CDC, as the body whose recommendations are relevant under federal statutes governing vaccine coverage under private insurance, Medicare, Medicaid, and the veterans' health system, as well as the federal program making childhood vaccines available free of charge. Although the Government frames its appeal as challenging only the district court's FACA relief, its position—that ACIP's composition is irrelevant because the only reviewable decision is the CDC Director's

[4] Jennifer Kates & Josh Michaud, *The New Federal Vaccine Schedule for Children: What Changed and What Are the Implications?,* Kaiser Family Found. (Jan. 9, 2026), https://perma.cc/S9VL-A4UP (emphasis omitted).

action—effectively requires this Court to overturn the district court's holding that an ACIP recommendation is a prerequisite to lawful action. Because an ACIP recommendation is required, Plaintiffs are injured if ACIP's composition violates FACA and they can raise that issue in challenging the CDC Director's approval of ACIP recommendations such as the downgrading of the COVID and Hepatitis B vaccines. And, of course, the absence of any ACIP recommendation regarding the Childhood Vaccine Schedule changes means that the CDC Director's January action was unlawful.

Even if the CDC could act without ACIP, its wholesale revision of the Childhood Vaccine Schedule qualifies as a legislative rule that the Administrative Procedure Act ("APA") required to be issued through notice-and-comment rulemaking, which never occurred. Separately, the COVID-19 and Hepatitis B downgrades independently disregarded ACIP's own procedural requirements.

Finally, each of the Vaccine Changes is arbitrary and capricious. Defendants discarded long-established procedural standards, ignored overwhelming evidence of the vaccines' safety and effectiveness, and rested their decisions on irrational grounds—including a superficial

"peer nations" comparison that borrowed other countries' conclusions while ignoring the reasons underlying them, reasons not applicable to the United States. Allowing these arbitrary and irrational changes to take effect would result in tens of thousands of deaths and serious injuries throughout our nation.

ARGUMENT

I. THE VACCINE CHANGES ARE INVALID BECAUSE DEFENDANTS FAILED TO FOLLOW THE PROCEDURES REQUIRED BY LAW

The APA requires courts to set aside agency action that is "not in accordance with law" or adopted "without observance of procedure required by law." 5 U.S.C. § 706(2). Federal law establishes a two-step process for immunization recommendations: ACIP recommends, and the recommendation is "in effect" if it is approved by the CDC Director. 45 C.F.R. § 147.130(a)(1)(ii). The CDC Director's authority is limited to approving or rejecting the ACIP recommendation. And ACIP may make a valid recommendation only if it complies with its longstanding procedures for determining whether a recommendation is warranted and what that recommendation should be.

A. An ACIP Recommendation Is A Legal Prerequisite For CDC Action.

ACIP's role is to "provide advice and guidance to the Director of the CDC regarding use of vaccines." United States Department of Health and Human Services ("HHS"), ACIP, ACIP Charter (Apr. 1, 2024), https://perma.cc/N42Y-3EZ9. HHS regulations provide that "a recommendation from [ACIP] is considered in effect after it has been adopted by the Director of the [CDC]," 45 C.F.R. § 147.130(a)(1)(ii), at which point the agency publishes the recommendation in CDC's Morbidity and Mortality Weekly Report. *See* ACIP Charter at 1.

The HHS regulation makes clear that an ACIP recommendation is an essential predicate for action by the CDC Director. The Director's role is to decide whether or not to "adopt" something ACIP has recommended, not to originate a recommendation independently. If ACIP has not recommended, there is nothing for the Director to adopt, and no recommendation can be "in effect" under the regulation. While the Director may decline to implement an ACIP recommendation and has

done so previously,[5] an ACIP recommendation is a necessary predicate step for any changes to the vaccine schedule.

Even more fundamentally, Congress has expressly delegated vaccine-recommendation authority to ACIP in a number of federal laws. Congress's designation of ACIP—not CDC—as the body responsible for evaluating and initiating changes in immunization standards constitutes a deliberate legislative choice that forecloses CDC-only action.

1. The Affordable Care Act

Under the Affordable Care Act (ACA), insurers are required to cover an immunization without cost-sharing when "a recommendation from [ACIP]" is "in effect." 42 U.S.C. § 300gg-13(a)(2). Congress thus designated ACIP as the body responsible for originating recommendations, not the CDC Director.

