

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF
PEDIATRICS, *et al.*,

Plaintiffs,

v.

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

Defendants.

CIVIL ACTION NO.: 1:25-CV-11916

**UNOPPOSED MOTION FOR LEAVE TO FILE BRIEF OF *AMICI CURIAE*
ROBERT WOOD JOHNSON FOUNDATION, AMERICAN ACADEMY OF ALLERGY,
ASTHMA & IMMUNOLOGY, AMERICAN COLLEGE OF CHEST PHYSICIANS,
AMERICAN THORACIC SOCIETY, NETWORK FOR PUBLIC HEALTH LAW, AND
119 DEANS, CHAIRS, AND PUBLIC HEALTH AND HEALTH POLICY SCHOLARS
IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION**

Amici Robert Wood Johnson Foundation, American Academy of Allergy, Asthma & Immunology, American College of Chest Physicians, American Thoracic Society, Network for Public Health Law, and 119 Deans, Chairs, and Public Health and Health Policy Scholars¹ respectfully move for leave to file a brief as *Amici Curiae* in support of Plaintiffs. The proposed brief is attached as **Exhibit A**. Plaintiffs have consented to *Amici*'s motion. Defendants do not oppose this motion.

¹ A complete list of the *Amici* is provided in Appendix A to the brief.

This Court retains “inherent authority” to approve the filing of *amicus* briefs. *Students for Fair Admissions v. President & Fellows of Harvard Coll.*, 2018 WL 9963511 (D. Mass. Oct. 3, 2018).

This action challenges Defendants’ changes to the pediatric vaccine schedule, which have reduced the number of vaccines the Advisory Committee on Immunization Practices (“ACIP”) and the Centers for Disease Control (“CDC”) recommend for children on a routine basis. Defendants made these disruptive changes without considering the overwhelming science or following ACIP’s longstanding procedural safeguards. Defendants’ actions will depress vaccination rates and cause increased vaccine-preventable outbreaks, preventable hospitalizations, and unnecessary deaths. Medically underserved communities and the safety-net providers who serve them will disproportionately suffer the consequences.

Amici are public health organizations and individual public health deans and scholars. The organizational *Amici* include the American Academy of Allergy, Asthma & Immunology, American College of Chest Physicians, American Thoracic Society, Network for Public Health Law, and the Robert Wood Johnson Foundation. These organizations collectively advocate for public health law and policy to make communities safer and are committed to improving health equity in the United States. The individual *Amici* are a group of 119 distinguished deans and professors of various health disciplines, law, and policy with extensive expertise in the issues presented in this brief—specifically in policies promoting population health and the alleviation of barriers to health care. *Amici* believe that providing their perspective on the issues presented in their brief will assist the Court in resolving this action.

The *Amici* submit their brief to further inform the Court’s analysis on three points: (1) there is strong scientific evidence of safety, efficacy, and public health benefits of the subject vaccines;

(2) Defendants' changes to the pediatric vaccine schedule will significantly reduce pediatric vaccination rates, endangering millions of children and threatening to undo decades of progress in avoidance of serious diseases; and (3) these policy changes threaten public health and affect not only children but providers, parents, state and local governments and the public at large.

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. Additionally, although the Court's Local Rules do not provide instructions about the length of an acceptable *amicus curiae* brief, *Amici* were guided by 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 proposed 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.

Respectfully submitted,

Dated: February 6, 2026

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CERTIFICATE OF COMPLIANCE WITH LOCAL RULE 7.1

I hereby certify that counsel for *Amici Curiae* conferred with counsel for the parties regarding this motion. Plaintiffs consent to the motion and the filing of this brief. Defendants do not oppose the motion.

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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 6, 2026

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EXHIBIT A

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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PHYSICIANS, AMERICAN THORACIC SOCIETY, NETWORK FOR PUBLIC
HEALTH LAW, AND 119 DEANS, CHAIRS, AND PUBLIC HEALTH AND HEALTH
POLICY SCHOLARS AS AMICI CURIAE IN SUPPORT OF
PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION**

CORPORATE DICLOSURE STATEMENT

Pursuant to Federal Rule of Civil Procedure 7.1, Amici Robert Wood Johnson Foundation, American Academy of Allergy, Asthma & Immunology, American College of Chest Physicians, American Thoracic Society, and Network for Public Health Law hereby state as follows:

Each Amici Curiae has no parent corporation and no publicly traded company owns 10% or more of its stock.

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INTEREST OF THE AMICI CURIAE¹

Amici public health organizations include the Robert Wood Johnson Foundation, American Academy of Allergy, Asthma & Immunology, American College of Chest Physicians, American Thoracic Society, and Network for Public Health Law. *Amici* collectively advocate for the power of public health law and policy to make communities safer and are committed to improving health equity in the United States.

The individual *Amici* are a group of 119 distinguished deans and professors of various health disciplines, law, and policy with extensive expertise in the issues presented in this brief—specifically in policies promoting population health and the alleviation of barriers to health care. Individual *Amici* are identified in Appendix A and joining in their personal and individual capacities, not as representatives of their respective institutions. With decades of experience among them, *Amici* are well positioned to opine on and place in proper context the consequences of the action at issue in this case.

Amici collectively file this brief to assist the Court in its consideration of the consequences of undermining both the Advisory Committee on Immunization Practices (“ACIP”) and the routine pediatric vaccination schedule as it existed prior to September 2025.

INTRODUCTION

Since May 2025, Defendants have taken a series of actions that reduce the number of vaccines the Advisory Committee on Immunization Practices (“ACIP”) and the Centers for Disease Control and Prevention (“CDC”) recommend for children on a routine basis without identifying any changes to the science underlying prior policy. Vaccines for Hepatitis B, Hepatitis

¹ Neither a party nor counsel to this lawsuit authored this brief in whole or in part, and no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than the *amici curiae* or their counsel made a monetary contribution to this brief’s preparation or submission.

A, Meningococcal diseases, Rotavirus, Influenza, and COVID-19 are no longer recommended for routine use in children. While some are now recommended for a narrower group of children based on risk and other factors, for most children these vaccines are now subject to the Shared Clinical Decision-Making (“SCDM”) framework. Defendants also removed certain vaccine doses previously on the routine vaccine schedule and limited age ranges for particular vaccine recommendations. We refer to these actions collectively as the “Routine Vaccination Changes.”

When ACIP and the CDC designate a vaccine as SCDM, it is “not recommended for everyone in a particular age group or everyone in an identifiable risk group,” but instead is recommended based on an individualized decision-making process between the health care provider and patient or parent/guardian.² CDC’s own website states that “ACIP makes shared clinical decision-making recommendations when individuals may benefit from vaccination, but broad vaccination of people in that group is unlikely to have population-level impacts”³ and vaccines with SCDM recommendations provide “no or minimal benefits” to the general population.⁴

The public health difference between placing a vaccine on the routine schedule and SCDM is stark. Placing a vaccine on the routine schedule does not create a mandate, but the routine schedule ensures that immunizations will be part of the preventive standard of practice for children and the default approach. SCDM has the opposite effect. The evidence shows that SCDM depresses acceptance and, ultimately, the rate of vaccine administration.⁵ Dr. Paul Offit, one of the nation’s leading vaccine experts, explains the distinction succinctly: “Shared clinical decision-

² Centers for Disease Control and Prevention, *ACIP Shared Clinical Decision-Making Recommendations* (Jan. 7, 2025), <https://www.cdc.gov/acip/vaccine-recommendations/shared-clinical-decision-making.html>.

