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Submitted Via Federal Rulemaking Portal (Regulations.gov)

Secretary Robert F. Kennedy, Jr.
Department of Health and Human Services
200 Independence Avenue SW
Washington, D.C. 20201

Dear Secretary Kennedy:

We, the undersigned Attorneys General of the States of Arizona, California, Colorado, Connecticut, Delaware, Hawai‘i, Illinois, Maine, Maryland, Massachusetts, Michigan, Minnesota, Nevada, New Jersey, New Mexico, New York, Oregon, Rhode Island, Vermont, the Commonwealth of Virginia, Washington, and Wisconsin, and the Governor of the Commonwealth of Pennsylvania, submit this response to the Department of Health and Human Services’ (Department or HHS) August 24, 2026, request for information entitled “Request for Information (RFI): Categories Used in Federal Vaccine Recommendations and the Role of Shared Clinical Decision-Making (SCDM),” Docket No. HHS-OS-2026-0332.¹

Preventing and mitigating the spread of vaccine-preventable disease is a critical governmental responsibility that has long been a joint endeavor between the States and HHS. Over the last year, however, HHS has dismissed subject matter experts, weakened the nation’s childhood immunization schedule, and promulgated false and misleading information about vaccine safety and efficacy. These actions have caused confusion that threatens public health and the States’ ability to rely on HHS for public health guidance.

The RFI tacitly acknowledges the public health risks posed by some of HHS’s recent actions. For example, the RFI cites evidence that equivocal SCDM recommendations impose a greater burden on providers and result in lower vaccine uptake. RFI at 54725. Yet, at the same time, the RFI appears to conflate SCDM with informed consent—ignoring that providers are always legally and ethically obligated to obtain the latter—while signaling HHS’s intent to proceed on a course that would only exacerbate SCDM’s costs and risks. For the reasons stated below, we urge the Department to adopt a policy of restraint and to engage in meaningful scientific deliberation before adopting any further changes to vaccine policies or recommendations.

¹ 91 Fed. Reg. 54724 (Aug. 24, 2026).

I. The Department must work to rebuild public trust by reversing its recent changes to vaccine policy.

The RFI focuses extensively—and appropriately—on how public health leaders earn and maintain public trust. As the Department aptly observes, “trust is not fixed;” rather, “[i]t is built, and forfeited over time through the conduct of institutions.” RFI at 54726. This insight should prompt some introspection by HHS, which under this Administration has consistently implemented policies that threaten to make Americans less healthy. In the last fifteen months alone, the Centers for Disease Control and Prevention (CDC) and Secretary Robert F. Kennedy, Jr., have abruptly fired experts on the Advisory Committee on Immunization Practices (ACIP) and replaced them with unqualified individuals who abandoned ACIP’s deliberative scientific process; unjustifiably weakened the CDC’s longstanding hepatitis B birth dose vaccination recommendation; and purported to remake the entire childhood immunization schedule via a January 2026 memorandum, without ACIP’s involvement. Each of these actions is presently enjoined by a court.

During this same period, President Trump has issued a Presidential Memorandum² and two Executive Orders³ urging the CDC and/or ACIP to restructure the nation’s childhood vaccine schedule in a manner that results in fewer vaccinations. Most recently, on August 10, 2026, the President “declared” that the “Gold Standard” in childhood vaccination is the adoption of the enjoined January 2026 vaccine schedule and the provision of “all childhood immunizations”—including vaccinations for measles, mumps, and rubella (MMR)—“at separate medical visits.”⁴ Vaccination for MMR is only available in the United States as a combined vaccine. Separate administration would therefore be impossible at this time—and, regardless, it would impose a senseless burden on American families. In tandem with these actions and official pronouncements, Secretary Kennedy and President Trump have also made numerous public statements about vaccines that lack scientific basis and that are often demonstrably false. For example, President Trump’s baseless assertion that the combined MMR vaccine may be “quite lethal”⁵ ignores decades of evidence and vaccine-safety data to the contrary. This type of misinformation also sows confusion and undermines public confidence in vaccines.