2. Veterans' Health Benefits

Veterans' medical benefits include "each immunization on the recommended adult immunization schedule at the time such immunization is indicated on that schedule." 38 U.S.C. § 1701(9)(G). The

[5] CDC, *CDC Statement on ACIP Booster Recommendations* (Sept. 24, 2021), https://perma.cc/Y69L-PHZM.

statute separately provides that "[t]he term 'recommended adult immunization schedule' means the schedule established (and periodically reviewed and, as appropriate, revised) by [ACIP]." *Id.* § 1701(10). As with the ACA provision, Congress designated ACIP as the body that "establishes" the operative schedule.

3. Medicare and Medicaid

Medicare plans may not impose cost-sharing obligations on patients "with respect to . . . adult vaccine[s] recommended by [ACIP]." 42 U.S.C. §§ 1395w-102(b)(8), (c)(8).

Similarly, the Medicaid statute requires coverage without cost-sharing for "diagnostic, screening, preventative, and rehabilitative services, including . . . with respect to an adult individual, approved vaccines recommended by [ACIP]." 42 U.S.C. §§ 1396a(a)(10)(A), 1396d(a)(13)(B); *see* Centers for Medicare & Medicaid Servs., *Coverage & Payment of Vaccine Administration Under Medicaid* 5 (Feb. 2024) (Medicaid coverage of vaccinations is "based on the types of recommendations made by [ACIP]"), https://perma.cc/Q76Y-594D. Again, Congress designated ACIP, not CDC.

4. The Vaccines for Children Program

To optimize childhood immunization rates among Medicaid-enrolled and certain other low-income children, Congress enacted the Vaccines for Children (VFC) program, which mandates that states provide free pediatric vaccines to eligible children. *See* 42 U.S.C. § 1396s(a)(1)(A). The HHS Secretary purchases vaccines from manufacturers and delivers them to states at no charge. *Id.* §§ 1396s(a)(2)(A), (d)(1). The statute provides that the Secretary "shall use, for the purpose of the purchase, delivery, and administration of pediatric vaccines under this section, the list established (and periodically reviewed and as appropriate revised) by [ACIP]." *Id.* § 1396s(e).

The statutory language "shall use" is mandatory and assigns the critical role to ACIP—not to the Secretary or CDC Director—of *establishing* the list and *revising* it. Indeed, the Government has conceded as much in a parallel lawsuit challenging the CDC's January 2026 changes to the Childhood Vaccine Schedule. *See* Defs.' Mot. to Dismiss at 15, *Arizona v. Kennedy*, No. 3:26-cv-01609 (N.D. Cal. June 25, 2026) (vaccine availability under the VFC program "is based on, among

other things, the ACIP's resolutions to include a vaccine in the VFC program").

* * * * *

When Congress enacted these laws designating ACIP as the expert body responsible for making recommendations, ACIP had long been in existence and utilized an evidence-based recommendation process, developed and refined over decades. *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).

Recognizing that expertise, Congress made clear that vaccine policy begins with ACIP's expert, deliberative process before triggering downstream legal and financial consequences. If the CDC Director or the Secretary could make changes to the immunization schedule without an initial recommendation from ACIP, it would nullify Congress's directives.

B. *Kennedy v. Braidwood Management, Inc.* Does Not Authorize the CDC Director To Circumvent the ACIP Process.

Defendants (Br. 49-52) lean heavily on *Kennedy v. Braidwood Management, Inc.*, 606 U.S. 748 (2025), in arguing that they may bypass ACIP and set vaccine policy through the CDC Director alone. But *Braidwood* provides no basis for circumventing ACIP. To the contrary, the Court's analysis reaffirms the constitutionality of the structure Congress designed, under which an ACIP recommendation is required, and the CDC Director's authority is limited to approving or rejecting that recommendation.

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. 42 U.S.C. § 300gg(a).

The two provisions operate identically: 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 Supreme Court cited ACIP as an example of how such advisory-committee processes operate, confirming the structural parallel between USPSTF and ACIP. *Braidwood*, 606 U.S. at 767 n.4 (citing 45 C.F.R. § 147.130(a)(1)(ii)).

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. U.S. Const. art. II, § 2, cl. 2. 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 automatically 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. *Braidwood*, 606

U.S. at 773-76. The Court's conclusion rested on its determination that the Secretary was empowered to appoint and remove the members of the USPSTF and in addition could review and block USPSTF recommendations before they take effect. *Id*. at 767.

Most relevant here, the *Braidwood* Court rejected the contention 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. The Court stated that the Secretary's power to veto recommendations and to appoint USPSTF members were sufficient to satisfy the Constitution. 606 U.S. at 777.

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 or CDC to circumvent ACIP by originating recommendations outside the advisory-committee process.

