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September 20, 2026

Robert F. Kennedy Jr., Secretary
U.S. Department of Health and Human Services
200 Independence Ave., S.W.
Washington, D.C. 20201

RE: Request for Information; Categories Used in Federal Vaccine Recommendations and the Role of Shared Clinical Decision-Making

Dear Secretary Kennedy:

For over 57 years, the National Health Law Program (NHeLP) has advocated, educated, and litigated to preserve, protect, and expand access to health care for low-income and underserved populations. We appreciate the opportunity to comment on this Request for Information (RFI) on the categories used as part of the federal vaccine recommendation process and the role of the shared clinical decision-making (SCDM) category.[1]

We are deeply concerned about the direction in which this Administration has taken the vaccine recommendation and classification process. The actions taken by the U.S. Department of Health and Human Services (HHS) to dismantle the prior membership of the Advisory Committee on Immunization Practices (ACIP) and downgrade classifications of various vaccines are not based on science or the best available evidence and put in danger the health of communities across the U.S. We have no reason to believe that any future changes to the vaccine recommendation system proposed by this Administration will be based on different assumptions or goals, as evidenced by the plethora of dubious claims and statements made by HHS throughout the RFI.

The current recommendation categories already provide a simple, scientifically sound method to classify vaccines that, when not misused by HHS, is approachable for patients and easy to follow by the medical community. Moreover, changes to the recommendation categories are likely incompatible with several acts of Congress endorsing the current system, as evidenced by recent court rulings that have put a halt on HHS's recent actions around vaccines. We therefore question whether HHS is seeking to propose changes to the recommendation categories as a way to bypass its limited authority as authorized by Congress and affirmed by the courts.

As such, and as explained further below, we oppose any potential changes to the current recommendation categories and call on HHS to reverse course and return to making decisions regarding vaccines based on science and clinical evidence.

I. The current vaccine recommendation system was designed to incorporate scientific evidence and does not negate patient autonomy.

A. <u>The vaccine classification process and standards have been traditionally applied in a consistent, thorough, and scientific manner.</u>

As designed, the current vaccine recommendation process prioritizes scientific and clinical consensus and is based on thorough and transparent evaluations of the available data. Evaluation of this data takes place at various levels within HHS and includes:

- approval of the vaccine based on safety and efficacy by the Food and Drug Administration (FDA);
- recommendations made by ACIP regarding which populations should get the vaccine based on various factors, such as safety and efficacy at specific ages, the seriousness of the disease in question, and the number of individuals who are likely to get the disease without the vaccine;
- approval of the Centers for Disease Control and Prevention (CDC) of the ACIP recommendation; and
- subsequent monitoring by the CDC and the FDA of the safety of vaccines after their approval.[2]

[1] Dep't of Health & Hum. Srvs., *Request for Information: Categories Used in Federal Vaccine Recommendations and the Role of Shared Clinical Decision-Making*, 91 Fed. Red. 54724 (Aug. 24, 2026).
[2] Ctrs. for Disease Control & Prevention, *How Vaccines are Developed and Approved for Use* (Aug. 10, 2024), https://www.cdc.gov/vaccines/basics/how-developed-approved.html.

This multi-layered process has been carefully crafted to ensure that vaccines are thoroughly vetted by public health and scientific experts before they are offered and recommended to the public.

ACIP, in particular, was created in 1964 given the need for "greater degree of continuity of expert technical advice rather than formation of *ad hoc* committees to address national immunization policy."[3] Since then, the committee has vetted numerous vaccines strictly following the available evidence and data before arriving at a recommendation.[4] Until this Administration began to dismantle and politicize its composition, ACIP had historically been characterized by the competency of its members, all of whom are required to have clinical, scientific, and public health expertise in immunization, be recommended for participation by other members of the scientific community, and complete an interview and background check before participating. Given this required competency level, ACIP recommendations have been described as the "gold standard for evidence-based guidance."[5]

The ACIP vaccine evaluation process is not only thorough, but it is also transparent. First, ACIP members are required to disclose any potential conflict of interest when evaluating a particular vaccine.[6] Second, when evaluating vaccines for recommendation, ACIP members participate in workgroups to review all the available evidence, they solicit public input, and present recommendations to the full committee.[7] Finally, ACIP makes proposed recommendations and the evidence on which they are based public so that nonvoting members (federal agencies and professional organizations) and the public can provide feedback on the recommendations.[8] Materials are traditionally released well in advance of one of the three annual meetings, in which the full

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[3] Jean Clare Smith, Alan R. Hinman, & Larry K. Pickering, *History and Evolution of the Advisory Committee on Immunization Practices – United States 1964-2014*, 63 MMWR MORB MORTAL WKLY REP 955–958 (Oct. 24, 2014), https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6342a5.htm.

[4] For a detailed list of vaccines historically recommended by ACIP that are supported by the science, see Jen Christiansen, Meghan Bartels, & Sarah Lewin Frasier, *See Vaccine Recommendations Backed By Science in These Handy Charts*, SCIENTIFIC AM. (June 25, 2025), https://www.scientificamerican.com/article/see-vaccine-recommendations-backed-by-science-in-these-handy-charts/.

[5] *See* MaryBeth Musumeci, *The Advisory Committee on Immunization Practices: What It Does and How Recent Changes to It Will Affect Vaccine Affordability and Access*, Commonwealth Fund (Aug. 14, 2025), https://www.commonwealthfund.org/publications/explainer/2025/aug/advisory-committee-immunization-practices-what-it-does.

[6] *Id.*

[7] Kavya Sekar, Cong. Rsch. Serv., IF12317, The Advisory Committee on Immunization Practices (ACIP) (2025), https://www.congress.gov/crs-product/IF12317.

[8] *Id.*

composition of ACIP discusses the recommendations and allows for oral public comments.

The current vaccine recommendation categories likewise reflect this thorough and scientific-based process. The three categories provide a straightforward and simple system that captures the different levels of certainty regarding vaccine efficacy and are based on the use of the "Evidence to Recommendations Framework" (EtR), a decision-making tool that enables ACIP to consider various scientifical and societal factors to arrive at conclusions.[9] Given the overwhelming evidence supporting most of the vaccines that have been recommended by ACIP, it follows that the vast majority of recommendations will be based on the "routine" classification, which advise universal immunization in a particular age group or for groups at increased risk of vaccine-preventable diseases.[10] Use of routine classification when evidence strongly indicates significant public benefit for widespread use of a vaccine has traditionally been, and should continue to be, the default. The category already allows ACIP to limit the recommendation to specific age or population groups to account for differences in the available evidence based on population factors.

