IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS, *et al.*, Plaintiffs, vs. ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the Department of Health and Human Services, *et al.*, Defendants.	Civil Action No. 1:25-cv-11916

UNOPPOSED MOTION FOR LEAVE FOR *AMICI CURIAE* PUBLIC HEALTH AND ADMINISTRATIVE LAW SCHOLARS TO FILE A BRIEF IN SUPPORT OF PLAINTIFFS

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Amici public health and administrative law scholars respectfully move for leave to file a brief as *amici curiae* in support of Plaintiffs.[1] The proposed brief is attached as **Exhibit A**. The list of *amici* is set forth in the appendix to the proposed brief. Plaintiffs consent to this motion and Defendants do not oppose the motion.

The Federal Rules of Civil Procedure do not contain a provision governing the filing of *amicus* briefs, but a district court has inherent authority to approve the filing of *amicus* briefs in a proceeding before it. *Students for Fair Admissions v. President & Fellows of Harvard Coll.*, 2018 WL 9963511 (D. Mass. Oct. 3, 2018); *see also Bos. Gas Co. v. Century Indem. Co.*, 2006 WL 1738312, at *1 n.1 (D. Mass. June 21, 2006) ("Although . . . no procedural rule provides for filing of amicus briefs in federal district court, courts have inherent authority and discretion to appoint amici.").

This Court has recognized that "'district courts frequently welcome amicus briefs from nonparties concerning legal issues that have potential ramifications beyond the parties directly involved or if the amicus has unique information or perspective that can help the court beyond the help that the lawyers for the parties are able to provide.'" *Arkansas Tchr. Ret. Sys. v. State St. Bank & Tr. Co.*, 523 F. Supp. 3d 181, 193 (D. Mass. 2018) (quoting *Conservation Cong. v. U.S. Forest Serv.*, 2015 WL 300754, at *1 (E.D. Cal. 2015)). This Court has found submissions from scholars, like *amici*, helpful in reaching its decisions. *See, e.g.*, *United States v. Richmond Joseph*, 2020 WL 4288425, at *2 n.2 (D. Mass. July 27, 2020) (finding the *amicus curiae* briefs of legal scholars especially helpful as to certain issues raised by the defendants).

This action challenges the Centers for Disease Control and Prevention's ("CDC") recent changes to vaccine recommendations, specifically (1) downgrading from "routine" to "shared

[1] The *Amici* are listed in the Appendix to the proposed brief.

clinical decision making" ("SCDM") status a significant number of vaccines on the Childhood Vaccine Schedule; (2) downgrading the COVID-19 vaccine from routine to SCDM for all people 6 months and older; and (3) downgrading the Hepatitis B vaccine from routine to SCDM. These changes represent a dramatic shift in the CDC's approach to recommending vaccines and, as the proposed *amicus* brief explains, that shift will have dramatic adverse consequences for the Nation's public health and for the availability of critical vaccines for the country's children.

Amici are scholars with extensive expertise in public health and administrative law. That expertise gives them a deep understanding of the issues in this case, 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. More specifically, by drawing on their unique perspectives and research, *Amici*'s proposed brief explains that the CDC vaccine changes are unlawful because the agency failed to follow the procedures required by law and its justifications for the changes are arbitrary and capricious.

The filing of the proposed *amicus* brief will not delay resolution of this case because it is being filed one week after Plaintiffs' motion and memorandum.

The Court's Local Rules do not provide instructions regarding the length of an acceptable *amicus curiae* brief. *Amici* have referred to Local Rule 7.1(b)(4), which generally limits a brief in support of a motion to 20 pages, and Federal Rule of Appellate Procedure 29(a)(5), which limits an amicus brief to one-half the maximum length of a party's principal brief, unless a court permits

a longer filing. The plaintiff's memorandum of law in support of their motion for a preliminary injunction is 54 pages. The proposed amicus brief does not exceed twenty pages.

For the foregoing reasons, *amici* respectfully request that the Court grant leave to file the attached brief as *amici curiae* and accept the proposed brief for filing.

Dated: February 2, 2026

Respectfully submitted,

/s/ Allison Aviki

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CERTIFICATE OF COMPLIANCE WITH LOCAL RULE 7.1

I hereby certify that counsel for *Amici Curiae* conferred with counsel for Plaintiffs and Defendants on January 30, 2026, regarding this motion. Plaintiffs consent to this motion and Defendants do not oppose the motion.