³ *See id.*

⁴ *See id.*

⁵ *See Section II, infra.*

making means you can *perfectly reasonably* choose not to get [a vaccine], whereas the recommendation means you *should be getting this because [your child is] at higher risk.*⁶

Both the scope and substance of Defendants' actions are unprecedented and unfounded. ACIP and the CDC rarely make SCDM recommendations, particularly after a vaccine has a routine recommendation.⁷ Prior to the Routine Vaccination Changes, only four vaccines were designated to SCDM and none were for young children.⁸ And the evidence is clear: the population-level benefits of the impacted vaccines are substantial. Defendants abruptly altered the routine pediatric vaccination schedule without considering the overwhelming science or following ACIP's longstanding procedural safeguards—deliberations would have required ACIP to confront the evidence it ignored when making these changes. As Dr. Peter Hotez, a world-renowned vaccinologist and Dean of the National School of Tropical Medicine at the Baylor University School of Medicine, writes, consigning safe and effective vaccines to a SCDM framework suggests “an all-out effort to undermine public confidence in vaccines and immunizations.”⁹

Defendants' actions will depress vaccination rates and cause increased vaccine-preventable outbreaks, preventable hospitalizations, and unnecessary deaths. These harms to both individual and public health are urgent and will be irreparable. More, the burden of the Routine Vaccine Changes will fall hardest on medically underserved communities, who heavily depend on public

⁶ Nyah Phengsithy, *Vaccine Panel Risks Confusion on Pregnancy Covid Shot Move*, Bloomberg Law (Oct. 9, 2025, 7:13 PM EDT), <https://news.bloomberglaw.com/health-law-and-business/vaccine-panel-risks-confusion-with-flip-on-pregnancy-covid-shot>.

⁷ Centers for Disease Control and Prevention, *ACIP Shared Clinical Decision-Making Recommendations* (Jan. 7, 2025), <https://www.cdc.gov/acip/vaccine-recommendations/shared-clinical-decision-making.html>.

⁸ Hepatitis B vaccination for adults aged 60 years or older; HPV vaccination for adults aged 27 to 45 years; Meningococcal B (MenB) vaccine for those 16 to 23 years of age, and Pneumococcal conjugate vaccine in a subgroup of adults 65 years of age and older. *See id.*

⁹ Hotez, Peter, et al., *Reaffirming Scientific Medicine through Physician Leadership in Health Care Technology and Innovation*, Rice University's Baker Institute for Public Policy (2025), <https://www.bakerinstitute.org/sites/default/files/2025-10/10292015-Hotez-Reaffirming%20Scientific%20Medicine-Working%20Paper.pdf>.

health clinics and pharmacies whose authority to vaccinate tends to be limited to routine vaccines.¹⁰

This Court should grant the Plaintiffs' motion for a preliminary injunction for the reasons described in Plaintiffs' memorandum. The *Amici* submit this brief to further inform the Court's analysis on three points: (1) there is strong scientific evidence of safety, efficacy, and public health benefits of the subject vaccines; (2) the Routine Vaccination Changes will significantly reduce pediatric vaccination rates, endangering millions of children and threatening to undo decades of progress in avoidance of serious diseases; and (3) the Routine Vaccination Changes threaten public health and affect not only children but providers, parents, state and local governments and the public at large. Defendants ignored this data in adopting the Routine Vaccination Changes, highlighting the arbitrary and capricious nature of the policy. *See Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

ARGUMENT

I. The Routine Vaccination Changes Ignore the Substantial Scientific Evidence.

Vaccines are one of the greatest achievements in science, public health, and modern medicine.¹¹ The enormous health and economic benefits of vaccines, especially for children, are well-documented. Pediatric vaccines save millions of lives, prevent millions of cases of hospitalization and illness, and have saved trillions of dollars. Among U.S. children born between 1994–2023, routine childhood vaccinations will have prevented approximately 508 million cases

¹⁰ U.S. Dept. Health and Human Services, Office of Disease Prevention and Health Promotion, *Access to Primary Care*, <https://odphp.health.gov/healthypeople/priority-areas/social-determinants-health/literature-summaries/access-primary-care> (last visited Jan. 30, 2026).

¹¹ Amanna IJ, Slifka MK, *Successful Vaccines*, Curr Top Microbiol Immunol., 2020;428:1-30, doi: 10.1007/82_2018_102.

of illness, 32 million hospitalizations, and over 1.1 million deaths.¹² The associated cost savings include \$540 billion in reduced medical expenditures and \$2.7 trillion in societal savings, like increased workforce productivity made possible by preventing illnesses and death.¹³ In 2011, the CDC lauded vaccination (and reductions in vaccine-preventable diseases) as one of the country's "top 10 public health achievements" of the 20th and 21st centuries.¹⁴ The CDC's adoption of the pediatric vaccine schedule has been critical to promoting widespread access and adoption to this lifesaving preventative care.

Defendants have upended the longstanding routine pediatric immunization schedule by forgoing the extensive research on which the schedule rests,¹⁵ abandoning the evidence-based deliberation process that has long guided ACIP's work, and, as a result, disregarding the weight of the evidence concerning the Routine Vaccination Changes. *See Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 106 (2015) ("[T]he APA requires an agency to provide more substantial justification when 'its new policy rests upon factual findings that contradict those which underlay its prior policy; or when its prior policy has engendered serious reliance interests that must be taken into account. It would be arbitrary or capricious to ignore such matters.'") (citations omitted). The efficacy in controlling vaccine-preventable disease in the U.S. for each of the vaccines affected is supported

¹² Zhou F, Jatlaoui TC, Leidner AJ, et al, *Health and Economic Benefits of Routine Childhood Immunizations in the Era of the Vaccines for Children Program — United States, 1994–2023*, MMWR Morb Mortal Wkly Rep 2024;73:682–685. DOI: <http://dx.doi.org/10.15585/mmwr.mm7331a2>.

¹³ *Id.* Previous studies (looking at a slightly narrower 1994–2013 cohort) found a similar impact. Whitney CG, Zhou F, Singleton J, Schuchat A, *Benefits from Immunization During the Vaccines for Children Program Era — United States, 1994–2013*, MMWR. April 25, 2014 / 63(16);352-355, <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6316a4.htm>

¹⁴ Centers for Disease Control and Prevention, *Domestic Public Health Achievements Team, Ten Great Public Health Achievements – United States, 2001–2010*, MMWR Morb Mortal Wkly Rep 2011 May 20; 60(19): 619-623, <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6019a5.htm>.

¹⁵ Centers for Disease Control and Prevention, ACIP, *Evidence to Recommendations Frameworks*, <https://www.cdc.gov/acip/evidence-to-recommendations/index.html>.

by robust clinical evidence.¹⁶ We discuss each in turn, with a particular focus on the recommendations for newborn Hepatitis B vaccination, which presents a particularly poignant example of Defendants sudden departure from past policy and failure to consider the overwhelming scientific support for widespread vaccination.