As the RFI correctly observes, childhood vaccination policy has historically been guided by scientific analysis, including through a properly constituted ACIP’s use of rigorous evidentiary frameworks. RFI at 54724-25. It is therefore troubling that the Department avowedly propounded the RFI “in furtherance” of the August 10, 2026 Executive Order and “in support of” the Task Force for Safer Childhood Vaccines—a defunct body that, as discussed below, would be operating far outside its legal scope and expertise if resurrected as the Administration is contemplating. RFI at 54725. Policy continuity and consistent, scientifically accurate messaging are essential to establishing and maintaining public trust and promoting public health. Conversely, unlawful and

² Aligning United States Core Childhood Vaccine Recommendations with Best Practices from Peer, Developed Countries), 2025 DAILY COMP. PRES. DOC. 01167 (Dec. 5, 2025).

³ Realigning United States Core Childhood Vaccine Recommendations with Best Practices from Peer, Developed Countries, 91 Fed. Reg. 33575 (May 29, 2026); E Delivering Gold Standard Childhood Vaccination Recommendations for Americans, 91 Fed. Reg. 53173 (Aug. 10, 2026).

⁴ 91 Fed. Reg. 53173 .

⁵ Jessica McDonald, *Trump’s False MMR Vaccine Claims*, FACTCHECK.ORG (Aug. 11, 2026), <https://www.factcheck.org/2026/08/trumps-false-mmr-vaccine-claims/>.

misleading edicts about vaccines and ad hoc changes to vaccination policy, especially when inappropriately influenced by politics, further undermine public trust and public health.

The States are unaware of any evidence-based rationale for remaking the existing routine, risk-based, and SCDM recommendation categories. As the RFI recites, the SCDM terminology replaced “Category A/Category B” recommendations seven years ago to facilitate CDC’s “Evidence to Recommendations” (EtR) analysis. RFI at 54725. Changing these labels again is far more likely to cause confusion than to solve any identifiable problem.

But nomenclature aside, the strength of a given recommendation must always align with the underlying science about the population-level benefits and risks of a given vaccine.⁶ The critical issue is therefore that the Administration’s repeated efforts to move safe and effective vaccines from the “routine” recommendation category to equivocal categories (SCDM and/or risk-based) without proper evidentiary support are unwarranted and dangerous. As the RFI acknowledges, there is evidence that “uptake of vaccines recommended under SCDM has been lower than uptake of routinely recommended vaccines.” RFI at 54725. This impact comports with commonsense; the risk-based and SCDM categories signal to the public that there is some doubt about a vaccine’s safety, efficacy, or utility, which diminishes trust in vaccination and reduces uptake. Thus, while SCDM is a useful “category for *appropriate* vaccines,” as the Department states, *id.* (emphasis added), this determination must be evidence-based—otherwise, the inevitable result will be lower uptake of lifesaving vaccines to the detriment of public health in states across the country.

In short, the Department should examine how its actions (and those of the Administration) over the last several months have fomented and exacerbated the public distrust that the RFI purports to address. And the Department should refrain from further modifying or complicating the childhood immunization schedule without evidence-based reasons.

II. The Task Force for Safer Childhood Vaccines is an inadequate and inappropriate workaround to ACIP.

The RFI states, without explanation, that HHS seeks public comment “in support of the Task Force on Safer Childhood Vaccines (Task Force)”— signaling that the Department intends to use the Task Force, rather than a properly constituted ACIP, to inform future federal vaccine policy changes. Reliance on the Task Force as a substitute for ACIP would be inappropriate and threaten public health.

A. ACIP is deeply entwined with federal and state law, and—when properly constituted—its recommendations confer reliability and validity to vaccine policy.

The HHS Secretary is statutorily obligated to advise and assist states on public health matters, including “in the prevention and suppression of communicable diseases.” 42 U.S.C.

⁶ Jake Scott, *When the Default is Inaction*, Substack (Mar. 5, 2026), https://jakescottmd.substack.com/p/when-the-default-is-inaction?r=1qy0gl&utm_campaign=post&utm_medium=web&triedRedirect=true.

§ 243(a). For the past sixty years, ACIP, as an advisory committee created under the Federal Advisory Committee Act (FACA), has assisted with this obligation.