/s/ Allison Aviki
Allison Aviki (BBO # 688328)

CERTIFICATE OF SERVICE

In accordance with Local Rule 5.4(c), I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants on the Notice of Electronic Filing (NEF) on February 2, 2026.

/s/ Allison Aviki
Allison Aviki (BBO # 688328)

EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS, *et al.*, Plaintiffs, vs. ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the Department of Health and Human Services, et al., Defendants.	Civil Action No. 1:25-cv-11916 Leave to file granted [Month Day], 2026

[PROPOSED] BRIEF OF PUBLIC HEALTH AND ADMINISTRATIVE LAW SCHOLARS AS AMICI CURIAE IN SUPPORT OF PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION AND DECLARATORY RELIEF

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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

The Centers for Disease Control ("CDC") recently made sweeping changes to vaccine recommendations that will have dramatic adverse consequences for public health (the "CDC Vaccine Changes"). These changes are also flatly contrary to settled principles of administrative law. Decisions of this magnitude must be made through procedure required by law, based on expert judgment, and grounded in scientific evidence. The CDC Vaccine Changes fall well short.

Vaccines have had a profound positive effect on public health. Vaccines reduce the risk of serious complications and death. Among US children born during 1994–2023, routine childhood vaccinations prevented approximately 508 million illnesses, 32 million hospitalizations, and over

[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.

1.1 million deaths.[2] Because of childhood vaccines, there are "fewer visible reminders of the suffering, injuries, and premature deaths" caused by vaccine-preventable diseases.[3]

Starting in 2025 and culminating in January 2026, the CDC made significant changes to vaccine recommendations. Prior to 2025, virtually all vaccines recommended by the U.S. Advisory Committee on Immunization Practices ("ACIP") were given a "routine" designation, which means that the vaccine is "recommended for everyone in a particular age group or everyone in an identifiable risk group"; "the default decision should be to vaccinate the patient based on age group or other indication, unless contraindicated."[4]

In September 2025, the CDC adopted ACIP's recommendation that the status of the COVID-19 vaccine be downgraded from "routine" to "shared clinical decision-making" ("SCDM") for all people six months and older.[5] In December 2025, the CDC adopted ACIP's recommendation that the Hepatitis B vaccine also be downgraded from routine to SCDM.[6] In January 2026, the CDC—this time without input from ACIP—overhauled the Childhood Vaccine Schedule. It "reduced the number of diseases targeted from 17 to 11 and the number of routine

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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 (2024), https://perma.cc/L6S3-J7YU; Jeff Goad & Luke Halpern, *Q&A: Expert Warns of Public Health Risks After Childhood Vaccine Schedule Changes* (Jan. 20, 2026), https://perma.cc/QV67-KCN7.

[3] Food & Drug Admin., *Vaccine Safety Questions and Answers*, https://perma.cc/TF5D-NC2A (last visited Feb. 1, 2026).

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

[5] U.S. Dep't of Health & Human Servs., *ACIP Recommends COVID-19 Immunization Based on Individual Decision-making* (Sept. 19, 2025), https://perma.cc/4RM4-4457.

[6] *ACIP Recommends Individual-Based Decision-Making for Hepatitis B Vaccine for Infants Born to Women Who Test Negative for the Virus*, CDC Newsroom (Dec. 5, 2025), https://perma.cc/4WKQ-JSER.

vaccines from 13 to 7."[7] Six vaccines are "no longer recommended for routine use by all children in the U.S.: rotavirus, COVID-19, influenza, Hepatitis A, Hepatitis B, and meningococcal vaccines."[8] Additionally, the HPV vaccine recommendation was changed from a multi-dose regimen to a single dose.[9]

The CDC describes SCDM as having "no default" recommendation; "the decision about whether or not to vaccinate may be informed by the best available evidence of who may benefit from vaccination; the individual's characteristics, values, and preferences; the health care provider's clinical discretion; and the characteristics of the vaccine being considered. There is not a prescribed set of considerations or decision points in the decision-making process."[10]

When vaccines are subject to SCDM, fewer people receive them.[11] SCDM reduces access to vaccines for multiple reasons. To begin with, when a vaccine is downgraded from routine to SCDM, doctors can no longer tell patients, and parents, that the U.S. government recommends the vaccine—and that confuses patients about the benefits of the vaccine.[12] In addition, doctors are uncertain about the factors they must discuss with patients to satisfy the SCDM standard—in particular, what information must be provided in addition to doctors' ordinary practice of obtaining informed consent by explaining the risks and benefits of any medication. Doctors also must follow

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[7] 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).