A. Defendants' Withdrawal of the Prior Recommendation for Universal Newborn Hepatitis B Immunization Illustrates their Failure to Act on Evidence.

Hepatitis B is one of the most contagious and serious illnesses a young child can experience. Prevention of Hepatitis B infection in infants is essential: when infants are infected at or around birth, 90% develop chronic, lifelong infection, and 25% will die from cirrhosis or liver cancer.¹⁷ Further, the Hepatitis B virus poses particular risks for impoverished and historically underserved children such as American Indian and Alaska Native children and Asian and Pacific Islander children.¹⁸

The impact of routine pediatric Hepatitis B immunization has been profound. Between 1994-2023, routine pediatric vaccines averted: 90,100 deaths; 940,000 hospitalizations; and 6

¹⁶ Mandavilli, Apoorva, *Rejecting Decades of Science, Vaccine Panel Chair Says Polio and Other Shots Should be Optional*, N.Y. Times, Jan. 23, 2026, at A1. <https://www.nytimes.com/2026/01/23/health/milhoan-vaccines-optional-polio.html>.

¹⁷ Scott, Jake, MD, CIDRAP Op-Ed: *Quiet Dismantling: How 'Shared Decision-making' Weakens Vaccine Policy and Harms Kids*, University of Minnesota CIDRAP (Jan. 6, 2026), <https://www.cidrap.umn.edu/childhood-vaccines/cidrap-op-ed-quiet-dismantling-how-shared-decision-making-weakens-vaccine-policy>.

¹⁸ Ayers JW, et al., *Hepatitis B vaccination prevalence and its predictors among Asian, Pacific Islander, Native American, and multiracial adults in the National Health and Nutrition Examination Survey*. J Immigr Minor Health. 2010 Dec;12(6):847-52. <https://pmc.ncbi.nlm.nih.gov/articles/PMC5508214/>. Asian and Pacific Islanders account for nearly half of all hepatitis b infections, while infection rates among Native Americans are infected at almost twice the rate as Anglo Americans. American Indian and Alaska Native populations are significantly more likely to be impoverished and significantly more likely to reside in communities isolated from medically necessary health care. See The Independent Source for Health Policy, *Poverty Rate by Race/Ethnicity*, KFF (2024), <https://www.kff.org/state-health-policy-data/state-indicator/poverty-rate-by-raceethnicity/?currentTimeframe=0&sortModel=%7B%22colld%22%22Location%22%22sort%22%22asc%22%7D>. See also U.S. Dept. Health and Human Services, Office of Minority Health, *Viral Hepatitis and American Indians/Alaska Natives*, <https://minorityhealth.hhs.gov/hepatitis-and-american-indiansalaska-natives>.

million illnesses.¹⁹ Between 1991-2019, the universal Hepatitis B birth dose helped cut infections in children and adolescents by 99%, preventing cirrhosis, liver cancer, and death over their lifetime.²⁰

Initially, the ACIP recommended the Hepatitis B vaccine only for “high risk” pediatric populations (i.e., babies born to mothers infected with Hepatitis B).²¹ But between 1981 and 1990 the nation experienced an exponential increase in Hepatitis B transmission (i.e., 200,000-300,000 new cases annually), whose sequelae included liver failure, cancer, and high death rates.²² To close this gap, the ACIP recommended a universal infant immunization schedule, with a recommended three-dose schedule, which was adopted by the CDC in 1991.²³

¹⁹ Zhou F, Jatlaoui TC, Leidner AJ, et al. Health and Economic Benefits of Routine Childhood Immunizations in the Era of the Vaccines for Children Program — United States, 1994–2023. MMWR Morb Mortal Wkly Rep 2024;73:682–685. DOI: <http://dx.doi.org/10.15585/mmwr.mm7331a2>

²⁰ Bixler D, Roberts H, Panagiotakopoulos L, Nelson NP, Spradling PR, Teshale EH. *Progress and Unfinished Business: Hepatitis B in the United States, 1980-2019*. Public Health Reports®. 2023;0(0). doi:10.1177/00333549231175548

²¹ Szabo, Liz, MA, *Vaccinating Newborns Against Hepatitis B Saves Lives. Why Might a CDC Panel Stop Recommending It?*, University of Minnesota CIDRAP (Dec. 3, 2025), <https://www.cidrap.umn.edu/childhood-vaccines/vaccinating-newborns-against-hepatitis-b-saves-lives-why-might-cdc-panel-stop#:~:text=A%2099%25%20drop%20in%20hepatitis,on%20Immunization%20Practices%20>.

²² Centers for Disease Control and Prevention, Immunization Practices Advisory Committee, *Hepatitis B Virus: A Comprehensive Strategy for Eliminating Transmission in the United States through Universal Childhood Vaccination: Recommendations of the Immunization Practices Advisory Committee (ACIP)*. MMWR Morb Mortal Wkly Rep 1991; 40(RR-13); 1-19; <https://www.cdc.gov/mmwr/preview/mmwrhtml/00033405.htm>.

²³ *Id.* See also APHA and Public Health Deans and Scholars’ Comments on the Centers for Disease Control and Prevention Notice announcing the meeting of the Advisory Committee on Immunization Practices (Docket ID: CDC-2025-0783-0001) (November 20, 2025),

[https://hpmmatters.publichealth.gwu.edu/sites/g/files/zaxdzs6671/files/2025-11/CDC_ACIP%20Hep%20B%20Public%20Comment%20Letter\(FILED%20112025.pdf](https://hpmmatters.publichealth.gwu.edu/sites/g/files/zaxdzs6671/files/2025-11/CDC_ACIP%20Hep%20B%20Public%20Comment%20Letter(FILED%20112025.pdf). In describing why only recommending the Hep B vaccine to only “high risk” infants wasn’t working, ACIP stated, “[T]his strategy has not lowered the incidence of hepatitis B, primarily because vaccinating persons engaged in high-risk behaviors, life-styles, or occupations before they become infected generally has not been feasible. In addition, many infected persons have no identifiable source for their infections and thus cannot be targeted for vaccination.” Schillie S, Vellozzi C, Reingold A, et al. Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices. MMWR Recomm Rep 2018;67(No. RR-1):1–31. DOI: <http://dx.doi.org/10.15585/mmwr.rr6701a1>.