Additionally, ACIP may classify vaccines as recommended only for individuals with certain characteristics that make them more susceptible to the vaccine-preventable disease and for whom the benefits would outweigh the risks. This category of recommendation allows ACIP to account for situations in which the available evidence indicates a clear link between vaccine administration and public health benefit, while also indicating increased possibility of adverse events associated with the administration of the vaccine.[11] Finally, the current classification system permits ACIP to classify vaccines as recommended based on SCDM in the rare and limited circumstances in which the evidence regarding the vaccine's safety and efficacy is mixed.[12] Classifying a vaccine as recommended based on SCDM calls for additional scrutiny and discussion between the patient and their medical provider, but, as explained further below, also carries the risk of creating confusion among patients, providers, and insurers, leading to potential barriers to vaccine access only justifiable in the rare cases where the available

[9] Ctrs. for Disease Control & Prevention, *Evidence-Based Recommendations for ACIP* (Jan. 7, 2025), https://www.cdc.gov/acip/evidence-based-recommendations/index.html.
[10] Ctrs. for Disease Control & Prevention, *Routine Vaccines* (Sep. 5, 2024), https://wwwnc.cdc.gov/travel/page/routine-vaccines.
[11] Applied Pol'y, *ACIP: The Committee Shaping Vaccine Policy* (Feb. 2025), https://www.appliedpolicy.com/acip-the-committee-guiding-vaccine-policy/.
[12] Am. Acad. of Pediatrics, *Shared Clinical Decision Making for Immunization* (Feb. 2, 2026), https://www.aap.org/en/patient-care/immunizations/shared-clinical-decision-making-for-immunizations/?srsltid=AU7gw4UH5yU2pek9RgCMzkrhynZfxuKDzAa6q6zZ_jRH4hwXIQY8QOPH.

evidence does not support a widespread recommendation. As a result, until this Administration began to unnecessarily expand its use, the SCDM category had been traditionally reserved for a very limited subset of vaccines.[13]

Clearly, the current categories are already broad enough to account for variability in the evidence that may justify conditioning recommendations. HHS puts forward no scientific evidence to support a need to modify the classification system and categories beyond the existing standards.

B. Changing the recommendation categories has no bearing on informed consent.

While HHS advances no discernible scientific reason to modify the current recommendation categories, the RFI does include various claims about the effects of the current recommendation standards on public trust and vaccine uptake. For instance, HHS suggests that establishing additional categories similar to SCDM or enhancing the use of the existing category is important in order to give "weight to the values and preferences of patients and parents/guardians, including considerations of personal autonomy, informed consent, and religious conviction."[14] In making this assertion, however, HHS confounds the practical effects and value of SCDM with informed consent and patient autonomy and ignores the fact that the current vaccine recommendation system does not in any way conflict with informed consent.

Informed consent is a legal requirement that guarantees that all patients are involved in decisions about their own health and treatment and have access to all the information necessary to make reasoned decisions. The requirement applies to *all* health care services, including all vaccines regardless of their classifications. That is, the fact that a vaccine has been recommended as routine does not lead to vaccine administration without patient consent or despite the patient's concern. Similarly, classifying a vaccine as recommended under SCDM does not, in and of itself, guarantee that providers will discuss additional layers of information with patients. In fact, when a vaccine is recommended as routine, providers are more likely to discuss the evidence around the vaccine during routine visits as part of the regular course of treatment, whereas

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[13] *See* Michael D. Hogue, Stephan Foster, Mitchel C. Rothholz, *Shared clinical decision making on vaccines: Nothing has really changed for pharmacists*, 27 J Am Pharm Assoc e91 (July 2020), https://pmc.ncbi.nlm.nih.gov/articles/PMC7384787/. *See also* Rob Stein, *Here's how 'shared decision making' for childhood vaccines could limit access*, NPR (Jan. 25, 2026), https://www.npr.org/2026/01/25/nx-s1-5686622/cdc-childhood-vaccines-shared-decision-rfk.

[14] 91 Fed. Red. 54724, 54725.

labeling a vaccine under SCDM adds a level of uncertainty that often leads providers to avoid discussing the vaccine altogether, unless first raised by the patient.[15]

HHS is therefore mistaken when it asserts that expanding the use of SCDM or similar classifications would enhance informed consent. If the Department was serious about improving the information patients receive about vaccines, it would ensure that ACIP retains the rigorous and transparent scientific process that has characterized the committee throughout its history. Instead, by amplifying vaccine misinformation and enabling anti-science views within ACIP, the CDC, and other departments, HHS's actions continue to sow confusion among the population regarding vaccine efficacy, weakening the possibility of informed consent and diminishing patient autonomy.

C. <u>The federal vaccine recommendation process does not create immunization mandates.</u>

To support the alleged need to consider potential changes to the vaccine classification system, HHS also advances the theory that the current categories (particularly the use of the routine category) give way to immunization mandates, which in turn hampers the public's trust in vaccines. Such implication cannot be further from the truth.

The federal vaccine classification and recommendation system does not create any mandates or requirements for any individuals to vaccinate. Neither ACIP nor the CDC have any legal authority to require vaccine administration or to compel citizens to get vaccinated. Their authority is limited to making *recommendations*, advising when individuals *should* be vaccinated as a measure to stop the spread of communicable diseases. Moreover, in all their history, neither ACIP nor the CDC have recommended that a vaccine mandate be implemented by any other public body or agency.

The vast majority of vaccine mandates in the U.S. come from state officials because states traditionally have the legal authority to compel citizens to get vaccinated under their police powers. States frequently use such powers not as blanket requirements, but as conditions for participation in public programs, including attending public schools. And while state officials often rely on federal recommendations, they are not obligated to do so and many, in fact, also rely on recommendations from other professional

[15] *See* Douglas J. Opel et al., *The Architecture of Provider-Parent Vaccine Discussion at Health Supervision Visits*, 132 PEDIATRICS 1037 (Dec. 2013), https://pmc.ncbi.nlm.nih.gov/articles/PMC3838535/. *See also* Jake Scott, *Quiet dismantling: How 'shared decision-making' weakens vaccine policy and harms kids*, Ctr. for Infectious Disease Rsch. An& Pol'y (Jan. 6, 2026), https://www.cidrap.umn.edu/childhood-vaccines/cidrap-op-ed-quiet-dismantling-how-shared-decision-making-weakens-vaccine-policy.

organizations, including the American Academy of Pediatrics (AAP).[16] As an example of states exercising independent judgement and how irrelevant federal vaccine classifications may be, several states have maintained the same immunization requirements for children attending public schools even after ACIP and the CDC downgraded the vaccine recommendations for several vaccines. For instance, 49 states and D.C. continue to require the hepatitis B vaccine for children entering public schools, despite recent changes in classification by HHS.[17]

At the federal level, the authority that officials have to institute vaccine mandates is typically limited in nature. For example, during the COVID-19 emergency, the Centers for Medicare and Medicaid Services (CMS) adopted a vaccine mandate that applied to provider facilities receiving Medicare or Medicaid funding.[18] That mandate was effectively ended as the declaration of a public health emergency came to an end.[19] While the original mandate was adopted in consultation with the CDC, CMS would have no authority to require patients, beneficiaries, or members of the public in general to receive a vaccine. Other agencies that tried to implement similar mandates during the COVID-19 pandemic were stopped by the courts, including the Occupational Health and Safety Administration's (OSHA) mandate that applied to all workers of employers with 100 workers or more. The Supreme Court invalidated the OSHA mandate reasoning that the agency had exceeded its statutory authority.[20]

None of these limited federal mandates responded to a decision from ACIP or the CDC, which merely recommended the COVID-19 vaccine under the routine category, but remained silent as to the benefits of mandates given their limited statutory authority. Irrespective of the effectiveness of mandates and their impact, if any, on public confidence in vaccines, the connection between the current federal vaccine

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

[17] Josh Michaud, Clea Bell, & Jennifer Kates, *State and Local Policies on School Vaccine Requirements: Overview and Current Status*, KFF (Aug. 21, 2026), https://www.kff.org/other-health/state-and-local-policies-on-school-vaccine-requirements-overview-and-current-status/.