[8] *Id*.

[9] *Id.;* CDC, *HPV Vaccination* (Aug. 20, 2024), https://perma.cc/3RYV-QXXX.

[10] *See supra* ACIP, n.4.

[11] Global Healthy Living Foundation, *Enhancing Adult Vaccine Uptake: Challenges in Shared Clinical Decision-Making and Risk-Based Recommendations* (Mar. 2025), https://perma.cc/T7Y4-G3PM.

[12] Stephanie Soucheray, *Confusion Surrounds CDC's 'Shared Clinical Decision-making' Paradigm for Childhood Vaccines*, CIDRAP (Jan. 6, 2026), https://perma.cc/LZ3N-EG48.

greater and unfamiliar documentation protocols. As a result, some doctors may "shift vaccination to a patient-initiated model" because they may feel it is inappropriate to raise the issue.[13] In sum, as experts recently explained, while SCDM "sounds reasonable, even collaborative[,] [i]t is neither. And it will put children's health and lives at risk."[14]

Amici respectfully submit that the CDC 2026 childhood vaccine changes are unlawful because the agency failed to follow required procedures when it bypassed ACIP. Even if CDC could act without ACIP, these revisions to the Childhood Vaccine Schedule qualify as legislative rules that, under the Administrative Procedure Act ("APA"), must be promulgated through notice-and-comment rulemaking, which did not occur. And while ACIP's traditional notice procedures obviate the need for notice-and-comment following an ACIP recommendation, ACIP did not follow those procedures when it recategorized the COVID-19 and Hepatitis B vaccines. Thus, all of the recommendations violated procedural requirements and must be vacated.

In addition, each of the CDC Vaccine Changes is arbitrary and capricious because CDC disregarded the governing ACIP standard and extensive evidence demonstrating vaccine benefits and safety, and rested its decisions on unreasonable grounds.

ARGUMENT

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

CDC's January 2026 changes to the Childhood Vaccine Schedule are invalid because CDC's decision was not based on a recommendation from ACIP. The APA requires courts to set aside agency action that is "not in accordance with law" or adopted "without observance of

[13] *See supra* Goad, n.2.

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

procedure required by law." 5 U.S.C. § 706(2). Federal law establishes a two-step process for immunization recommendations: ACIP recommends, and the CDC Director decides whether to adopt an ACIP recommendation; only then is a recommendation "in effect." 45 C.F.R. § 147.130(a)(1)(ii). CDC's unilateral revision of the childhood schedule violates that framework.

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."[15] United States Department of Health and Human Services ("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 CDC Director may decline to implement an ACIP recommendation and has done so previously,[16] an ACIP recommendation is a necessary predicate step for any changes to the vaccine schedule.

Moreover, although ACIP was initially created by HHS, Congress has specifically referred to ACIP in a number of federal health statutes, and Congress's definition of ACIP's role confirms that an ACIP recommendation is an essential predicate for government action. Courts have an obligation to interpret related statutes and regulations as part of "'a symmetrical and coherent

[15] ACIP, *ACIP Charter* (Apr. 1, 2024), https://perma.cc/N42Y-3EZ9.

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

regulatory scheme.'" *Mellouli v. Lynch*, 575 U.S. 798, 809-10 (2015) (quoting *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000)). Congress's designation of ACIP—not CDC—as the body that establishes the immunization schedules triggering federal obligations embodies a deliberate choice that forecloses CDC-only action.

1. The Affordable Care Act's Preventive-Services Mandate

The Affordable Care Act ("ACA") requires health plans to cover certain preventive services without cost-sharing, and it specifically names ACIP as the body whose immunization recommendations trigger the coverage obligations. Under the ACA, a health plan's obligation to cover an immunization without cost-sharing arises only when there is "a recommendation from [ACIP]" that is "in effect." 42 U.S.C. § 300gg-13(a)(2). The statute specifically identifies ACIP as the originating body, not CDC.

2. Veterans' Health Benefits

Federal law governing health benefits for veterans follows the same pattern. The relevant statute provides that veterans may receive, as part of their medical benefits, "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 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—not CDC acting alone. If CDC could make changes to the immunization schedule without an initial recommendation by ACIP, it would effectively nullify Congress's directive.

3. Medicaid

Congress also required all state Medicaid programs to cover, without cost-sharing, adult vaccines recommended by ACIP when it enacted the Inflation Reduction Act. *See* Pub. L. No.