Defendants separately claim (Br. 49) that the district court's remedy conflicts with *Braidwood* because, by staying individual appointments, it overrides the Secretary's appointment discretion and prevents the committee from convening—thereby denying the Secretary

the appointment and removal authority that *Braidwood* held essential to compliance with the Appointments Clause. But that argument rests on a mischaracterization of the district court's order.

The order does not bar the Secretary from reconstituting ACIP; it requires only that he do so in compliance with FACA. *See* Dist. Ct. Op. 43-45. The Secretary remains free to appoint a new committee immediately—he need only assemble one that satisfies FACA's fair-balance requirement. What the Government really seeks is not the ability to reconstitute ACIP, but the ability to reconstitute it in a manner that would violate FACA.

The Government is equally wrong in contending (Br. 51) that treating ACIP's recommendations as legally consequential would transform ACIP members into principal officers requiring Senate confirmation. As discussed above, *Braidwood* held that the members of an advisory committee qualify as inferior officers so long as they are adequately supervised by a principal officer. 606 U.S. at 767. The same supervisory controls govern ACIP: the Secretary may remove ACIP's members at will, and the CDC Director may review and decline to adopt any ACIP recommendation before it takes effect. *See* 45 C.F.R. §

147.130(a)(1)(ii). Those features defeat any suggestion that ACIP's members exercise the kind of unsupervised authority that would make them principal officers.

C. An ACIP Recommendation Is Valid—And Provides The Basis For CDC Director Action—Only If ACIP Complies With Its Own Procedural And Substantive Rules.

An ACIP recommendation can serve as the predicate for the CDC Director's action only if ACIP actually followed its own rules in making it—both the procedural rules that govern how it reaches a recommendation and the substantive standards that govern whether a recommendation is warranted. *See* 5 U.S.C. § 704 ("A preliminary, procedural, or intermediate agency action or ruling not directly reviewable is subject to review on the review of the final agency action."). The downgrading of the COVID-19 and Hepatitis B recommendations satisfies neither requirement.[6]

ACIP's policies require that "[a]t least 60 days prior to the meeting, the meeting date, items to be discussed, and location are published in the

[6] For the same reason, Plaintiffs' challenge to the CDC Director's COVID-19 and Hepatitis B decisions required the district court to address Plaintiffs' FACA challenge. If ACIP was not properly constituted under FACA, then its recommendations were invalid—and could not provide a basis for those decisions by the CDC Director.

Federal Register," because public comment is "an essential aspect of the Committee's deliberations." CDC, *Advisory Committee on Immunization Practices Policies and Procedures* 7, 9 (June 2022), https://perma.cc/M38J-3VQ8 ("ACIP Policies"). And when ACIP cannot meet that deadline, the notice must "include the reasons for providing less than 60 days' notice as provided under GSA regulations at 41 C.F.R. § 102-3.150(b)." *Id.* at 7.

Those safeguards were not observed. For the downgrade of COVID-19 vaccination to SCDM, CDC published notice on August 29, 2025, for a meeting held just weeks later, on September 18, 2025—far short of 60 days—and did not include any explanation for the shortened notice; and it allowed only 16 days for the submission of written comments. *See* Meeting of the Advisory Comm. on Immunization Practices, 90 Fed. Reg. 42245 (Aug. 29, 2025).

Likewise, for the Hepatitis B changes, CDC published notice on November 13, 2025, for a December 4, 2025, meeting—again, well under 60 days—and again without explaining the reasons for the shortened notice period. It allowed only 11 days for the submission of written comments. *See* Meeting of the Advisory Comm. on Immunization

Practices, 90 Fed. Reg. 50944 (Nov. 13, 2025). Neither Federal Register notice explained "the reasons for providing less than 60 days' notice." ACIP Policies at 7.

This is not a technicality. ACIP itself treats timely Federal Register notice and meaningful public comment as central to its deliberations. By bypassing its own 60-day rule and omitting the required reasons for shortened notice, CDC denied stakeholders the process ACIP deems "essential." ACIP Policies at 9.

Moreover, the Supreme Court explained in *Braidwood* that the USPSTF's notice and comment procedures substituted for the notice-and-comment that otherwise would be required by the Administrative Procedure Act. 606 U.S. at 756. But ACIP proceedings cannot qualify as a substitute for APA notice-and-comment when ACIP's own notice requirements were not met and the opportunity provided for comment was so much shorter than the 30 days required by the APA. 5 U.S.C. § 553(d).