[18] Ctrs. for Medicare & Medicaid Srvs., *Press Release, Biden-Harris Administration Takes Additional Action to Protect America's Nursing Home Residents from COVID-19* (Aug. 18, 2021), https://www.cms.gov/newsroom/press-releases/biden-harris-administration-takes-additional-action-protect-americas-nursing-home-residents-covid-19.

[19] Timothy J. Fry & Kristen H. Chang, *CMS Ends COVID-19 Vaccine Mandate for Medicare- and Medicaid-Certified Providers and Supplies*, McGuireWoods (June 7, 2023), https://www.mcguirewoods.com/client-resources/alerts/2023/6/cms-ends-covid-19-vaccine-mandate-medicare-medicaid-certified-providers-suppliers/.

[20] *Nat'l Fed. Of Indep. Bus. v. OSHA*, 595 U.S. 109 (2022).

recommendation system and mandates is tenuous at best, and does not justify potential changes to the recommendation categories.

II. Any decision that leads to downgrading vaccine recommendations will have a negative impact on access to vaccines.

A. Enhancing the use of SCDM or similar categories is particularly harmful for rural and low-income communities.

Vaccine access is a key component of combating unnecessary human suffering and death from preventable illness. Barriers to care exist for many, including those in rural areas, low-income individuals, and other underserved populations. Reclassifying routine vaccinations to SCDM increases these access disparities.

Rural vaccine uptake is notably different from urban areas. The AAP's Immunization Across America series tracks the differences in vaccination rates by geography. For the combined seven vaccine series, rural vaccination rates are approximately 62.20% compared to urban and suburban areas which were approximately 67.20% and 68%, respectively.[21] These disparities in vaccination rates carries through HPV, Influenza, MMR, and Varicella. The CDC has noted similar disparities in COVID-19 vaccination. The CDC notes that uptake for the first dose of primary vaccination series of COVID-19 was lower in rural (58.5%) than in urban counties (75.4%).[22] Further, the CDC data shows that the gap in COVID-19 vaccination coverage between urban and rural areas has more than doubled since April 2021.[23]

Similarly, the AAP Immunization Across America data series shows that disparities persist through income levels and type of insurance. For the combined seven vaccine series, those at and above poverty level had a higher rate of vaccination (70.8%) compared to those below the poverty level (57.1%).[24] Also for the combined seven vaccine series, those with private insurance have the highest rates of vaccination compared to the uninsured who have the lowest rates (74.20% compared to 44.60%).[25] The Commonwealth Fund found that the combined seven vaccine series

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[21] Am. Acad. of Pediatrics, *Immunization Across America* (Aug. 26, 2026), https://www.aap.org/en/patient-care/immunizations/immunizations-across-america.
[22] Ryan Saelee et al., *Disparities in COVID-19 Vaccination Coverage Between Urban and Rural Counties — United States*, December 14, 2020–January 31, 2022 71 MMWR MORB MORTAL WKLY REP 335–340 (Mar. 4, 2022), http://dx.doi.org/10.15585/mmwr.mm7109a2.
[23] *Id.*
[24] Am. Acad. of Pediatrics, *supra* note 21.
[25] *Id.*

completion rate has consistently been lower for children of lower-income families. Also, they found that children in lower-income families are less likely to receive these vaccinations on time and, in some cases, may receive some doses but do not receive the complete series.[26]

Access to vaccination is multifactorial. Rural communities face both structural and geographic barriers to access. This is exacerbated by the ongoing provider shortages across the United States. The National Rural Health Association notes that about two-thirds of health professional shortage areas are in rural communities.[27] Other barriers include lack of provider recommendation, financial concerns, and perception that vaccinations are not needed or may be harmful.[28] Medical system mistrust and vaccine hesitancy is also a factor for many communities of color who have been historically harmed and marginalized by medical systems combined with persistent racial bias and a lack of provider representation.[29] Low-income families and rural communities face barriers like long travel times in rural areas and appointment scheduling issues especially in medically underserved areas and with provider shortages. They also face caregiver challenges like navigating the lack of guaranteed time off or parental leave.[30] These barriers combined with misinformation, politicization of health care, and vaccine hesitancy increase the risks of preventable disease.

All of these challenges will be exacerbated by downgrading routine vaccinations to SCDM. The United States is experiencing a measles outbreak at the highest level since 1991 with 93% of people who have contracted measles in 2026 being unvaccinated or of unknown status.[31] Stanford University researchers found that measles, rubella, and polio could become endemic to the U.S. again if vaccination rates continue to decline.[32]

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[26] Kristen Kolb, *Lower-Income Kids Are At a Higher Risk of Going Unvaccinated*, Commonwealth Fund (Nov. 12, 2025), https://www.commonwealthfund.org/blog/2025/lower-income-kids-are-higher-risk-going-unvaccinated.
[27] Cynthia Calixte et al., *Pediatric Vaccination Rates in Rural America*, Nat'l Rural Health Ass'n (2024), https://www.ruralhealth.us/getmedia/2a3e75f9-a066-474d-a47e-8503baec5008/2024-NRHA-Rural-Immunizations-policy-brief.pdf.
[28] Sarah E. Brewer et al., *"But then that's another barrier": A qualitative study of parent and provider perspectives on rural versus urban disparities in adolescent vaccination*, 42 VACCINE 126456 (Dec. 2024), https://www.sciencedirect.com/science/article/pii/S0264410X24011381.
[29] Sandra C. Quinn & Michele P. Andrasik, *Addressing Vaccine Hesitancy in BIPOC Communities – Toward Trustworthiness, Partnership, and Reciprocity*, 385 N ENGL J MED 97 (Mar. 31, 2021), https://www.nejm.org/doi/full/10.1056/NEJMp2103104.
[30] Kolb, *supra* note 26.
[31] Melissa Jenco, *AAP President: Measles Milestone An 'Avoidable Crises'*, AAP NEWS (July 24,2026), https://publications.aap.org/aapnews/news/35632/AAP-president-Measles-milestone-an-avoidable.
[32] Jamie Hansen, *Five Things To Know About Measles, and Its Risks to the Young and Old*, STANFORD MEDICINE NEWS CENTER (May 12, 2025), https://med.stanford.edu/news/insights/2025/05/measles-risk-vaccination-young-old.html.

The resurgence of these previously controlled diseases would lead to unnecessary suffering, strain on medical systems, economic impacts, and preventable death. One researcher notes that if vaccinations were to fall by 10%, measles cases could increase to 11 million over the next 25 years.[33] The burden of these outbreaks falls disproportionately on rural and low-income communities that already face strained health care systems, provider shortages, and long traveling distances to access necessary services, in addition to vaccine scarcity.

B. Downgrading routine vaccines to SCDM or similar categories leads to confusion and increases vaccine hesitancy.

Contrasting with access barriers to vaccination, vaccine hesitancy and distrust is influenced by individual thoughts and feelings as well as societal and cultural views. With hesitancy and distrust as consistent barriers to uptake for vaccinations, shifting routine vaccinations to SCDM is likely to increase hesitancy and confusion for families. Likewise, complicating vaccination schedules increases confusion among providers and places significant burden on those doing individual health-level work.