FACA is “designed to ensure ‘public accountability’ on the part of the Executive Branch.” *Pub. Citizen v. Nat’l Advisory Comm. on Microbiological Criteria for Foods*, 886 F.2d 419, 433 (D.C. Cir. 1989) (Edwards, J., concurring in part). It requires federal advisory committees like ACIP to be “fairly balanced,” and for their work not to be “inappropriately influenced by the appointing authority or by any special interest.” 5 U.S.C. § 1004(b)(2)–(3). As a body subject to FACA and its mandate to ensure public accountability, ACIP has historically operated with transparency—holding public meetings, utilizing evidentiary and evaluative frameworks such as GRADE (Grading of Recommendations Assessment, Development and Evaluation) and EtR,⁷ and abiding by conflict-of-interest disclosure requirements. *See* Ctrs. for Disease Control & Prevention, *Advisory Committee on Immunization Practices Policies and Procedures* 1, 4 (Jun. 2022).

ACIP’s recommendations form the bedrock of federal vaccine policy as Congress intended. Under the 21st Century Cures Act, for example, ACIP *must* consider *any* newly licensed vaccine or any new indication (i.e., clinical use) for an existing vaccine. 21 U.S.C. § 360bbb-4 note. ACIP’s recommendations also set the floor for which vaccines must be covered under State Plans for Medicaid and the Children’s Health Insurance Program (CHIP). 42 U.S.C. § 1396a(a)(10)(A); 42 U.S.C. § 1396d(a)(13)(B), (a)(4)(B), (r)(1)(B)(iii); 42 U.S.C. § 1397bb(a)(7)(A); 42 C.F.R. § 457.520(b)(4). And the Affordable Care Act requires insurers to cover, without cost-sharing, all vaccines that have in effect a recommendation from ACIP. 42 U.S.C. § 300gg-13(a)(2). Moreover, among ACIP’s essential functions is its responsibility to establish, review, and revise the schedule for pediatric vaccines covered by the Vaccines for Children (“VFC”) Program. *See* 42 U.S.C. § 1396s(e) (requiring the HHS Secretary to “use, for the purpose of the purchase, delivery, and administration of pediatric vaccines under this section, the list established (and periodically reviewed and as appropriate revised) by [ACIP]”).

ACIP recommendations are also a cornerstone of state health codes, often incorporated into state scope of practice laws, school entry requirements, and insurance coverage requirements, among other places.⁸ Until June 2025, nearly 600 statutes and regulations across forty-nine states, territories, and Washington, D.C., incorporated ACIP recommendations by reference.⁹

⁷ *See, e.g.*, Gordon H. Guyatt, et al., *GRADE: an emerging consensus on rating quality of evidence and strength of recommendations*, Nat’l Lib. of Med. (Apr. 26, 2008), <https://pmc.ncbi.nlm.nih.gov/articles/PMC2335261/> (explaining that GRADE promotes a “[t]ransparent process or moving evidence to recommendations”); Doug Campos-Outcalt D & Jonathan Temte, *Advisory Committee on Immunization Practices Standards for Assessing Evidence*, JAMA (Oct. 22, 2025), doi: 10.1001/jama.2025.20060; Ctrs. for Disease Control and Prevention, *Advisory Committee on Immunization Practices Policies and Procedures* (Jun. 2022), <https://www.cdc.gov/acip/downloads/Policies-Procedures-508.pdf>.

⁸ Ass’n of State and Territorial Health Offs., *Impact of the Advisory Committee on Immunization Practices Recommendations on State Law* (Jun. 23, 2025), <https://www.astho.org/topic/resource/impact-of-acip-recommendations-on-statelaw>.

⁹ *Id.*

In June 2025, Secretary Kennedy abruptly dismissed all seventeen voting members of ACIP.¹⁰ Two days later, the Secretary reconstituted ACIP with eight new members—none of whom completed the typical vetting or appointment process¹¹—and continued to appoint additional members with dubious qualifications thereafter.¹² The reconstituted ACIP has since abandoned its science- and evidence-based decision-making frameworks that previously grounded its recommendations¹³ and that the RFI recognizes have been central to its work. *See* RFI at 54725. Because of the importance of having a reliable and credible ACIP shaping our nation’s vaccine policy, ACIP’s reconstitution is the subject of ongoing litigation.