ACIP also failed to apply the substantive criteria its charter requires. ACIP's charter provides that its decisions must be guided by "disease epidemiology and burden of disease, vaccine safety, vaccine

efficacy and effectiveness, the quality of evidence reviewed, economic analyses, and implementation issues." ACIP Policies at 1. As explained pp. 22-37, *infra*, ACIP disregarded those governing standards, discounting the overwhelming evidence of the vaccines' safety and effectiveness rather than weighing the charter's enumerated factors. The result is that the COVID-19 and Hepatitis B downgrades rest on no valid recommendation at all. That failure independently invalidates the downgrades, and for the reasons explained in Part II, it also renders the changes arbitrary and capricious.

D. If CDC Were Permitted to Circumvent the ACIP Process, It Could Do So Only Through Notice-and-Comment Rulemaking.

Even if CDC could take action without an ACIP recommendation, its changes to the Childhood Vaccine Schedule would still be procedurally invalid because the agency failed to conduct notice-and-comment rulemaking as required by the APA.

The APA "generally requires that before an agency adopts a rule it must first publish the proposed rule in the Federal Register and provide interested parties with an opportunity to submit comments and information concerning the proposal." *N.H. Hospital Ass'n v. Azar*, 887

F.3d 62, 70 (1st Cir. 2018) (citing 5 U.S.C. § 553). "Failure to abide by these requirements renders a rule procedurally invalid." *Id.* (citing *Warder v. Shalala*, 149 F.3d 73, 75 (1st Cir. 1998)).

The APA's notice-and-comment requirements apply to legislative rules. Legislative rules "grant rights, impose obligations, or produce other significant effects on private interests." *Batterton v. Marshall*, 648 F.2d 694, 701-02 (D.C. Cir. 1980). Whether agency action qualifies as a legislative rule turns on whether the agency action, "as a practical matter, ha[s] a binding effect." *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1021 (D.C. Cir. 2000).

CDC's decision to revise the childhood immunization schedule "produce[s] . . . significant effects on private interests" and is thus a legislative rule requiring notice-and-comment rulemaking. *Batterton*, 648 F.2d at 702. As explained below, downgrading vaccine recommendations from "routine" to SCDM impacts clinical workflows, provider-patient communications, and vaccine access—real-world effects that change private parties' behavior. *See infra* Part II.A.

Moreover, the conclusion that CDC's recommendation downgrades constitute legislative rules is consistent with the government's own

characterization of changes in vaccine recommendations. The government has previously taken the position that "ACIP's recommendations comply with notice and comment" as required under 5 U.S.C. § 553.[7] As the government has explained, ACIP publishes notices in the Federal Register at least 60 days before meetings at which they will vote on the recommendations.[8] The notices identify the subjects to be discussed and voted upon, and ACIP invites written and oral comments.[9] "Once a vote is taken at the ACIP meeting and the CDC Director adopts it, the recommendation is published in CDC's Morbidity and Mortality Weekly Report and incorporated into the CDC's immunization schedules."[10] The government cannot have it both ways: It cannot argue that ACIP's procedures satisfy the APA when defending the existing ACIP process, and then claim that no notice-and-comment is required when the agency circumvents that process.

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[7] Defs.' Mot. To Dismiss pursuant to Rules 12(b)(1) & 12(b)(6), at 35, No. 4:20-cv-00283-O (N.D. Tex. June 29, 2020), https://perma.cc/ML3T-D94H.

[8] *Id.*

[9] *Id.*

[10] *Id.*

Here, CDC did not conduct notice-and-comment rulemaking. The January 2026 revisions were announced without prior Federal Register notice, without an opportunity for public comment, and without the deliberative process that ACIP's procedures ordinarily provide. The agency simply issued new guidance and expected it to take immediate effect. That is precisely the kind of agency action the APA's procedural requirements are designed to prevent.

II. THE CDC VACCINE CHANGES ARE ARBITRARY AND CAPRICIOUS.

An agency's action is arbitrary and capricious, and must be set aside, 5 U.S.C. § 706(2)(A), if the agency "relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency," or is "so implausible" that the action cannot "be ascribed to a difference in view or the product of agency expertise." *Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co.,* 463 U.S. 29, 43 (1983). "[T]he 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." *Id.*

Here, Defendants failed to engage in reasoned decisionmaking. They ignored overwhelming evidence that the affected vaccines are safe and effective, relied on rationales disconnected from the evidence before the agency, and failed to explain why downgrading vaccine recommendations from routine to SCDM would advance public health rather than predictably undermine it.

A. Downgrading Vaccine Recommendations from "Routine" to "Shared Clinical Decision-Making" Will Increase Illnesses and Deaths.