As explained above, SCDM designations have been used for immunizations that are beneficial for some, but not necessarily all, children.[34] By contrast, routine vaccination schedules and designations are used to prevent diseases that are detrimental to society at the population-level and beneficial for all children to receive. Routine vaccine schedules reach the highest number of children and are more seamlessly integrated into pediatric medical visits. Identifying children and adults with contraindications is already a routine part of administering vaccinations.[35]

When a vaccine designation is changed from routine to SCDM, families may believe that the change indicates it may not be safe or effective for some populations. Thus, changing a vaccine designation should only occur when it is scientifically demonstrated to be potentially dangerous or not effective. This is especially concerning and

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[33] Katie Savchuk, *Measles May Be Making A Comeback In the U.S., Stanford Medicine-led Research Finds*, STANFORD MEDICINE NEWS CENTER (Apr. 24, 2025), https://med.stanford.edu/news/all-news/2025/04/measles-vaccination.html.
[34] Am. Acad. of Pediatrics, *supra* note 12.
[35] Am. Acad. of Pediatrics, *7 Rights of Vaccine Administration* (Oct. 13, 2025), https://www.aap.org/en/patient-care/immunizations/implementing-immunization-administration-in-your-practice/vaccine-administration; Mike Ybarra, *Why Shifting Childhood Vaccines To "Shared Clinical Decision-Making" Puts Kids At Risk*, PHRMA (Feb. 23, 2026), https://phrma.org/blog/why-shifting-childhood-vaccines-to-shared-clinical-decision-making-puts-kids-at-risk.

inappropriate for well-established vaccinations that have already prevented millions of cases of illness, hospitalizations, and deaths.[36]

The available evidence around SCDM in practice indicates that the general public may not understand what SCDM means, especially when considering mistrust and misinformation regarding medical systems and vaccines. Researchers at the Annenberg Public Policy Center at the University of Pennsylvania found that 68% understood that SCDM means they should review their or their child's medical history with their health care provider before deciding whether the vaccine is right for them or their child.[37] Similarly, 68% responded about the COVID-19 vaccine for healthy children and teens.[38] Further, 22% thought that SCDM means that "taking the vaccine many not be a good idea for everyone but would benefit some."[39] In addition, more than two in five people responded that SCDM means it is up to an individual to consult with their provider before taking a vaccine about whether it would be a good idea. Moreover, about a quarter of those surveyed thought that SCDM means they should discuss their vaccination decisions with their family.[40]

Many were also unclear who counted as a "health care provider" with only 66% indicating physician assistants or nurse practitioners are included as a health care providers, 50% noting that a registered nurse is a health care provider, and only 33% indicating that a pharmacist can be a health care provider.[41] This confusion is especially concerning as pharmacists are able to administer vaccinations in many states and can ease access barriers. For example, approximately 70% of all COVID-19 booster shots were administered at pharmacies by the final year of the pandemic, and pharmacies remain a common setting for both COVID-19 and flu immunizations.[42] While pharmacists are licensed to administer vaccines, state regulation may limit which

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[36] Fangjun Zhou et al., *Health and Economic Benefits of Routine Childhood Immunizations in the Era of the Vaccines for Children Program — United States, 1994–2023*, 73 MMWR MORB MORTAL WKLY REP 682–685 (Aug. 8, 2024), http://dx.doi.org/10.15585/mmwr.mm7331a2.
[37] Annenburg Public Policy Institute, *CDC Urges 'Shared Decision-Making' on Some Childhood Vaccines; Many Unclear About What That Means* (Jan. 4, 2026), https://www.annenbergpublicpolicycenter.org/cdc-urges-shared-decision-making-on-some-childhood-vaccines-many-unclear-about-what-that-means/.
[38] *Id.*
[39] *Id.*
[40] *Id.*
[41] *Id.*
[42] [42] Roua El Kalach et al., *Federal Retail Pharmacy Program Contributions to Bivalent mRNA COVID-19 Vaccinations Across Sociodemographic Characteristics — United States, September 1, 2022–September 30, 2023*, 73 MMWR MORB MORTAL WKLY REP 286–290 (Apr. 4, 2024), https://www.cdc.gov/mmwr/volumes/73/wr/mm7313a2.htm; Ctrs. for Disease Control & Prevention, *National and state-specific estimates of settings where adults received influenza, updated COVID-19, and RSV vaccinations, 2023-2024 respiratory virus season* (June 10, 2024), https://archive.is/Wlz9v.

vaccines pharmacists can administer depending on age and prescription.[43] States may also limit pharmacists from administering vaccines other than those with routine recommendations.[44] In addition, states may limit pharmacists from engaging in SCDM and pharmacists may be hesitant to engage in SCDM as they do not have access to patient records.[45]

SCDM shifts the responsibility to families and providers. Vaccines with SCDM designation require providers to spend additional time discussing a vaccine prior to administration compared to vaccines with a routine designation. SCDM designation relies on trusting and cooperative relationships between families and providers at a time when, as HHS recognizes, mistrust in health care systems is an ongoing concern in public health.

Further, providers have limited time with each patient during visits. One study found that primary care providers interacted with a family for a median of approximately 16 minutes and most of this time was devoted to non-vaccination health concerns.[46] The overall time a provider spends with a patient in the first year of life is approximately 45 to 90 minutes and this declines to less than 30 minutes per year thereafter as the number of recommended visits are reduced. This limited time is further shortened when considering how many visits a child attends. The AAP recommends six well-child visits in the first year of life, however, most children are more likely to attend three to four visits. Vulnerable and low-income children are more likely to attend fewer well-child

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[43] Jill Rosenthal, *6 Ways States Can Protect Vaccine Access While the Trump Administration Dismantles the Federal System*, Ctr. for Am. Progress (Nov. 20, 2025), https://www.americanprogress.org/article/6-ways-states-can-protect-vaccine-access-while-the-trump-administration-dismantles-the-federal-system/; Nat'l All. of State Pharmacy Ass'n, *Pharmacist and Pharmacy Technician Vaccination Authority* (Jan. 3, 2025), https://naspa.us/resource/2024-pharmacist-immunization-authority/.

[44] Spreeha Choudhury, *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.

[45] Austin Littrell, *Complicated Vaccine Guidelines are Slowing Adult Immunization Rates*, Medical Economics (Apr. 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.

[46] Charles W. LeBaron, Lance Rodewald, & Sharon Humiston, *How Much Time Is Spent on Well-Child Care and Vaccinations?*, 153 ARCH PEDIATR ADOLESC MED. 1154–1159 (1999), https://pubmed.ncbi.nlm.nih.gov/10555717/. *See also* Neal Halfon et al., *Duration of A Well-Child Visit: Association with Content, Family-Centeredness, and Satisfaction*, 128 PEDIATRICS 657 (Oct. 2011), https://pubmed.ncbi.nlm.nih.gov/21930541/.

visits.[47] With limited time and confusion, providers may choose to forgo recommending a vaccine with a SCDM designation entirely. AAP underscores this reality in their legal challenge to the harmful changes to ACIP instigated by HHS Secretary Kennedy. Downgrading routine vaccines to SCDM disrupts care delivery, consumes valuable time needed for other medical issues, fosters distrust of medical professionals, and reduces access to care.[48]

SCDM also forces providers to abandon the "presumptive approach" to vaccination with parents. Research shows that the presumptive approach and a strong endorsement from a provider is the single strongest driver of vaccine acceptance.[49] If HHS truly wanted to improve trust and communication between medical providers and families, the research strongly supports clear communication and messaging strongly impacts parents' decision to vaccinate their children.[50] Further, Americans with children under 18 report that they always or sometimes vaccinate their children based on doctor recommendations.[51] For vaccinations with decades of safety and efficacy evidence, the use of SCDM creates unneeded uncertainty, erodes scientific expertise, and burdens families, providers, and the medical system.