In adopting the routine recommendation, the CDC published a landmark, exhaustive review in their scientific journal,²⁴ known as MMWR, detailing the scientific rationale for adopting universal Hepatitis B newborn immunization as a routine standard of care. The study found that the non-routine approach to Hepatitis B vaccination failed because selective screening could not reliably identify every infant at risk, as infected expectant mothers were frequently not screened for the virus and 35% to 65% of infected mothers had no identifiable risk factors, and thus testing during pregnancy failed to identify approximately 22,000 infected mothers annually.²⁵ Furthermore, in certain immigrant communities with endemic Hepatitis B, “children born to HBsAg-negative immigrant mothers are still at high risk of acquiring HBV infection, usually from other HBV carriers in their families or communities.”²⁶

In other words, universal pregnancy testing – without universal vaccination – left thousands of newborns unprotected. ACIP concluded that “HBV transmission cannot be prevented through vaccinating only the groups at high risk of infection. No current medical treatment will reliably eliminate chronic HBV infection and thus eliminate the source of new infections in susceptible persons.”²⁷ At the same time, although evidence was limited, ACIP found that “there is no apparent risk of adverse effects to developing fetuses when hepatitis B vaccine is administered to pregnant women,”²⁸ nor was there evidence of safety problems for infants. Over the ensuing decades, the safety of the Hepatitis B vaccine has been borne out. For example, according to a study conducted by the Vaccine Integrity Project at the University of Minnesota found that research, including “randomized trials, large national safety monitoring programs, and long-term follow-up studies,”

²⁴ Centers for Disease Control and Prevention, *Immunization Practices Advisory Committee, Hepatitis B Virus: A Comprehensive Strategy for Eliminating Transmission in the United States through Universal Childhood Vaccination: Recommendations of the Immunization Practices Advisory Committee (ACIP)*, *supra* n. 23.

²⁵ *Id.*

²⁶ *Id.*

²⁷ *Id.*

²⁸ *Id.*

consistently demonstrate the safety of the Hepatitis B vaccine regardless of vaccine timing. Further, “[n]o safety benefits were identified for a delayed first dose versus vaccination at birth.”²⁹

What makes the Hepatitis B case so extraordinary is the ease with which Defendants seemingly swept this work away. In a matter of weeks, Defendants’ actions dismantled the recommendation, replacing the policy with essentially the same discredited policy replaced in 1991. In contrast to the thorough assessment on which the 1991 policy rested, the 2025 vote to end the recommendation for universal immunization was accompanied by a mere 450-word factsheet filled with inaccurate statements unsupported by evidence. For example, the fact sheet trumpeted the “high reliability” of prenatal screening, while ignoring the problem of extremely low prenatal screening rates. Further, Defendants asserted the “very low rate” of perinatal transmission, but failed to account for the fact that such transmission is no longer closely measured because of the success of universal newborn immunization.

In order to accomplish their political objective to create “flexibility” in pediatric vaccination, Defendants turned a blind eye to the overwhelming evidence in favor of universal protection and the complete lack of evidence suggesting any change in risk since the 1991 recommendations were made.³⁰ This failure to consider evidence and rationally explain departures from past policy is quintessential arbitrary and capricious decision-making, precluded by the Administrative Procedure Act. *See Perez*, 575 U.S. at 105-106; *FDA v. Wages & White Lion Invs.*, L.L.C., 604 U.S. 542, 570 (2025) (when evaluating whether change in procedure is arbitrary and

²⁹ Center for Infectious Disease Research and Policy, University of Minnesota, *Universal Hepatitis B Vaccination at Birth: Safety, Effectiveness, and Public Health Impact* (Dec. 2, 2025), <https://www.cidrap.umn.edu/sites/default/files/searchable-download/Universal%20Hepatitis%20B%20Vaccination%20at%20Birth%20Dec2025.pdf>.

³⁰ Centers for Disease Control and Prevention, *Fact Sheet Hepatitis B Immunization* (Dec. 16, 2025), <https://www.cdc.gov/media/releases/2025/fact-sheet-hepatitis-b-immunization.html>.

capricious, courts ask: “Did the agency ‘display awareness that it *is* changing position’ and offer ‘good reasons for the new policy’?”).

B. The Public Health Benefits of the Other Affected Vaccines Are Equally Profuse

Hepatitis A. Hepatitis A infection in children can cause fever, jaundice, loss of appetite, diarrhea, and nausea, which can lead to malnutrition.³¹ While most individuals recover, 10-15% of infected individuals have prolonged or relapsing symptoms, and remain infectious for over 6-9 months.³² Severe complications can include acute liver failure and are more commonly seen in those who are immunocompromised or have underlying liver disease.³³

The pediatric Hepatitis A vaccine was introduced to the ACIP routine immunization schedule in 1996 for “high-risk” geographic areas. Following the successful reduction of pediatric infections after this initial recommendation,³⁴ ACIP extended the recommendation to “all areas” in 2006.³⁵ Scientific estimates have concluded that between 1994-2023, the pediatric Hepatitis A vaccine averted: 1,500 deaths; 78,000 hospitalizations, and 4 million illnesses.³⁶ Following the

³¹ World Health Organization, *Hepatitis A Fact Sheet* (Feb. 12, 2025), <https://www.who.int/news-room/fact-sheets/detail/hepatitis-a>

³² Centers for Disease Control and Prevention, *Yellow Book – Hepatitis A* (Apr. 23, 2025). <https://www.cdc.gov/travel/destinations/traveler/none/hepatitis-a.html>

³³ Nelson, Noe P., et al., *Prevention of Hepatitis A Virus Infection in the United States: Recommendations of the Advisory Committee On Immunization Practices, 2020*, MMWR Recomm Rep. 2020 Jul 3; 69(5):1-38. <https://pmc.ncbi.nlm.nih.gov/articles/PMC8631741/>

³⁴ Fiore, Anthony E. et al, *Prevention of Hepatitis A through Active or Passive Immunization – Recommendations of the Advisory Committee on Immunization Practices (ACIP)*, MMWR Recomm Rep. May 19, 2006; 55(RR07); 1-23. <https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5507a1.htm>

³⁵ *Id.*

³⁶ Zhou F, Jatlaoui TC, Leidner AJ, et al. Health and Economic Benefits of Routine Childhood Immunizations in the Era of the Vaccines for Children Program — United States, 1994–2023. MMWR Morb Mortal Wkly Rep 2024;73:682–685. DOI: <http://dx.doi.org/10.15585/mmwr.mm7331a2>

2006 modification specifically, Hepatitis A infection reached a historic low,³⁷ and the increase in vaccinations caused a 96% decrease in Hep A infections by 2011.³⁸

Meningococcal Disease. Protection against meningococcal disease is essential because the disease is often deadly and can cause lifelong complications among those who survive. Even among those who obtain treatment, 10-15% of those with the disease will die.³⁹ Without rapid treatment, fatality rates can be even higher.⁴⁰ Of those who survive the disease, 1 in 5 may suffer serious and permanent complications, including brain and nervous system damage, kidney damage, hearing loss, and amputation of the arms, legs, fingers, and toes.⁴¹

After the ACIP introduced the pediatric meningococcal vaccine to the routine immunization schedule in 2005, the incidence of meningococcal disease declined significantly in vaccinated adolescent age groups, with the greatest decline occurring in states in which vaccination rates against the disease reached the highest levels.⁴² Between 2005-2021, the vaccine prevented an estimated 500 cases of the disease and 54 deaths among individuals aged 11 to 23. Without vaccination, incidence of the disease between 2005-2021 would have been 59% higher than reported during the vaccine era.⁴³

³⁷ Centers for Disease Control and Prevention, *Hepatitis Vaccination Coverage Among U.S. Children Aged 12-23 Months – Immunization Information System Sentinel Sites, 2006-2009*. MMWR Morb Mortal Wkly Rep July 2, 2010; 59(25); 776-779. <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5925a3.htm>

³⁸ Centers for Disease Control and Prevention, *Prevention of Hepatitis A Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices*, 2020. MMWR Morb Mortal Wkly Rep July 3, 2020; 69(5); 1-38. <https://www.cdc.gov/mmwr/volumes/69/rr/rr6905a1.htm>.