Defendants ignored overwhelming evidence showing that downgrading vaccine recommendations from "routine" to SCDM will have an adverse impact on public health. Vaccines with a routine recommendation must be offered to every eligible patient; and the doctor's discussion of the benefits and possible risks includes the fact that the U.S. government recommends the vaccine for everyone in the specified population group, unless the patient has contraindications. That allows for "automatic prompts in electronic health records"; "enable[s] standing orders, the protocols that allow nurses and pharmacists to vaccinate without a specific physician examination or direct order for each patient"; "shape[s] what providers discuss and

when"; and generally signals to patients that substantial scientific evidence supports administering the vaccinations.[11]

With SCDM, there is no default. The doctor may no longer say that the U.S. government recommends the vaccine for everyone in the specified population group. Imparting that information is important in the doctor-patient interaction because it gives doctors an easily understandable way to explain to their patients that a broad scientific consensus supported administration of the vaccine.[12] Instead, uncertainty is the new baseline. CDC states that "[t]here is not a prescribed set of considerations or decision points in the decision-making process."[13] Indeed, according to CDC, a doctor may choose not to even mention a SCDM vaccine.[14] Many medical providers are unsure how to

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[11] *See* Scott, *supra* note 3.

[12] *Id.*

[13] ACIP, *ACIP Shared Clinical Decision-Making Recommendations* (Jan. 7, 2025), htttp://perma.cc/LLK2-ALSW.

[14] *Id.*

implement SCDM because the CDC has not provided guidance, and SCDM "signal[s] uncertainty where none exists."[15]

When a vaccine is no longer routine, the usual tools that drive vaccination—standing orders, checklists, and electronic prompts—drop away.[16] The predictable result is a decline in vaccinations. To take just one example, "the PCV13 pneumococcal vaccine saw uptake decline from over 70% to under 60% following SCDM implementation, including among vulnerable and immunocompromised individuals."[17]

SCDM also limits vaccine access. Vaccines recommended as "routine" may be administered by nurses and pharmacists, but when a vaccine is downgraded to SCDM, state laws may limit or prohibit them from administering the vaccine—depriving pharmacists of a service they formerly provided and making vaccines less available.[18]

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[15] Erika L. Thompson et al., *Implementation of Mid-Adult HPV Vaccination Guidelines into Clinical* Practice, 51 Vaccine 12687 (2025), https://perma.cc/3SMF-J37C; *see also* Scott, *supra* note 3.

[16] *Id.*

[17] *Global Healthy Living Foundation Report Warns That Complex Vaccine Guidelines May Be Slowing Adult Immunization Rates*, FirstWord Pharma (Mar. 28, 2025), https://perma.cc/HG6M-Q2S4.

[18] Rob Stein, *CDC Childhood Vaccine Changes Tied to "Shared Decision-Making,"* NPR (Jan. 25, 2026), https://perma.cc/32TU-7LML; Ass'n of State & Territorial Health Officials (ASTHO), *Impact of the Advisory*

The resulting consequences are especially serious for immunocompromised individuals, who make up approximately 6.6% of the population.[19] Many immunocompromised individuals cannot be vaccinated and therefore depend on routine vaccination to help the overall population achieve herd immunity.[20] "Without vaccination, herd immunity might only be achieved if a very large number of people get sick—and potentially die—very quickly."[21] Attending school or doctor's appointments will become dangerous for immunocompromised people.[22]

Committee on Immunization Practices (ACIP) Recommendations on State Law (June 23, 2025), https://perma.cc/U5QY-SSPP.

[19] Melissa L. Martinson & Jessica Lapham, *Prevalence of Immunosuppression Among US Adults*, National Library of Medicine (Feb. 15, 2024), https://perma.cc/6N7Q-4XJD.

[20] Alden Woods, *Q&A: UW Expert on the Rising Rates of Immunosuppression Among U.S. Adults*, Univ. of Wash. News (Mar. 13, 2024), https://perma.cc/3P9E-CZYB; Cleveland Clinic, *Herd Immunity*, MyClevelandClinic.org (medically reviewed) (Oct. 20, 2025), https://perma.cc/NTU3-GZAL.

[21] *See* Cleveland Clinic, *supra* note 20.

[22] Lauran Neergaard, *What to Know About the Unprecedented Changes to the Child Vaccine Recommendations*, NBC New York (Jan. 5, 2026), https://perma.cc/YC6L-YCUR.