Absent any evidence to support vaccines being downgraded to SCDM, these changes would increase mistrust of public health information and further vaccine hesitancy. HHS leadership suggests its actions on vaccines are a necessary response to an increasing lack of confidence in vaccination, when in fact they are a cause.[52] If HHS was truly

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[47] *See* Elizabeth R. Wolf et al., *Gaps in Well-Child Care Attendance Among Primary Care Clinics Serving Low-Income Families*, 142 PEDIATRICS e20174019 (Nov. 2018), https://publications.aap.org/pediatrics/article-abstract/142/5/e20174019/38551/Gaps-in-Well-Child-Care-Attendance-Among-Primary?redirectedFrom=fulltext.

[48] *See* Declaration of Dr. Suzanne Berman, *AAP et al., v Kennedy*, Exhibit B, Case No. cv-11916 (Mar. 3, 2026), https://litigationtracker.law.georgetown.edu/wp-content/uploads/2025/07/American-Academy-of-Pediatrics_2026.03.02_PLAINTIFFS-SUPPLEMENTAL-DECLARATIONS.pdf.

[49] Jane Tuckerman, Jessica Kaufman, & Margie Danchin, *Effective Approaches to Combat Vaccine Hesitancy*, e243 PEDIATR INFECT DIS J e243 (May 1, 2022), https://pmc.ncbi.nlm.nih.gov/articles/PMC8997018; Jason L. Schwartz, *Revised Recommendations for Covid-19 Vaccines – U.S. Vaccination Policy Under Threat*, 393 N ENGL J MED 417–419, https://www.nejm.org/doi/full/10.1056/NEJMp2507766.

[50] Heather M.R. Ames, Claire Glenton, & Simon Lewin, *Parents' and informal caregivers' views and experiences of communication about routine childhood vaccination: a synthesis of qualitative evidence*, 2(2) COCHRANE DATABASE SYST REV. (Feb. 7, 2017), https://pmc.ncbi.nlm.nih.gov/articles/PMC5461870/.

[51] 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.

[52] *See, e.g.*, U.S. Dep't of Health and Hum. Srvs., *Press Release, HHS Takes Bold Steps to Restore Public Trust in Vaccines by Reconstituting ACIP* (June 9, 2025), https://www.hhs.gov/press-room/hhs-restore-public-trust-vaccines-acip.html. *See, e.g.*, Kaitlin Brumbaugh, Frances Gellert, & Ali H. Mokdad,

concerned with solving vaccine hesitancy, it would not have canceled federal research grants aimed at identifying solutions.[53] In fact, HHS would not have canceled these grants if the Department had any level of confidence that they would justify all the recent actions HHS has taken to restrict access to vaccines. We believe HHS already knows the answer and is actively trying to conceal the reality that increased vaccine hesitancy responds directly to misinformation, particularly when endorsed by the agency tasked with protecting the public's health.

Downgrading routine vaccine recommendations may also have consequences for health insurance coverage of vaccines. Vaccines recommended for SCDM continue to be covered by Medicare, Medicaid, and most private health insurance plans. However, patients, pharmacists, and other vaccine providers often mistakenly believe that absent a prescription or other documentation from a clinician, coverage of the vaccine in question will be denied. Moreover, private health plans have an uneven record of compliance with the Affordable Care Act's (ACA) mandate to cover vaccines recommended by the CDC. Some plans have refused to apply the coverage mandate to vaccines recommended under SCDM, while others have incorporated coverage rules that make confusing distinctions between routine use and SCDM recommendations.[54] For instance, United Healthcare's policy states that vaccines are generally not covered when they do not have an explicit recommendation by ACIP.[55] That language can confuse beneficiaries and potentially lead to a denial of coverage. Other insurers

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Understanding Vaccine Hesitancy: Insights and Improvement Strategies Drawn from a Multi-Study Review, 13(10) VACCINES 1003 (Sep. 2025), https://pmc.ncbi.nlm.nih.gov/articles/PMC12567618/ (finding that "misinformation, safety concerns, and political decisions have contributed to declining vaccination rates, posing threats to public health). *See also* Oluwatosin Goje & Aanchal Kapoor, *Meeting the challenge of vaccine hesitancy*, 91(9) CLEVELAND CLINIC J OF MED. 550 (Sep. 2024), https://www.ccjm.org/content/91/9_suppl_1/S50 (concluding that due to the rise of misinformation, "legislation, policy interventions, research, innovation, and technology are needed to enhance vaccine uptake and ensure equitable access").

[53] Rob Stein & Will Stone, *NIH cuts funding for vaccine-hesitancy research. mRNA research may be next,* NPR (Mar. 12, 2025), https://www.npr.org/2025/03/12/nx-s1-5325863/nih-trump-vaccine-hesitancy-mrna-research. *See also* Matt Motta et al., *Attacks On Vaccine Hesitancy And Promotion Research Undermine Public Health*, HEALTH AFFAIRS (Mar. 3, 2026), https://www.healthaffairs.org/content/forefront/attacks-vaccine-hesitancy-and-promotion-research-undermine-public-health.

[54] Amy Killelea & Justin Giovannelli, *New Federal Vaccine Recommendations Introduce Ambiguity and Could Lead to Coverage Headaches*, Commonwealth Fund (June 3, 2026), https://www.commonwealthfund.org/blog/2026/new-federal-vaccine-recommendations-introduce-ambiguity-and-could-lead-coverage-headaches.

[55] Richard Hughes IV & Spreeha Choudhury, *With the Word 'May', ACIP Leaves Seniors Vulnerable to RSV This Winter*, HEALTH AFFAIRS (July 5, 2023), https://www.healthaffairs.org/content/forefront/word-may-acip-leaves-seniors-vulnerable-rsv-winter.

explicitly tie vaccine coverage to routine recommendations, even though the federal coverage requirement extends to other categories.[56]

SCDM removes clear recommendations and implies a lack of definitive expert and scientific consensus while placing additional burdens on families and providers. Downgrading routine vaccinations with decades of evidence regarding their safety and efficacy is undoubtedly a politicization of public health rather than a good faith effort to improve public health.

III. HHS's recent actions, rather than current categories, threaten the use of sound scientific evidence in the vaccine classification system.

A. <u>In order to improve public confidence in the vaccine recommendation system, HHS should restore the rigorous, scientific-based process that used to characterize ACIP.</u>

In June 2025, Secretary Kennedy fired all 17 members of ACIP.[57] Most of the replacements he named had little to no relevant experience and a demonstrated history of spreading lies about vaccines.[58] After ACIP's composition changed, the committee began to systematically change their recommendations on vaccines that had been recommended as routine for years while turning its back to the transparent and rigorous process that until recently had characterized the committee's endeavors. A

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[56] Richard Hughes IV, Reed Maxim, & Alessandra Fix, *Vague Vaccine Recommendations May Be Leading To Lack Of Provider Clarity, Confusion Over Coverage*, HEALTH AFFAIRS (May 7, 2019), https://www.healthaffairs.org/content/forefront/vague-vaccine-recommendations-may-leading-lack-provider-clarity-confusion-over-coverage.