³⁹ Centers for Disease Control and Prevention, *Meningococcal Disease Symptoms and Complications* (Sept. 26, 2025), <https://www.cdc.gov/meningococcal/symptoms/index.html>

⁴⁰ Centers for Disease Control and Prevention, *Yellow Book – Meningococcal Disease* (Apr. 23, 2025), <https://www.cdc.gov/travel/travel-associated-infections-diseases/meningococcal-disease.html>

⁴¹ National Foundation for Infectious Diseases, *Meningococcal Disease*, <https://www.nfid.org/infectious-disease/meningococcal/>.

⁴² Mbaeyi S, Pondo T, Blain A, et al., *Incidence of Meningococcal Disease Before and After Implementation of Quadrivalent Meningococcal Conjugate Vaccine in the United States*. JAMA Pediatr. Vol. 174(9):843–851. July 20, 2020, <https://jamanetwork.com/journals/jamapediatrics/fullarticle/2768552>.

⁴³ Shin T, Wells CR, Shoukat A, et al., *Quadrivalent Conjugate Vaccine and Invasive Meningococcal Disease in US Adolescents and Young Adults*, JAMA Netw Open. Vol. 7(11) Nov. 6, 2024, <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2825811>.

Rotavirus. In severe cases, rotavirus can manifest as severe diarrhea with vomiting and fever that can result in dehydration with shock, electrolyte imbalance, and death.⁴⁴ Those who are immunocompromised can experience severe or prolonged rotavirus gastroenteritis and resulting abnormalities in multiple organ systems, with a focus on the kidney, liver, and intestines.⁴⁵

Prior to routine vaccination, 80% of U.S. children had rotavirus gastroenteritis by age 5,⁴⁶ and rotavirus was responsible for 30%-50% of all hospitalizations for gastroenteritis among children under 5.⁴⁷ The pediatric rotavirus vaccine was added to the ACIP routine immunization schedule in 2006. Between 1994-2023, the pediatric rotavirus vaccine averted: 400 deaths; 819,000 hospitalizations; and 30.2 million illnesses.⁴⁸ Experts say that rotavirus will resurge quickly if coverage rates fall.⁴⁹

Influenza. Influenza can lead to severe illness and death in children. The ACIP introduced the pediatric flu vaccine to the routine immunization schedule in 2002 for children ages 6-23 months, leading to a universal annual flu vaccination recommendation for everyone 6 months and older by 2010.

⁴⁴ Cortese, M et al., *Prevention of Rotavirus Gastroenteritis Among Infants and Children Recommendations of the Advisory Committee on Immunization Practices (ACIP)*, MMWR Morb Mortal Wkly Rep February 6, 2009; 58(RR02); 1-25. <https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5802a1.htm>.

⁴⁵ Cortese, M. et al., *Chapter 19: Rotavirus*, Centers for Disease Control and Prevention, Pink Book (Apr. 25, 2024), <https://www.cdc.gov/pinkbook/hcp/table-of-contents/chapter-19-rotavirus.html>; Bruijning-Verhagen, P., et al. *Rotavirus Disease Course Among Immunocompromised Patients; 5-year Observations from a Tertiary Care medical Centre*, Journal of Infection, Nov. 01, 2017, vol. 75, issue 5, 448-454, <https://www.clinicalkey.com/#!/content/playContent/1-s2.0-S0163445317302633?returnurl=https%3A%2F%2Flinkinghub.elsevier.com%2Fretrieve%2Fpii%2FS0163445317302633%3Fshowall%3Dtrue&referrer=https%3A%2F%2Fpubmed.ncbi.nlm.nih.gov%2F>.

⁴⁶ Cortese, M et al., *Prevention of Rotavirus Gastroenteritis Among Infants and Children Recommendations of the Advisory Committee on Immunization Practices (ACIP)*, MMWR Morb Mortal Wkly Rep February 6, 2009; 58(RR02); 1-25, <https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5802a1.htm>.

⁴⁷ Cortese, M. et al., *Chapter 19: Rotavirus*, Centers for Disease Control and Prevention, Pink Book (Apr. 25, 2024), <https://www.cdc.gov/pinkbook/hcp/table-of-contents/chapter-19-rotavirus.html>.

⁴⁸ Zhou F, Jatlaoui TC, Leidner AJ, et al., *Health and Economic Benefits of Routine Childhood Immunizations in the Era of the Vaccines for Children Program — United States, 1994–2023*, MMWR Morb Mortal Wkly Rep 2024;73:682–685, DOI: <http://dx.doi.org/10.15585/mmwr.mm7331a2>.

⁴⁹ Wu, Katherine J., *Rotavirus Could Come Roaring Back – Very Soon*, The Atlantic (Jan 5, 2026), <https://www.theatlantic.com/health/2026/01/childhood-vaccine-schedule-rotavirus-paul-offit/685513/>.

The routine pediatric flu vaccine drastically reduces child hospitalizations and deaths. The pediatric flu vaccine reduces a child's risk of severe, life-threatening flu by 75%⁵⁰ and reduces flu-related emergency room visits by half.⁵¹ In the 2023-2024 flu season alone, the pediatric flu vaccine prevented: 4.5 million illnesses among children; 2.5 million medical visits; 20,000 child hospitalizations; and 266 child deaths, including 173 deaths among children 6 months-4 years.⁵²

The vast majority of pediatric flu-related fatalities occur in unvaccinated children -- 90% of the children who die from the flu are unvaccinated.⁵³ Anti-vaccine messages from the federal government appear to have already been contributing to increased child flu deaths: declining flu vaccinations in 2024-2025 contributed to 280 pediatric flu deaths, the highest number in a nonpandemic flu season in more than 20 years.⁵⁴

COVID-19. The ACIP added the COVID-19 vaccine to the routine immunization schedule in 2021 for children ages 5 and older, and in 2022 for children 6 months and older. Numerous

⁵⁰ Olson SM, et al., *Vaccine Effectiveness Against Life-Threatening Influenza Illness in US Children*, Clin Infect Dis. 2022 Aug 25;75(2):230-238. doi: 10.1093/cid/ciab931. PMID: 35024795, <https://pubmed.ncbi.nlm.nih.gov/35024795/>.

⁵¹ Campbell AP, et al., *Vaccine Effectiveness Against Pediatric Influenza Hospitalizations and Emergency Visits*. Pediatric (Nov. 2020), PMID: 33020249, <https://pubmed.ncbi.nlm.nih.gov/33020249/>.

⁵² Centers for Disease Control and Prevention, *Flu Burden Prevented by Vaccination 2023-2024 Flu Season* (Jan. 14, 2025), <https://www.cdc.gov/flu-burden/php/data-vis-vac/2023-2024-prevented.html>.