117-169, § 11405, 136 Stat. 1900 (2022). The Medicaid statute links coverage to "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

The Vaccines for Children ("VFC") program is another example. To optimize childhood immunization rates among Medicaid enrolled and certain other low-income children, Congress mandated 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). Critically, federal law 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 ACIP—not the Secretary or CDC Director—the role of *establishing* the list and *revising* it.

* * * * *

The consistency of this pattern is significant. Congress repeatedly designated ACIP as the decisionmaker across related immunization statutes governing health insurance coverage, veterans' health benefits, and pediatric vaccines. Congress legislated health entitlements under the assumption that changes to the vaccine schedule would be initiated by ACIP. The Court should interpret these statutes together with HHS regulations establishing ACIP as part of a coherent

regulatory scheme. Vaccine policy begins with ACIP's expert, deliberative process before triggering downstream legal and financial consequences.

B. The Supreme Court's Decision in *Kennedy v. Braidwood Management, Inc.* Confirms That the CDC Director May Not Circumvent the ACIP Process.

The Supreme Court's decision in *Kennedy v. Braidwood Management, Inc.*, 606 U.S. 748 (2025), confirms that ACIP may not be bypassed. *Braidwood* addressed 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.

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 the ACIP as an example of how such advisory-committee processes operate, underscoring 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)).

The plaintiffs in *Braidwood* raised an Appointments Clause challenge, arguing 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 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 because USPSTF recommendations automatically trigger coverage mandates affecting private parties, USPSTF members exercise significant executive authority without adequate supervision, making them principal officers.

The Court rejected that challenge, holding that USPSTF members are inferior officers because the Secretary of HHS (a principal officer) retains sufficient supervisory authority over their work. *Braidwood*, 606 U.S. at 773-76. Critically, the Court's reasoning depended on Congress's two-step advisory-committee structure: USPSTF recommends, but the Secretary can review and block those recommendations before they take effect. *Id*. at 767; *see id*. at 773-75 (analogizing to *United States v. Arthrex*, 594 U.S. 1 (2021), where the remedy for an Appointments Clause violation was to give the Senate-confirmed official Director authority to review the inferior officers' decisions).

Most significantly, the *Braidwood* Court explicitly refused to hold that the HHS Secretary circumvent USPSTF and could initiate a preventive services recommendation by himself, stating 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.

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

Even if CDC could lawfully alter the Childhood Vaccine Schedule without ACIP's recommendation, its changes 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 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, but not to interpretive 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. E.P.A.*, 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 701-02. The decision changes how vaccines are actually administered in clinics and pharmacies—real-world effects that change private parties' behavior.

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.[17]

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

[17] *See supra* Scott, n.14.

information was important in the doctor-patient interaction because it gave doctors an easily understandable way to explain to their patients that a broad scientific consensus supported administration of the vaccine.[18] 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."[19] Indeed, according to CDC, a doctor may choose not to even mention a SCDM vaccine.[20] Many medical providers are unsure how to implement SCDM because the CDC has not provided guidance.[21] The shift to SCDM thus changes doctor-patient discussions, day-to-day workflows, staffing, and paperwork in a real, immediate way.[22]

Moreover, 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.[23]

The effects on private parties' behavior resulting from the change from "routine" to "SCDM" naturally also affect how many children receive vaccines. When a vaccine is no longer routine, the usual tools that drive vaccination—standing orders, checklists, and electronic prompts—drop away.[24] The predictable result is a decline in vaccinations. To take just one

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[18] *Id.*

[19] *See supra* ACIP, n.4.

[20] *Id.*

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

[22] *See supra* Scott, n.14.

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

[24] *Id.*

example, "the PCV13 pneumococcal vaccine saw uptake decline from over 70% to under 60% following SCDM implementation, including among vulnerable and immunocompromised individuals."[25]

Moreover, the conclusion that CDC's recommendation downgrades constitute legislative rules is consistent with how ACIP itself operates. The government has previously taken the position that "ACIP's recommendations comply with notice and comment" as required under 5 U.S.C. § 553.[26] 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.[27] The notices identify the subjects to be discussed and voted upon, and ACIP invites written and oral comments.[28] "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."[29] 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.

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

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[25] *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.

[26] 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.

[27] *Id.*

[28] *Id.*

[29] *Id.*

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.