[57] HHS, *supra* note 52. In March 2026, Federal District Judge Brian Murphy stayed the appointment of the new ACIP members and set aside all votes taken. The court observed that many of the new appointees lacked the requisite expertise in vaccinations and that HHS had circumvented its normal two-year application and vetting process. *See American Academy of Pediatrics v. Kennedy*, 823 F.Supp.3d 141, 169 (2026).

[58] Julia Bonavitacola, *Vaccine Skeptics Among CDC Vaccine Panel Replacements Named by RFK Jr.*, AM. J. OF MANAGED CARE (June 12, 2025), https://www.ajmc.com/view/vaccine-skeptics-among-cdc-vaccine-panel-replacements-named-by-rfk-jr; Ctr. for Am. Progress, *RFK Jr. is Systematically Undermining Vaccine Science and Endangering Health* (June 27, 2025), https://www.americanprogress.org/article/rfk-jr-is-systematically-undermining-vaccine-science-and-endangering-health/; Nat'l Found. For Infectious Diseases, *Flawed ACIP Process Leads to Confusion and Distrust* (June 27, 2025), https://www.nfid.org/flawed-acip-process-leads-to-confusion-and-distrust/; Mike Stobbe, *Kennedy's new CDC panel includes members who have criticized vaccines and spreads misinformation*, AP HEALTH (June 12, 2025), https://fox40.com/health-and-fitness/ap-health/ap-kennedy-names-8-vaccine-committee-replacements-including-covid-shot-critic/; Melissa Jenco, *AAP 'deeply troubled and alarmed' by ousting of CDC vaccine advisory committee*, AAP NEWS (June 9,2025), https://publications.aap.org/aapnews/news/32371/AAP-deeply-troubled-and-alarmed-by-ousting-of-CDC?autologincheck=redirected.

recent analysis comparing the ACIP meetings and deliberations before and after June 2025 shows that resulting recommendations after recent meetings often lack supporting evidence, a significantly higher number of inaccurate statements were accepted, and the committee has failed to use the EtR framework to justify recommendation changes.[59] In addition, the analysis found that new ACIP members often appear to have inappropriately discussed issues behind closed doors and would post meeting notices and agenda items late, make unjustified changes to it, and provide an unreasonably short amount of time for the public to submit comments.[60] These changes hamper the public's ability to participate and provide meaningful feedback before and during meetings.

Additionally, in January 2026, Secretary Kennedy announced a major overhaul of the childhood vaccine schedule, abandoning the high evidentiary standards ACIP has long followed where each change to the childhood vaccine schedule has been carefully weighed and thoroughly vetted by scientists and medical experts.[61] This announcement deviated completely from that approach. Secretary Kennedy did not release any evidence to justify removing vaccines from the recommended list. The announcement was not rooted in science or medicine and intentionally circumvented decades of vaccine safety evidence.[62]

These changes are significant because they directly affect public trust and confidence in federal recommendations on vaccines, which is precisely what HHS mentions in the RFI as potential justification for changes in the recommendation categories. We therefore urge HHS to reconsider the decisions that have been made about ACIP's composition to ensure that only individuals with deep expertise and knowledge about vaccines and without clear anti-vaccine agendas are appointed. Furthermore, HHS should ensure that ACIP closely follows a transparent process for deliberating recommendations.

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[59] Jamie Loehr et al., *Science for vaccine policy: Lack of transparency, misinformation, and poor decision processes at the December 2025 ACIP meeting*, 76 VACCINE 128338 (Mar. 19, 2026), https://www.sciencedirect.com/science/article/abs/pii/S0264410X26001465.

[60] *Id.*

[61] Ctrs. for Disease Control & Prevention, *Press Release, CDC Acts on Presidential Memorandum to Update Childhood Immunization Schedule CDC Acts on Presidential Memorandum to Update Childhood Immunization Schedule* (Jan. 5, 2026), https://www.cdc.gov/media/releases/2026/2026-cdc-acts-on-presidential-memorandum-to-update-childhood-immunization-schedule.html.

[62] *See, e.g.*, Am. Acad. of Pediatrics, *AAP: CDC plan to remove universal childhood vaccine recommendations 'dangerous and unnecessary'* (Jan. 5, 2026), https://publications.aap.org/aapnews/news/34104/AAP-CDC-plan-to-remove-universal-childhood-vaccine; Daniel Payne, *Hospitals and doctors are ignoring RFK Jr.'s new vaccine schedule and relying on pediatrician's guidelines instead*, STAT (Jan. 15, 2026), https://www.statnews.com/2026/01/15/new-vaccine-schedule-largely-ignored-major-healthcare-providers/.

B. <u>The recent actions taken by HHS regarding the hepatitis B, MMRV, and COVID-19 vaccines ignore available scientific and clinical evidence,</u>

Despite its longstanding status on the routine pediatric immunization schedule, ACIP downgraded birth dose hepatitis vaccines. Birth dose hepatitis B vaccinations were added as a routine vaccination in 1991 after ACIP conducted an exhaustive review of the scientific rationale for adopting it.[63] Indeed, the CDC also found that a non-routine approach to hepatitis B vaccination failed because selective screening could not reliably identify every infant at risk, as infected mothers were not frequently screened for the virus and had no identifiable risk factors.[64] ACIP concluded that

> [hepatitis B] transmission cannot be prevented through vaccinating only the groups at high risk of infection. No current medical treatment will reliably eliminate chronic [hepatitis B] infection and thus eliminate the source of new infections in susceptible persons.[65]

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," nor was there evidence of safety problems for infants.

The safety and efficacy of the hepatitis B vaccination have been demonstrated over the last three decades. Between 1994 and 2023, routine pediatric hepatitis B vaccines averted: 90,100 deaths; 940,000 hospitalizations; and 6 million illnesses.[66] Between 1991 and 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.[67] Furthermore, according to a study conducted by the Vaccine Integrity Project at the University of Minnesota, "randomized trials, large national safety monitoring programs, and long-term follow-up studies" consistently demonstrate the safety of the hepatitis B

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[63] Ctrs. for Disease Control & Prevention, Immunization Prac. Advisory Comm., *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)*, 40 MMWR MORB MORTAL WKLY REP 1–19 (1991); https://www.cdc.gov/mmwr/preview/mmwrhtml/00033405.htm. *See also* Sarah Schillie et al., *Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices*, 67 MMWR RECOMM REP 1–31 (Jan. 2018), http://dx.doi.org/10.15585/mmwr.rr6701a1.

[64] CDC, *supra* note 63.