⁵³ Katie Reinhart et. al., "Influenza-Associated Pediatric Deaths — United States, 2024–25 Influenza Season," *Morbidity and Mortality Weekly Report* 74 (36) (2025): 565–569, <https://www.cdc.gov/mmwr/volumes/74/wr/mm7436a2.htm>.

⁵⁴ Katie Reinhart et. al., *Influenza-Associated Pediatric Deaths — United States, 2024–25 Influenza Season*, *Morbidity and Mortality Weekly Report* 74 (36) (2025): 565–569, <https://www.cdc.gov/mmwr/volumes/74/wr/mm7436a2.htm>.

research studies and systematic reviews of the evidence have confirmed that the COVID-19 vaccine is highly effective and safe for pediatric populations.^{55 56 57}

The vaccine drastically reduces COVID-19 hospitalizations and Long COVID among children. The pediatric vaccine is 76% effective against COVID-19-related emergency room visits for young children (aged 9 months-4 years old) and 56% effective against emergency room visits for children aged 5-17.⁵⁸ On the other hand, unvaccinated children and adolescents are 20 times more likely to develop Long COVID than their vaccinated peers.⁵⁹

II. The Routine Vaccination Changes Will Significantly Reduce Childhood Vaccination Rates.

When the CDC changes its vaccination schedule, it has tangible impacts on childhood access to and adoption of important preventative care. Vaccines on the routine schedule reach the highest number of children because the routine recommendation ensures the vaccines are discussed and recommended during pediatric medical visits. The CDC's immunization schedules serve as the pediatric standard of care.⁶⁰ Once a vaccine is designated routine for infants and children, uptake grows steadily. For example, following the CDC's recommendation for routine pediatric use in 1991, Hepatitis B vaccine rates among children ages 19-35 months rose from 16% to 90%

⁵⁵ Gao, P., Kang, LY., Liu, J. et al. *Immunogenicity, effectiveness, and safety of COVID-19 vaccines among children and adolescents aged 2–18 years: an updated systematic review and meta-analysis*, *World J Pediatr* 19, 1041–1054 (2023), <https://link.springer.com/article/10.1007/s12519-022-00680-9>.

⁵⁶ Watanabe A, 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*, *JAMA Pediatr.*, 2023;177(4):384–394, doi:10.1001/jamapediatrics.2022.6243. <https://jamanetwork.com/journals/jamapediatrics/fullarticle/2800743>.

⁵⁷ Fangyuan Tian, et al., *Safety and Efficacy of COVID-19 Vaccines in Children and Adolescents: A Systematic Review of Randomized Controlled Trials*, *J. Med Virol.* Vol 94 Issue 10, pp 4644-4653, <https://onlinelibrary.wiley.com/doi/abs/10.1002/jmv.27940>.

⁵⁸ Irving SA, Rowley EA, Chickery S, et al, *Effectiveness of 2024–2025 COVID-19 Vaccines in Children in the United States — VISION, August 29, 2024–September 2, 2025*, *MMWR Morb Mortal Wkly Rep* 2025;74:607–614, <https://www.cdc.gov/mmwr/volumes/74/wr/mm7440a1.htm>.

⁵⁹ Qiong Wu, et al., *Real World Effectiveness and Causal Mediation Study of BNT162b2 on Long Covid Risks in Children and Adolescents*, *eClinical Medicine, Part of The Lancet Discovery Science* (Dec. 6, 2024), [https://www.thelancet.com/journals/eclim/article/PIIS2589-5370\(24\)00541-8/fulltext](https://www.thelancet.com/journals/eclim/article/PIIS2589-5370(24)00541-8/fulltext).

⁶⁰ Centers for Disease Control and Prevention, *Healthcare Professionals: Child and Adolescent Immunization Schedule by Age* (Oct. 7, 2025), <https://www.cdc.gov/vaccines/hcp/imz-schedules/child-adolescent-age.html>.

(from 1993-2000). Dramatic gains also were seen among children aged 13 to 15 years, rising from near zero to 67%.⁶¹ Similarly, rotavirus immunization increased from 44% to 59% between 2009-2010, after being added to the routine pediatric schedule in 2006.⁶² By 2020, pediatric rotavirus immunization had reached 77%.⁶³

On the other hand, uptake for vaccines subject to SCDM is low. A recent CDC analysis found that only 12% of eligible adolescents received the Meningococcal B vaccine under SCDM, while 61% of the same group received meningococcal A vaccine, which carries a routine recommendation.⁶⁴ While there are no direct empirical studies regarding the uptake of HPV as it relates to changes in SCDM, data confirms adults 27-45 have a significantly lower vaccine uptake (16%), for whom the HPV vaccine is SCDM, compared to adolescents (62%), for whom vaccination is routine.⁶⁵

III. The Routine Vaccination Changes Threaten Public Health.

The lifesaving public health achievements made possible by routine childhood immunizations in the United States risk being undone. As explained above, *supra* Section II, replacing routine vaccine recommendations with SCDM will predictably reduce vaccine uptake. This will negatively impact a variety of different stakeholders, including providers, parents, state and local governments and the public health at large. There is no evidence that Defendants

⁶¹ Centers for Disease Control and Prevention, *Achievements in Public Health: Hepatitis B Vaccination --- United States, 1982—2002*, MMWR Morb Mortal Wkly Rep. 2002;51(25):549-552,563, <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5125a3.htm>.

⁶² Centers for Disease Control and Prevention, *National and state vaccination coverage among children aged 19-35 months--United States, 2010*, MMWR Morb Mortal Wkly Rep. 2011;60(34):1157-1163.

⁶³ Centers for Disease Control and Prevention, *Vaccination Coverage by Age 24 Months Among Children Born in 2019 and 2020 — National Immunization Survey-Child, United States, 2020–2022* (Nov. 3, 2023), https://www.cdc.gov/mmwr/volumes/72/wr/mm7244a3.htm?s_cid=mm7244a3_w#T1_down.

⁶⁴ Popovian, Robert, PharmD, MS, *Enhancing Adult Vaccine Uptake – Challenges in Shared Clinical Decision Making and Risk Based Recommendations*, Global Healthy Living Foundation (March 2025), https://ghlf.org/wp-content/uploads/2025/03/Enhancing-Adult-Vaccine-Uptake-Report.pdf#gf_93.

⁶⁵ *Id.*

considered the impact of eliminating routine status for multiple childhood vaccines on any of these critical components of our public health ecosystem. *See Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 43 (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’) (citations omitted).

A. Impact on Patients and Public Health

Immunization of children with safe and effective vaccines is a basic matter of public health. A routine pediatric schedule facilitates widespread vaccine adoption,⁶⁶ which improves health outcomes both for those who are vaccinated as well as children and adults who are immunocompromised by serious and life-threatening health conditions, for whom immunization is severely limited.⁶⁷ These immunocompromised individuals depend on the immunization of others to limit their exposure to vaccine-preventable diseases. As childhood immunization rates begin to fall, illness and death from preventable causes will soar—a situation already playing out now, as the U.S. faces a serious measles outbreak.⁶⁸

B. Impact on Providers.

Providers report several barriers to effectively implementing SCDM, all of which contribute to a lack of “skills” in SCDM.⁶⁹

For example, pediatric visits are short and providers generally have limited time with their patients. Vaccines with a SCDM recommendation require clinicians to spend additional time discussing a vaccine prior to administration compared to vaccines on the routine schedule, and

⁶⁶ See Section II, *supra*.