B. The CDC's "Peer Nations" Justification For The Schedule Changes Was Arbitrary And Capricious

The Childhood Vaccine Schedule changes cannot plausibly "be ascribed to a difference in view or the product of agency expertise." *State Farm,* 463 U.S. at 43. The CDC relied on two documents: (1) a January 2, 2026, memorandum entitled, "Assessment of the U.S. Childhood and Adolescent Immunization Schedule Compared to Other Countries";[23] and (2) a January 5, 2026, decision memorandum from the Acting Director for the CDC.[24] Both rested on a comparison to "peer nations"—a factor found nowhere in the criteria that govern vaccine-schedule decisions, and one that, even on its own terms, collapses because the CDC simply copied Denmark's result without assessing the country-specific reasons underlying it.

To begin, both memoranda focused on purported "peer nations' best practices,"[25] a factor found nowhere in the criteria that govern vaccine-

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[23] U.S. Dep't of Health & Human Servs., *Assessment of the U.S. Childhood and Adolescent Immunization Schedule Compared to Other Countries* 1 (Jan. 2, 2026), https://perma.cc/Y5QA-K6VE.

[24] U.S. Dep't of Health & Human Servs., *Decision Memo Adopting Revised Childhood and Adolescent Immunization Schedule* 1 (Jan. 5, 2026), https://perma.cc/2YS6-RK7K.

[25] *Id.* at 1.

schedule decisions. While ACIP revised its charter in May 2026 to permit consideration of "immunization recommendations, schedules, and practices from other countries," that cannot rescue the January 2026 changes. The revised charter was not in place when HHS acted, and agency action must be judged against the standards in effect at the time; an "agency may not . . . simply disregard rules that are still on the books." *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009).[26]

Even on its own terms, the agency's justification is arbitrary. The U.S. previously recommended only a few more vaccines than 37 other countries in Europe, the Middle East, Asia, and Australia.[27] Now, the

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[26] There are serious questions whether HHS has the authority to make significant changes to the substantive standards that guide ACIP's decisionmaking. The government has explained that Congress in the ACA "incorporate[d]" and "adopted" ACIP's "well-established framework"—the "preexisting, evidence-based recommendation process[ ] . . . used and updated over the course of decades," which "includes analysis of disease surveillance and epidemiology." Br. for Cross-Resp. in Opp. 13-16, *Braidwood Mgmt., Inc. v. Becerra*, No. 24-475 (U.S. Dec. 2, 2024). Indeed, the government argued that this incorporation of "past administrative practice" supplied the intelligible principle that saved the statute from the nondelegation challenge, because the ACA's text does not itself specify substantive standards for ACIP recommendations. *Id.* at 15. Congress's endorsement of ACIP's long-established standards bars HHS from adopting a new substantive framework that deviates from those that Congress incorporated.

[27] Helen Branswell, *When it Comes to Vaccine Schedules, the U.S. is Now the Outlier*, STAT (Jan. 9, 2026), https://perma.cc/4VFG-NJBQ.

pared-down U.S. vaccine schedule protects children against fewer diseases than 19 of the 20 "peer countries."[28] Only Denmark has the same or fewer vaccines on its schedule, and there are significant differences between the U.S. and Denmark that the memoranda fail to acknowledge.

As one scientific study explained, "Denmark has 6 million people, a homogeneous population, universal healthcare with guaranteed rapid access, and a robust public health infrastructure"; also, health records automatically link maternal and infant health records, "ensuring virtually zero loss to follow-up."[29] In contrast, "[t]he United States has 330 million people, profound health disparities, 27 million uninsured, and a fragmented system."[30] At bottom, Denmark is "an outlier among wealthy nations, not a model."[31]

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[28] *Id.*

[29] *See* Scott, *supra* note 3.

[30] *Id.*

[31] *Id.*; Vaccine Integrity Project Staff & Advisers, *Viewpoint: The Myth of an Over-Vaccinated America: The U.S. DOES Follow Global Consensus*, University of Minnesota (Dec. 22, 2025), https://perma.cc/Z32M-6HMN.

The deeper flaw is that the CDC never actually assessed Denmark's "best practices" at all—it simply copied Denmark's result. Denmark omits vaccines like rotavirus not because it doubts their efficacy, but because, in a country with universal healthcare coverage, ready access to care, and lower inequality, the disease "rarely leads to deaths or long-term harm."[32] In the United States, by contrast, rotavirus caused an estimated 55,000 to 70,000 hospitalizations and 20 to 60 childhood deaths each year before the vaccine was introduced.[33]

By adopting Denmark's conclusion while disregarding the country-specific evidence and reasoning behind it, the CDC did precisely the opposite of what a "best practices" review requires—and offered "an explanation for its decision that runs counter to the evidence before the agency." *State Farm*, 463 U.S. at 43.