[65] *Id.*

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

[67] Danae Bixler et al., *Progress and Unfinished Business: Hepatitis B in the United States, 1980-2019*, Public Health Reports (June 9, 2023), https://pubmed.ncbi.nlm.nih.gov/37300309/.

vaccine regardless of vaccine timing. Researchers also found that "[n]o safety benefits were identified for a delayed first dose versus vaccination at birth."[68]

Despite clear scientific consensus, HHS dismantled the hepatitis B routine birth dose recommendation, replacing the evidence-based policy with essentially the same discredited policy prior to ACIP's extensive review 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.[69] Without vaccination, as many as 9 in 10 infants infected with hepatitis B in their first year of life will develop chronic infection that can lead to liver failure and death.[70]

The combined measles, mumps, and rubella (MMR) vaccine has likewise been a target for this Administration. The most recent executive order on vaccines called for HHS Secretary Kennedy to offer the combined vaccination into separate single vaccinations.[71] This policy is nonsensical considering that there is no single component vaccine currently licensed in the U.S.[72] And no evidence exists that single component vaccinations for measles, mumps, or rubella are safer.[73] In fact, when Japan moved away from the combined MMR vaccination in the 1990s, measles, mumps, and rubella outbreaks increased.[74] The combined vaccine reduces access barrier discussed

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[68] Ctr. for Infectious Disease Rsch. & Pol'y, Univ. 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%202Dec2025.pdf.

[69] Ctrs. for Disease Control & Prevention, *Fact Sheet Hepatitis B Immunization* (Dec. 16, 2025), https://www.cdc.gov/media/releases/2025/fact-sheet-hepatitis-b-immunization.html.

[70] Kaiser Permanente, *The Importance of Hepatitis B Vaccination for Newborns* (Dec. 5, 2025), https://about.kaiserpermanente.org/news/the-importance-of-hepatitis-b-vaccination-for-newborns; Am. Acad. of Pediatrics, *Hepatitis B* (July 24, 2026), https://www.aap.org/en/patient-care/hepatitis-b/.

[71] Exec. Order No. 14420, 91 Fed. Reg. 53173–53175 (Aug. 14, 2026), https://www.govinfo.gov/content/pkg/FR-2026-08-14/pdf/2026-16730.pdf.

[72] Food & Drug Admin., *Vaccines Licensed for Use in the United States* (Aug. 6, 2026), https://www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states.

[73] Am. Acad. of Pediatrics, *The MMR (Measles, Mumps, and Rubella) Vaccine is Safe and Effective* (Mar. 20, 2025), https://www.aap.org/en/news-room/fact-checked/fact-checked-the-measles-vaccine-is-safe-and-effective/.

[74] Ctrs. for Disease Control & Prevention, *Progress Toward Measles Elimination – Japan, 1999-2008*, 57 MMWR MORB MORTAL WKLY REP 1049, https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5738a5.htm; Naruhito Otani, Masaki Ohmuraya, & Toshiomi Okuno, *Mumps Vaccination Policies and Epidemiological Consequences: A Comparative Review of the United States and Japan*, 7 EPIDEMIOLOGIA 95 (2026), https://doi.org/10.3390/epidemiologia7040095; Yusuke Tanaka et al., *History Repeats Itself in Japan: Failure to Learn From Rubella Epidemic leads to Failure to Provide the HPV Vaccine*, 13 HUM VACCIN IMMUNOTHER 1859-1860 (June 12, 2017), https://pmc.ncbi.nlm.nih.gov/articles/PMC5557250/.

previously by reducing the amount of visits and shots needed while giving the best possible protection against dangerous and preventable illnesses.[75]

The COVID-19 vaccine has also been downgraded to SCDM designation. The AAP recommends that the all infants and children 6 through 23 months of age who do not have contraindications should receive the COVID-19 vaccines. Further, the AAP recommends that all children and adolescents 2 through 18 years of age at increased risk of severe COVID-19 receive a single dose of the COVID-19 vaccines. They also recommend that children and adolescents in the same age category, who are not at increased risk of severe infection, but whose parents would like protection from COVID-19, should receive a single dose of the vaccine.[76] The rate of COVID-19 hospitalizations among pediatric age groups is highest among children under 2 years and, for children ages 6 through 23 months, the rate is comparable to people ages 50-64years. In addition, the risk of hospitalization for young children and those with high-risk conditions remains high.[77]

C. HHS should not base recommendations on vaccine schedules in countries that are demographically, culturally, and systemically different.

In proposing changes to the recommended vaccine schedule, HHS has stated that it is largely following the lead of Denmark, which it describes as a "peer nation."[78] However, most researchers, medical experts, and public health officials disagree that Denmark is an appropriate peer nation to the U.S. Denmark differs from the United States in population size, demographics, and health care access. As one study explained, "Denmark has 6 million people, a homogeneous population, universal healthcare with

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[75] Samantha K. Kurosky, Keith L. Davis, & Girishanthy Krishnarajah, *Effects of combination vaccines on completion and compliance of childhood vaccination in the United States*, 13 HUM VACCIN IMMUNOTHER 2494 (2017), https://pmc.ncbi.nlm.nih.gov/articles/PMC5703402/pdf/khvi-13-11-1362515.pdf (finding that "combination vaccines were associated with improved completion and compliance and should be encouraged among children who are under-vaccinated or who received single-antigen vaccines only").
[76] Am. Acad. of Pediatrics, *Recommendations for COVID-19 Vaccines in Infants, Children, and Adolescents, 2026-2027: Policy Statement*, PEDIATRICS (2026), https://publications.aap.org/pediatrics/article/doi/10.1542/peds.2026-079045/208785/Recommendations-for-COVID-19-Vaccines-in-Infants.
[77] Melissa Jenco, *AAP Provides Logistical Guidance After CDC Approves COVID Vaccine Use*, AAP NEWS (Oct. 6, 2025), https://publications.aap.org/aapnews/news/33471/AAP-provides-logistical-guidance-after-CDC.
[78] Jim O'Neill, Acting Director, Ctrs. for Disease Control & Prevention, *Decision Memo, Adopting Revised Childhood and Adolescent Immunization Schedule* (Jan. 5, 2026), https://www.hhs.gov/sites/default/files/decision-memo-adopting-revised-childhood-adolescent-immunization-schedule.pdf. *See also* Helen Branswell, *When it Comes to Vaccine Schedules, the U.S. is Now the Outlier*, STAT (Jan. 9, 2026), https://perma.cc/4VFG-NJBQ.

guaranteed rapid access, and a robust public health infrastructure."[79] Also, Denmark's health records automatically link maternal and infant health records, "ensuring virtually zero loss to follow-up."[80] In contrast, "[t]he United States has 330 million people, profound health disparities, 27 million uninsured, and a fragmented system."[81] Anders Hviid of the Danish Statens Serum Institute remarked that the U.S. and Denmark are "two very different countries. Public health is not a one size fits all."[82] He continues, stating that in Denmark citizens have access to excellent prenatal and childhood care and "as I understand it, that is not the case for everyone in the U.S. […] Vaccines prevent infections that may have poor outcomes for children who do not have access to good healthcare."[83] It simply does not make sense to adopt the vaccine schedule of a country with a smaller and more homogenous population than New York City.

Denmark itself is an outlier among other European countries for vaccine scheduling.[84] According to the European Centers for Disease Control's vaccine scheduler tool, none of the other 29 ECDC countries recommend a schedule that targets only 10 diseases as Denmark does. Many countries recommend vaccines for 15 or more diseases, including Germany, Greece, Ireland, and Poland, and Austria recommends a vaccine schedule that includes 17 diseases.[85] The U.S. vaccine schedule is closely aligned with countries like Canada, Britain, Australia, and Germany.