⁶⁷ Moore DL., *Immunization of the Immunocompromised Child: Key Principles*. *Paediatr Child Health*, 2018 May 11;23(3):203-205, <https://pmc.ncbi.nlm.nih.gov/articles/PMC5951088/>.

⁶⁸ Centers for Disease Control and Prevention, *Measles Cases and Outbreaks* (last visited Jan. 30, 2026), <https://www.cdc.gov/measles/data-research/index.html>. See also U.S. Dept of Health and Human Services, *Vaccines Protect your Community* <https://www.hhs.gov/immunization/basics/work/protection/index.html>.

⁶⁹ van der Woude LA, Welker GA, Brand PLP, Festen S., *Barriers to Implementing Shared Decision-Making in Postgraduate Medical Education: The Role of Disease-Centered Beliefs*, *Perspect Med Educ*. 2025 Jul 25;14(1):436-446. doi: 10.5334/pme.1465. PMID: 40718372; PMCID: PMC12292059.

providers may choose to forgo recommending the vaccine at all. In a recent survey, 67% of providers who experienced obstructions to implementing SCDM for adults indicated the lack of time as a barrier.⁷⁰ In another survey, nearly 20% of health providers in Texas cited the necessary time commitment as an anticipated barrier to implementing SCDM for HPV.⁷¹ Further, providers report lack of compensation for time spent engaging in SCDM as a barrier.⁷²

Fears of liability, as well as providers' sense of ultimate responsibility for treatment decisions also complicate implementation of SCDM.⁷³ And further barriers like patients' limited health literacy and challenges to accessing full patient medical histories also contribute to the issue.⁷⁴

C. Impact on Pharmacies.

Pharmacies play a central role in routine vaccination administration, but SCDM limits pharmacy access to vaccines. For example, roughly 70% of all COVID-19 booster shots were administered at pharmacies by the final year of the pandemic,⁷⁵ and pharmacies remain the most

⁷⁰ See *id.*

⁷¹ Desai M, Sharma SV, et al, *Healthcare professionals' awareness of and barriers to shared-clinical-decision-making for HPV vaccination among adults 27-45 years*, *Hum Vaccin Immunother*, 2025 Sep 18; 21(1), <https://pmc.ncbi.nlm.nih.gov/articles/PMC12452441/>.

⁷² Littrell, Austin, *Complicated Vaccine Guidelines are Slowing Adult Immunization Rates*, *Medical Economics* (April 10, 2025), <https://www.medicaleconomics.com/view/complicated-vaccine-guidelines-are-slowing-adult-immunization-rates>; Children's Hospital of Philadelphia, *Vaccine Update for Healthcare Professionals, News & Views – Shared Clinical Decision-Making: What it is and Why it Matters* (June 17, 2025), <https://www.chop.edu/vaccine-update-healthcare-professionals/newsletter/shared-clinical-decision-making-what-it-and-why-it-matters>.

⁷³ Popovian, Robert, PharmD, MS, *Enhancing Adult Vaccine Uptake – Challenges in Shared Clinical Decision Making and Risk Based Recommendations*, *supra* n. 64; van der Woude LA, Welker GA, Brand PLP, Festen S., *Barriers to Implementing Shared Decision-Making in Postgraduate Medical Education: The Role of Disease-Centered Beliefs*. *Perspect Med Educ.*, *supra* n. 69.

⁷⁴ Littrell, Austin, *Complicated Vaccine Guidelines are Slowing Adult Immunization Rates*, *supra* n. 72; Children's Hospital of Philadelphia, *Vaccine Update for Healthcare Professionals, News & Views – Shared Clinical Decision-Making: What it is and Why it Matters*, *supra* n. 72; van der Woude LA, Welker GA, Brand PLP, Festen S, *Barriers to Implementing Shared Decision-Making in Postgraduate Medical Education: The Role of Disease-Centered Beliefs*, *supra* n. 69.

⁷⁵ El Kalach R, Jones-Jack N, Elam MA, et al, *Federal Retail Pharmacy Program Contributions to Bivalent mRNA COVID-19 Vaccinations Across Sociodemographic Characteristics — United States, September 1, 2022–September 30, 2023*, *MMWR Morb Mortal Wkly Rep* April 4, 2024;73:286–290, <https://www.cdc.gov/mmwr/volumes/73/wr/mm7313a2.htm>.

common setting for flu and COVID-19 shots.⁷⁶ Ninety percent of the U.S. population lives within just 5 miles of a community pharmacy, which is particularly impactful for providing underserved and rural populations access to health care.⁷⁷

Pharmacists in all 50 states and Washington, D.C., are licensed to administer vaccines, but state regulations often limit which vaccines pharmacists can administer, at what ages, and whether patients must have a prescription.⁷⁸ Most importantly, states differ in whether pharmacists may administer vaccines other than those with routine recommendations—many state laws restrict pharmacists from engaging in the kind of clinical decision making required by SCDM.⁷⁹

Even where pharmacists may be authorized to administer vaccines subject to SCDM, they may be hesitant to do so. One reason is because they do not have complete access to patient records and must rely on patient attestation of relevant risk factors. Finally, pharmacies operate in high-traffic environments not conducive to the time and privacy required for SCDM.⁸⁰ SCDM may also raise legal liability concerns.⁸¹

⁷⁶ Centers for Disease Control and Prevention, *National and state-specific estimates of settings where adults received influenza, updated COVID-19, and RSV vaccinations, 2023-2024 respiratory virus season*, <https://archive.is/Wlz9v> (last accessed Feb. 5, 2026).

⁷⁷ Berenbrok, Lucas A. et al., *Access to Community Pharmacies: A Nationwide Geographic Information Systems Cross-Sectional Analysis*, J Am Pharm Assoc, 2022 vol 62, Issue 6, 1816-1822.e2, [https://www.japha.org/article/S1544-3191\(22\)00233-3/fulltext](https://www.japha.org/article/S1544-3191(22)00233-3/fulltext).

⁷⁸ Rosenthal, Jill, *6 Ways States Can Protect Vaccine Access While the Trump Administration Dismantles the Federal System*, Report, Center for American Progress (Nov 20, 2025), <https://www.americanprogress.org/article/6-ways-states-can-protect-vaccine-access-while-the-trump-administration-dismantles-the-federal-system/>; National Alliance of State Pharmacy Associations, *Pharmacist and Pharmacy Technician Vaccination Authority* (January 3, 2025), <https://naspa.us/resource/2024-pharmacist-immunization-authority/>.

⁷⁹ Choudhury, Sreeha, PharmaD, JD, *Implications for Pharmacies Navigating Shared Clinical Decision-Making in Vaccination*, *Pharmacy Times* (June 13, 2024), <https://www.pharmacytimes.com/view/implications-for-pharmacies-navigating-shared-clinical-decision-making-in-vaccination>.