C. The CDC's Justifications For Each Individual Vaccine Decision Were Arbitrary And Capricious

The CDC's justification for each individual downgrade fares no better. As shown below, the agency ignored overwhelming evidence of

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[32] Josh Michaud, *Do We Want to Outsource U.S. Vaccine Policy to Denmark?*, KFF (Dec. 19, 2025), https://perma.cc/DNX4-QPM8.

[33] *Id.*

safety and efficacy and invoked rationales it applied inconsistently across the COVID-19, Hepatitis B, meningococcal, and rotavirus vaccines.

COVID-19. The CDC ignored evidence that the COVID-19 vaccine is safe and effective: "COVID-19 vaccines underwent the most intensive safety analysis in U.S. history."[34] Numerous studies have shown the vaccine is safe.[35] Evidence that HHS provided to justify removal of the routine pediatric COVID-19 vaccine from the immunization schedule has been debunked by numerous authors.[36] CDC did not address that evidence or explain why the record supported eliminating the routine recommendation.

Hepatitis B. The Hepatitis B downgrade suffers from the same defects. *First*, the CDC ignored evidence that the routine Hepatitis B

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[34] CDC, *COVID-19 Vaccine Safety* (Jan. 31, 2025), https://perma.cc/UT4Q-455S.

[35] Atsuyuki Watanabe et al., *Assessment of Efficacy and Safety of mRNA COVID-19 Vaccines in Children Aged 5 to 11 Years: A Systematic Review and Meta-analysis*, 177 JAMA Pediatrics 384 (2023), https://perma.cc/NF4K-5EU6; Fangyuan Tian, et al., *Safety and Efficacy of COVID-19 Vaccines in Children and Adolescents: A Systematic Review of Randomized Controlled Trials*, 94 J. Med. Virol. 4644, 4644-53 (2022), https://perma.cc/3P9Y-RCJH.

[36] Gwen Roley, AFP Canada & AFP USA, *Experts Say HHS Document Misrepresents Studies on COVID-19 Vaccine*, AFP Fact Check (June 27, 2025), https://perma.cc/A78B-GB66.

vaccine is safe. The CDC's own safety monitoring confirms as much: its review of a decade of adverse-event reports "did not detect any new or unexpected safety concerns," and a study comparing vaccinated and unvaccinated newborns "found no difference" in deaths—findings the CDC described as "consistent with pre-licensure clinical trials and other post-licensure monitoring and research."[37]

Second, the CDC ignored overwhelming evidence of efficacy. The universal Hepatitis B vaccine birth dose has prevented over 500,000 childhood infections and prevented an estimated 90,100 childhood deaths.[38] In 2021 and 2022, the U.S. reported only 17 and 13 cases of perinatal Hepatitis B, respectively.[39]

Moreover, the agency's new approach repeats a strategy that ACIP previously found inadequate. Before the first Hepatitis B vaccine was available in the United States, an estimated 20,000 children were

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[37] CDC, *Hepatitis B Vaccine Safety* (Dec. 20, 2024), https://perma.cc/3LH2-7GL3 (citing additional safety studies).

[38] *Why We Give Hepatitis B Vaccines to Infants*, National Foundation for Infectious Diseases (Oct. 20, 2025), https://perma.cc/7K7X-MATF.

[39] American Academy of Pediatrics, *Fact Checked: Hepatitis B Vaccine Given to Newborns Reduces Risk of Chronic Infection* (June 25, 2025), https://perma.cc/L632-29TB.

infected annually.[40] From 1982 to 1991, ACIP recommended that only high-risk individuals receive the vaccine. By 1991, it was apparent children who later contracted the disease were not being vaccinated, and ACIP recommended *all* babies receive the Hepatitis B vaccine.[41]

The success of routine vaccinations underscores the arbitrariness of reversing course. Between 1994 and 2023, routinely administering the pediatric Hepatitis B vaccine averted an estimated 90,100 deaths, 940,000 hospitalizations, and six million illnesses.[42] The CDC's action reverts to a strategy that will result in more children contracting the disease.

Third, the CDC ignored implementation issues. The Hepatitis B vaccine is now recommended for "high risk" children based on maternal testing. But approximately 15% of pregnancies are not screened.[43] For

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[40] *Achievements in Public Health: Hepatitis B Vaccination --- United States*, 1982--2002, 51 Morbidity and Mortality Weekly Report 549-52, 563 (June 28, 2002), https://perma.cc/5SNK-H2UX.

[41] *Id.*

[42] *See* Zhou, *supra* note 2.