Further, Denmark has made vaccine recommendations based on their own population needs. For example, Denmark does experience some cases of rotavirus infections yearly, however, the infection rarely leads to death or long-term harm to children due to their access to universal health care and lower levels of inequality compared to the U.S. The U.S. experienced an estimated 2.7 million infections annually prior to the introduction of the rotavirus vaccine, leading to 55,000 to 70,000 hospitalizations and 20 to 60 deaths in children under five.[86] The rotavirus vaccine as part of a routine vaccination schedule aligns with Denmark's neighbors, Norway and Finland.[87]

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[79] Scott, *supra* note 15.
[80] *Id.*
[81] *Id.*
[82] Janice Hopkins Tanne, *RFK Slashes US Vaccines For Children As Medical Groups Threaten Legal Action*, BMJ (Jan. 07, 2026), https://www.bmj.com/content/392/bmj.s34.
[83] *Id.*
[84] *Id.*; Vaccine Integrity Project Staff & Advisers, *Viewpoint: The Myth of an Over-Vaccinated America: The U.S. DOES Follow Global Consensus*, Univ. of Minnesota (Dec. 22, 2025), https://perma.cc/Z32M-6HMN.
[85] Josh Michaud, *Do We Want To Outsource U.S. Vaccine Policy To Denmark?*, KFF (Dec. 19, 2025), https://www.kff.org/quick-insights/do-we-want-to-outsource-u-s-vaccine-policy-to-denmark/.
[86] *Id.*
[87] *Id.*

Additionally, Denmark's vaccine schedule skips immunization for respiratory syncytial virus (RSV) which is a leading cause of infant hospitalization in the U.S.[88] Indeed, officials in Denmark and Germany note that the childhood vaccine schedule in the U.S. had been tailored to our large and diverse population and patchwork medical system.[89]

IV. Changing the recommendation categories runs afoul of congressional intent and judicial decisions.

A. Congress has repeatedly approved the current federal vaccine recommendation system.

Congress has recognized the importance of vaccine access to the public's health by passing legislation creating standards that significantly expand vaccine availability and coverage. In so doing, Congress has also approved the current recommendation framework. For example, Congress has passed laws that, among other things, require coverage of vaccines recommended by ACIP and approved by the CDC in individual and small-group market plans, Medicaid and Medicare.[90] Congress has also given its seal of approval to the ACIP recommendation process through the creation of the Vaccines for Children (VFC) Program, under which states are required to provide vaccine coverage to all Medicaid and CHIP minor beneficiaries.[91] As with other insurance programs, coverage under the VFC program extends to all immunizations recommended by ACIP, in recognition of the widespread societal benefits of childhood vaccination.[92]

While the categories of vaccine recommendations are not set in statute, federal law is clear that the framework for recommendations must be prescribed by ACIP as a body that, while acting under the purview of HHS, exercises independent professional judgment. This approach is sound because it protects the process from undue political intervention and ideologically driven agendas. And while the Supreme Court, in the case of *Braidwood v. Kennedy*, reaffirmed HHS's authority over independent expert committees, such as ACIP, the Department is still bound by statutes creating ACIP and

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[88] Apoorva Mandavilli, *R.F.K. Jr. Likely to Swap U.S. Childhood Vaccine Schedule for Denmark's*, THE NEW YORK TIMES (Dec. 19, 2025) https://www.nytimes.com/2025/12/19/health/kennedy-childhood-vaccine-schedule-denmark.html.
[89] *Id.*
[90] 42 U.S.C. § 300gg–13 (requiring coverage of ACIP-recommended vaccines as preventive services in all non-grandfathered individual and small-group market plans); 42 U.S.C. § 1395w-102(b) (requiring coverage of ACIP-recommended vaccines without cost-sharing in Medicare Part D plans); 42 U.S.C. § 1396d(a)(13)(B) (requiring coverage of ACIP-recommended vaccines in Medicaid).
[91] 42 U.S.C. § 1396s.
[92] 42 U.S.C. § 1396s(e).

subsequently endorsing its processes.[93] The Supreme Court decision in *Braidwood* also affirms that HHS has no authority to circumvent the professional judgment of advisory committees and that control over the committee is limited to the composition of the committee and approving or disproving the recommendations.[94]

As such, by making changes to the ACIP recommendation process, framework, and categories without sound scientific evidence to justify the changes, HHS seemingly would be acting arbitrarily and capriciously, exceeding its own powers under federal law.

B. By suggesting changes to the recommendation categories, HHS seeks to bypass recent court orders prohibiting the Department from changing vaccine schedules in an arbitrary and capricious manner.

The idea that HHS's authority to dismantle ACIP's processes and recommendations framework is limited and can only happen when evidence justifies the changes has already been tested in courts. In March 2026, a federal district court in Massachusetts ruled that HHS acted arbitrarily and capriciously in replacing ACIP members because it had bypassed long-standing scientific and administrative norms without explanation.[95] The court similarly stayed all votes related to vaccines that ACIP had taken since the 2025 overhaul.[96] Finally, the court also granted an injunction halting the vaccine schedule established in January 2026 by the CDC without consulting ACIP.[97]

Evidently, legal questions abound about HHS's authority to control the processes at ACIP even after the *Braidwood* decision. Those questions are likely to extend to any future decision from HHS to overhaul the vaccine recommendation categories, when that decision clearly rests on ACIP and should be made without political pressure.

We are also deeply concerned by the fact that HHS seems to be evaluating changes to the recommendation categories in response to courts halting previous agency decisions. It appears that HHS is looking for a different avenue to pursue an agenda that prioritizes misinformation and vaccine hesitancy over scientific evidence given ongoing

[93] *See, generally, Braidwood v. Kennedy*, 606 U.S. 748 (2025).
[94] *Id.* ("The [U.S. Preventive Services] Task Force members are removable at will by the Secretary of HHS, and their recommendations are reviewable by the Secretary before they take effect. So Task Force members are supervised and directed by the Secretary, who in turn answers to the President, preserving the chain of command in Article II." The same principles apply to ACIP).
[95] *Am. Acad. of Pediatrics v. Kennedy*, 823 F.Supp.3d 141.
[96] *Id.*
[97] *Id.*

legal challenges to the Department's previous actions. However, HHS cannot escape the reality that all actions it takes are subject to the same administrative law standards that require abiding by federal statutes and adopting changes that are justified by the evidence. Since none of the goals of this Administration around vaccines are based on science or the best available clinical evidence, HHS will continue having a hard time defending itself against claims of acting in an arbitrary and capricious way.

V. Conclusion

For the reasons outlined above, NHeLP urges HHS to refrain from any changes to the current vaccine recommendation categories and framework. In addition, we call on ACIP to limit recommendations based on SCDM only to those vaccines for which the evidence does not clearly indicate a benefit for the entire population or for particular groups. Finally, ACIP, the CDC, and HHS should follow the science throughout the vaccine recommendation process and ensure that recommendations and changes to the ACIP composition are always based on the best available evidence and the goals of promoting immunization to preserve and protect the public's health. We have included numerous citations to supporting research, including direct links to research. We direct HHS to each of the materials we have cited and made available through active links, and we request that the full text of each of the studies and articles cited, along with the full text of our comment, be considered part of the formal administrative record for purposes of the Administrative Procedure Act.

Thank you for the opportunity to submit feedback on this RFI and for considering our comments. We are available to further discuss our comments. If you have any questions or to coordinate a meeting, please contact Héctor Hernández-Delgado at hernandez-delgado@healthlaw.org or Alexis Robles-Fradet at robles-fradet@healthlaw.org.

Sincerely,

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