D. CDC Changes to the COVID and Hepatitis B Vaccines Did Not Comply with ACIP's Own Processes.

The downgrading of the COVID-19 and Hepatitis B recommendations are invalid on a separate procedural ground: ACIP did not follow its own procedural requirements.

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 *Federal Register*," because public comment is "an essential aspect of the Committee's deliberations." CDC, *Advisory Comm. on Immunization Pracs. 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. 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).

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 Manufacturers 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.*

ACIP's actions are governed by its charter, which states that 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."[30]

The three CDC Vaccine Changes are arbitrary and capricious and should be set aside.

[30] *See supra* ACIP, n.15 (emphasis added).

A. Changes to the Childhood Vaccine Schedule.

First, there is no question that the vaccines are safe. The CDC itself states that vaccines are safe, and it has not explained its changed position.[31]

Second, the CDC ignored evidence that the routine childhood vaccines are highly effective. "For most of the vaccine-preventable diseases, there has been a 95 percent or more reduction in incidence."[32] In the 2023-2024 flu season, the pediatric influenza vaccine prevented 4.5 million illnesses among children, 20,000 child hospitalizations, and 266 child deaths globally.[33] Ninety percent of children who die from the flu are unvaccinated, and the declining number of vaccinations due to vaccine skepticism contributed to 289 children dying from flu in the 2024-2025 season, the highest number since CDC started tracking.[34] And prior to routine vaccination, 80% of U.S. children had rotavirus gastroenteritis by age five, and rotavirus was responsible for 30%-50% of all hospitalizations for gastroenteritis among children under five.[35] Additionally, ACIP in 1996 initially recommended the Hepatitis A vaccine only to high-risk populations; but then, recognizing the strategy did not protect all children who later contracted the disease, expanded the recommendation to all children in 2006. By 2011, there was a 96% decrease in

[31] *See*, *e.g.*, *supra* CDC, n.9 (describing HPV vaccine as "safe and effective"); CDC, *Influenza (Flu) Vaccine Safety* (Dec. 20, 2024), https://perma.cc/U8YY-4RTQ ("Hundreds of millions of Americans have safely received flu vaccines for more than 50 years. The body of scientific evidence overwhelmingly supports their safety.").

[32] *See supra* Food & Drug Admin., n.3.

[33] CDC, *Flu Burden Prevented by Vaccination 2023–2024 Flu Season* (Jan. 14, 2025), https://perma.cc/7W6X-9XBJ.

[34] Melissa Jenco, *CDC: 9 Children Have Died of Flu This Season; Previous Season Sets Record*, AAP News (Jan. 6, 2026), https://perma.cc/PWQ7-BK7E; Reinhart, K. et al., *Influenza-Associated Pediatric Deaths — United States, 2024–25 Influenza Season*, 74 Morbidity and Mortality Wkly. Report 565 (Sept. 25, 2025), https://perma.cc/73X4-D5NL.

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

Hepatitis A infections. Between 1994 and 2023, the Hepatitis A vaccine has averted an estimated 1,500 deaths, 78,000 hospitalizations, and 4 million illnesses.

Third, the CDC ignored the serious adverse consequences for immuno-compromised individuals, who make up approximately 6.6% of the population or one in 15 people, and depend on people receiving routine vaccinations so that the overall population achieves herd immunity.[36] "Without vaccination, herd immunity might only be achieved if a very large number of people get sick—and potentially die—very quickly."[37] Attending school or doctor's appointments will become dangerous for immunocompromised people.[38]

Fourth, the CDC's reasoning is "implausible." *State Farm Mut. Auto. Ins. Co.,* 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"[39] and (2) a January 5, 2026, decision memoranda from the Acting Director for the CDC.[40] For three reasons, the justifications are implausible.

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[36] 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; Melissa L. Martinson & Jessica Lapham, *Prevalence of Immunosuppression Among US Adults*, National Library of Medicine (2024), https://perma.cc/6N7Q-4XJD; Cleveland Clinic, *Herd Immunity*, MyClevelandClinic.org (medically reviewed) (Oct. 20, 2025), https://perma.cc/NTU3-GZAL.

[37] *See supra* Cleveland Clinic, n.36.

[38] 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.

[39] 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.