[43] CDC, *Births and Natality* (Sept. 17, 2025), https://perma.cc/7WMP-64TU; 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. (2023) 52, https://perma.cc/5XRE-9RWY (noting the CDC

those who test positive, only 35% receive recommended follow-up care.[44] A mother can become infected after her test, or a child can be infected from another adult.[45] Thus, tying the vaccine to a maternal test will leave many children vulnerable to Hepatitis B, which has no cure.[46]

Meningococcal. The memoranda's treatment of the meningococcal vaccine exhibits the same defects. The memoranda attempt to cast doubt on the vaccine's safety by pointing to a supposed lack of large-scale clinical trials in children—yet the CDC ignored its own "body of scientific evidence that overwhelmingly supports [the vaccine's] safety."[47]

The memoranda also justified downgrading the vaccine on the ground that "incidence of meningococcal disease ha[d] declined during the past decades," invoking a World Health Organization (WHO) position paper recommending the vaccine only "for defined risk groups, such as

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"estimated that 20,678 women who gave birth in 2015 were infected with hepatitis B virus").

[44] *See* Scott, *supra* note 3.

[45] CDC, *Clinical Signs and Symptoms of Hepatitis B* (Feb. 14, 2024), https://perma.cc/55UK-E38C.

[46] Cleveland Clinic**,** *Hepatitis B* (Feb. 8, 2025), https://perma.cc/E4H7-SCPS.

[47] CDC, Meningococcal Vaccine Safety (Dec. 20, 2024), https://perma.cc/35GK-SLVY.

children and young adults residing in closed communities" for countries where the disease occurs less frequently.[48] But that rationale ignores the current trajectory of the disease. Meningococcal disease—which kills 10 to 15% of those it infects—has risen sharply since 2021.[49] The United States saw roughly 503 cases in 2024, with a troubling concentration among infants under one year old.[50] Downgrading the recommendation as cases climb, and focusing instead on a decades-long decline attributable to the vaccine, is not reasoned decisionmaking.

Rotavirus. The downgrade of the rotavirus vaccine cannot be squared with the very standard the CDC used to justify removing the meningococcal vaccine. If the WHO's position on a vaccine is the touchstone—as the memoranda invoked it for the meningococcal vaccine decision—then rotavirus plainly should have remained on the schedule, because the WHO's position on childhood rotavirus immunization is

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[48] World Health Organization, Meningococcal Vaccines: WHO Position Paper, 86 Weekly Epidemiological Rec. 521 (2011), https://perma.cc/EN6E-355P.

[49] Chris Dall, *CDC Data Show Sharp Rise in Rates of Meningococcal Disease*, CIDRAP (Nov. 14, 2024), https://perma.cc/9MFM-HWAQ.

[50] CDC, Meningococcal Disease Surveillance and Trends (June 4, 2026), https://perma.cc/BR8D-9YJ3.

categorical: "rotavirus vaccines should be included in all national immunization programmes."[51]

The memoranda's explanation that rotavirus is a "common infection" and less deadly than meningitis does not withstand scrutiny. In the pre-vaccine era, rotavirus was responsible for more than 200,000 child hospitalizations and between 20 to 60 child deaths annually.[52] Widespread vaccinations as a result of ACIP recommendations have sharply decreased these outcomes.[53]

* * * * *

In sum, the CDC's actions are "so implausible" they cannot "be ascribed to a difference in view or the product of agency expertise." *State Farm*, 463 U.S. at 43. They are arbitrary and capricious. They are contrary to Congress's intent and threaten the most vulnerable.

CONCLUSION

The district court's order should be affirmed.

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[51] WHO, *Rotavirus vaccines: WHO position paper – July 2021*, 28 Weekly Epidemiological Rec. 301, 316, https://perma.cc/J3TY-SDCV.

[52] Margaret M. Cortese & Penina Haber, Chapter 19: Rotavirus, Epidemiology and Prevention of Vaccine-Preventable Diseases (14th ed. 2021) (Apr. 25, 2024), https://perma.cc/9UEA-CGGP.

[53] *Id.*

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CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rule of Appellate Procedure 32(g), undersigned counsel certifies that this brief:

(i) complies with the type-volume limitation of Rule 29(a)(5) because it contains 6,364 words, including footnotes and excluding the parts of the brief exempted by Rule 32(f); and

(ii) complies with the typeface requirements of Rule 32(a)(5) and the type style requirements of Rule 32(a)(6) because it has been prepared using Microsoft Word for Microsoft 365 and is set in Century Schoolbook font in a size equivalent to 14 points or larger.

Dated: July 23, 2026

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CERTIFICATE OF SERVICE

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

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APPENDIX

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