⁸⁰ *Id.*

⁸¹ Littrell, Austin, *Complicated Vaccine Guidelines are Slowing Adult Immunization Rates*, Medical Economics (April 10, 2025), <https://www.medicaleconomics.com/view/complicated-vaccine-guidelines-are-slowing-adult-immunization-rates>.

D. Impact on Parents.

Parents look to their child's providers for clear vaccine messaging. But HHS's misuse of the SCDM designation sets a dangerous new precedent, forcing providers to abandon the "presumptive approach" with parents, where a provider informs a parent that shots are due for the child. Now, providers may decide not to discuss or recommend the vaccines affected by the Routine Vaccination Changes at all. This is likely to cause confusion among parents.

Research shows that the presumptive approach and a strong endorsement from a clinician is the single strongest driver of vaccine acceptance.⁸² Clear communication and messaging, along with trust in health care providers, strongly impacts parents' decision to vaccinate their children.⁸³ Nearly 90% of Americans with children under 18 report they always or sometimes vaccinate their children based on doctor recommendations.⁸⁴

SCDM entails an open-ended negotiation that signals a physician's ambivalence to parents.⁸⁵ Although still formally considered a recommendation, a SCDM designation acknowledges that vaccination is permissible in a particular population rather than affirmatively encouraging its use.⁸⁶

⁸²Tuckerman J, Kaufman J, Danchin M. *Effective Approaches to Combat Vaccine Hesitancy*, Pediatr Infect Dis J. 2022 May 1;41(5):e243-e245, <https://pmc.ncbi.nlm.nih.gov/articles/PMC8997018>; Schwartz, Jason L., *Revised Recommendations for Covid-19 Vaccines – U.S. Vaccination Policy Under Threat*, N Engl J Med 2025; vol 393 no. 5:417-419, <https://www.nejm.org/doi/full/10.1056/NEJMp2507766>.

⁸³ Ames HM, Glenton C, Lewin S., *Parents' and informal caregivers' views and experiences of communication about routine childhood vaccination: a synthesis of qualitative evidence*, Cochrane Database Syst Rev. 2017 Feb 7;2(2), <https://pmc.ncbi.nlm.nih.gov/articles/PMC5461870/>.

⁸⁴ Partnership to Fight Infectious Disease, *New Poll: Majority of Americans Support Keeping Vaccines Widely Available to Protect Children and Communities* (Jan. 29, 2025), <https://www.fightinfectiousdisease.org/post/new-poll-majority-of-americans-support-keeping-vaccines-widely-available-to-protect-children-and-co>.

⁸⁵ Scott, Jake, MD, *CIDRAP Op-Ed: Quiet Dismantling: How 'Shared Decision-making' Weakens Vaccine Policy and Harms Kids*, University of Minnesota CIDRAP (Jan. 6, 2026), <https://www.cidrap.umn.edu/childhood-vaccines/cidrap-op-ed-quiet-dismantling-how-shared-decision-making-weakens-vaccine-policy>.

⁸⁶ Schwartz, Jason L., *Revised Recommendations for Covid-19 Vaccines – U.S. Vaccination Policy Under Threat*, N Engl J Med 2025; vol 393 no. 5:417-419, <https://www.nejm.org/doi/full/10.1056/NEJMp2507766>.

E. Impact on State Vaccination Policy.

States hold broad legal and operational authority over the childhood vaccination system. They determine which vaccines are required for school and childcare entry, regulate medical practice, oversee insurance markets and Medicaid programs, and partner with the CDC to administer the Vaccines for Children Program.⁸⁷

In nearly every state, three territories, and Washington, D.C., statutes and regulations reference ACIP recommendations.⁸⁸ If the ACIP recommendations change, then any state or territorial policy that depends on them will be altered as well. The changes states may make are considerable: immunization requirements for school entry,⁸⁹ public vaccination clinics hosted by local departments of health, and the provision of vaccine information, all of which may be tied to the ACIP's routine recommendations.⁹⁰

CONCLUSION

For the foregoing reasons, and those set forth in Plaintiffs' memorandum, the Court should grant the Plaintiffs' motion for a preliminary injunction.

⁸⁷ Cohen, Mandy, et al., *The Essential Role of States in Protecting Immunization Access*, N Engl J Med 2026; vol 394; 420-422, <https://www.nejm.org/doi/full/10.1056/NEJMp2517029>.

⁸⁸ Baker-White, Andy, *States Seek Policy Guidance Beyond ACIP Vaccine Recommendations*, ASTHO Blog 2025 (Oct. 24, 2025), <https://www.astho.org/communications/blog/2025/states-seek-policy-guidance-beyond-acip-vaccine-recommendations>.

⁸⁹ Advisory Committee on Immunization Practices, *Impact of the Advisory Committee on Immunization Practices Recommendations on State Law*, ASTHO (June 23, 2025), <https://www.astho.org/topic/resource/impact-of-acip-recommendations-on-state-law>.

⁹⁰ See *id.*

Respectfully submitted,

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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 6, 2026

/s/ Andrew M. London

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APPENDIX A

LIST OF AMICI CURIAE

A. Public Health Organizations

1. Robert Wood Johnson Foundation

The Robert Wood Johnson Foundation (RWJF) is a leading national philanthropy dedicated to taking bold leaps to transform health in our lifetime. A core feature of RWJF's philanthropic approach is funding research to identify evidence-based methods of improving health outcomes for all. As part of those efforts, RWJF has supported research demonstrating the benefits of comprehensive coverage for no-cost preventive health services.

2. American Academy of Allergy, Asthma & Immunology

The American Academy of Allergy, Asthma & Immunology is a professional association with more than 7,500 members in the United States and beyond. This membership includes allergist/immunologists, other medical specialists, allied health and related healthcare professionals with a special interest in the research and treatment of patients with allergic and immunologic diseases.

3. American College of Chest Physicians

The American College of Chest Physicians (CHEST) is comprised of more than 18,000 physicians, advance practice providers, respiratory therapists, and other front line health care professionals who provide patient care in pulmonary, critical care, and sleep medicine. CHEST serves as an important connection to clinical knowledge, research, and resources, including through its highly respected peer reviewed journal, clinical practice guidelines, and consensus statements. CHEST is interested in providing evidence-based guidance on respiratory disease-related public health issues and advocating for best practices in patient care.

4. American Thoracic Society

The American Thoracic Society is an international non-profit organization of more than 30,000 physicians, scientists, nurses, and health care professionals dedicated to the detection, prevention, treatment, and cure of respiratory disease, critical care illnesses, and sleep-disordered breathing. ATS members provide direct care to patients who succumb to preventable serious diseases like respiratory syncytial virus, influenza, measles and COVID-19. As such, the ATS has a compelling interest in ensuring a science-based childhood and adult vaccination schedule to protect the patients we serve.

5. Network for Public Health Law

The Network for Public Health Law is a nonprofit organization composed of public health law and policy experts with a vision of truly fair health conditions for all. The Network's mission is to protect and improve the health of all people and their communities through better, more just laws and policies.

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