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

To begin with, the memoranda focused on purported "peer nations,"[41] which is not a factor in the ACIP charter. *See* above at p. 14. But 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, and Australasia.[42] Now, the pared-down U.S. vaccine schedule protects children against fewer diseases than 19 of the 20 "peer countries."[43] 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. "Denmark has 6 million people, a homogeneous population, universal healthcare with guaranteed rapid access, and a robust public health infrastructure" and health records automatically link maternal and infant health records, "ensuring virtually zero loss to follow-up."[44] In contrast, "[t]he United States has 330 million people, profound health disparities, 27 million uninsured, and a fragmented system."[45] Moreover, Denmark is "an outlier among wealthy nations, not a model."[46]

Next, the memoranda cite low-vaccination uptake and distrust. But they do not explain how changing many vaccines to SCDM will increase trust. To the contrary, SCDM "signal[s] uncertainty where none exists" and introduces confusion.[47] Already, doctors report patients and

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[41] *Id.*

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

[43] *Id.*

[44] *See supra* Scott, n.14.

[45] *Id.*

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

[47] *See supra*, Scott n.14.

parents are showing greater distrust of vaccines.[48] And "[w]hen parents are uncertain, many delay. Some opt out entirely. And as vaccination rates fall, preventable diseases return."[49]

Finally, and counter-intuitively, the memoranda rely on the very success of the routine childhood vaccine schedule. The January 5 decision memoranda notes that the number of meningococcal and Hepatitis A infections are low.[50] But the number of infections is low *because of routine childhood vaccines*. By one estimate meningococcal disease incidence would have been at least 59% higher than reported from 2005 to 2021.[51] The same memorandum notes that Hepatitis A mortality is highest among older men. This is unsurprising *because* the routine status of the Hepatitis A vaccine resulted in vaccination of the vast majority of children born since 1996.[52]

B. Changes to the COVID-19 vaccine recommendation.

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."[53] Numerous studies have

[48] *See*, *e.g.*, Fourth Amended Compl. ¶¶ 141-142. Jade Cobern, *Some Pediatricians Are Already Seeing Negative Effects of Changing Vaccine Recommendations*, ABC News (Jan. 7, 2026), https://perma.cc/HXB8-YW7U.

[49] Michael T. Osterholm & Sarah Despres, *COMMENTARY: When Confusion Replaces Clarity About Vaccines, Children Pay the Price*, CIDRAP (Jan. 21, 2026), https://perma.cc/23Q5-E7GK.

[50] *See supra* U.S. Dep't of Health & Human Servs., n.40. As of January 22, the United States is no longer a member of the World Health Organization.

[51] Kate Yandell & Jessica McDonald, *The Facts on the Vaccines the CDC No Longer Recommends for All Kids*, FactCheck.org (Jan. 15, 2026), https://perma.cc/HW2Y-D655.

[52] *Hepatitis A Vaccination Coverage Among U.S. Children Aged 12–23 Months — Immunization Information System Sentinel Sites, 2006–2009*, 59 Morbidity and Mortality Wkly. Report 776, 776–79 (July 2, 2010), https://perma.cc/DQY6-MCHW.

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

shown the vaccine is safe.[54] Evidence that HHS provided to justify removal of the routine pediatric COVID-19 vaccine from the immunization schedule has been debunked by numerous authors.[55]

C. Changes to the Hepatitis B vaccine recommendation.

First, the CDC ignored evidence that the routine Hepatitis B vaccine is safe.[56] *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.[57] In 2021 and 2022, the U.S. reported only 17 and 13 cases of perinatal Hepatitis B, respectively.[58] Before the first Hepatitis B vaccine was available in the United States, an estimated 20,000 children were infected annually.[59] 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.[60] Between 1994 and 2023, routinely administering the pediatric Hepatitis B vaccine

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[54] 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.

[55] 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.

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

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

[58] 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.

[59] *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.

[60] *Id.*

averted an estimated 90,100 deaths, 940,000 hospitalizations, and six million illnesses.[61] 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 (approximately 54,000) are not screened.[62] For those who test positive, only 35% receive recommended follow-up care.[63] A mother can become infected after her test, or a child can be infected from another adult.[64] Thus, tying the vaccine to a maternal test will leave many children vulnerable to Hepatitis B, which has no cure.[65]

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 Mut. Auto. Ins. Co.*, 463 U.S. at 43. They are arbitrary and capricious.

CONCLUSION

This Court should grant Plaintiffs' motion for preliminary injunctive and declaratory relief.

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[61] *See supra* Zhou, n.2.

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

[63] *See supra* Scott, n.14.

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

[65] Cleveland Clinic**,** *Hepatitis B: What It Is, Symptoms, Transmission & Treatment* (Feb. 8, 2025), https://perma.cc/E4H7-SCPS.

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