B. HHS should not rely on an unaccountable Task Force to advise on vaccine policy.

In August 2025, HHS reinstated the Task Force for Safer Childhood Vaccines¹⁴ after nearly three decades of dormancy. The RFI specifically notes that public comment will “support” the Task Force’s work, while explaining that the August 10, 2026, Executive Order “directs the Secretary, working with the Task Force [], to present plans within 90 days addressing, among other subjects, the timing and sequencing of the Federal immunization schedule and the continuous evaluation of the risk-benefit profile of recommended vaccines.” RFI at 54725. The Task Force lacks the requisite legal authority to make vaccine policy, and supplanting ACIP with the Task Force is otherwise improper and imprudent.

1. The Task Force was established with limited authority for a narrow purpose that it has already accomplished.

The Task Force was never intended to set federal vaccine policy. Rather, it was established in the mid-1980s with a manufacturing and surveillance mandate, in connection with adverse reactions to vaccines on the market on December 22, 1987. *See* National Childhood Vaccine Injury Act of 1986, 42 U.S.C. § 300aa-27 (“NCVIA”). The NCVIA directed the Task Force to:

promote the development of childhood vaccines that result in fewer and less serious adverse reactions than those on the market on December 22, 1987, and promote the refinement of such vaccines, and

make or assure improvements in, and otherwise use the authorities of the Secretary with respect to, the licensing, manufacturing, processing, testing, labeling, warning, use instructions, distribution, storage, administration, field surveillance, adverse

¹⁰ *See* Press Release, U.S. Dep’t of Health & Human Servs., *HHS Takes Bold Step to Restore Public Trust in Vaccines by Reconstituting ACIP* (Jun. 9, 2025), <https://www.hhs.gov/press-room/hhs-restore-public-trust-vaccines-acip.html>.

¹¹ Alexander Tin, *CDC purges career officials from oversight of vaccine committee*, CBS NEWS (Jun. 11, 2025), <https://www.cbsnews.com/news/cdc-purges-career-officials-vaccine-recommendations-process/>.

¹² *See, e.g.*, Press Release, U.S. Dep’t of Health & Human Servs., *Secretary Kennedy Appoints Two OB-GYNs to CDC’s Advisory Committee on Immunization Practices* (Jan. 13, 2025), <https://www.hhs.gov/press-room/secretary-kennedy-appoints-two-ob-gyns-cdc-advisory-committee-immunization-practices.html>.

¹³ *See* Doug Campos-Outcalt & Jonathan Temte, note 8, *supra* at 1, 4.

¹⁴ Press Release, Dep’t of Health & Hum. Servs., *HHS Revives Task Force on Safer Childhood Vaccines* (Aug. 14, 2025), <https://www.hhs.gov/press-room/hhs-reinstates-task-force-on-safer-childhood-vaccines.html>.

reaction reporting, and recall of reactogenic lots of batches, of vaccines, and research on vaccines, in order to reduce the risks of adverse reactions to vaccines.

Id. § 300aa-27(a)(1) and (2). The NCVIA also directed that the Task Force consist of “the Director of the National Institutes of Health (NIH), the Commissioner of the Food and Drug Administration and the Director of the Centers for Disease Control,” with the NIH Director serving as chairman. *Id.* § 300aa-27(b)(1) and (2). And the Task Force was to work “[i]n consultation with the Advisory Commission on Childhood Vaccines,”¹⁵ to “prepare recommendations to the Secretary concerning implementation of the requirements of subsection (a).” *Id.* § 300aa-27(b)(3).

The Task Force long ago fulfilled its statutory purpose. The vaccines available in the late 1980s have already been replaced with safer and more efficacious vaccines, satisfying § 300aa-27(a)(1)’s charge to refine the vaccines “on the market on December 22, 1987.” And the licensing and surveillance improvements that § 300aa-27(a)(2) called for have been developed and institutionalized for decades. Today, vaccines are scrutinized for their safety and any adverse effects both before FDA licensure and after recommendations are made by ACIP and HHS through multiple systems, including the Vaccine Adverse Event Reporting System, Vaccine Safety Datalink, and the Clinical Immunization Safety Assessment project.¹⁶ The Task Force was disbanded in 1998¹⁷ and defunct for decades because its narrow and time-limited role has already been accomplished and supplanted.

2. The Task Force cannot lawfully usurp ACIP’s role or otherwise assume functions outside its prescribed statutory purpose.

The August 10, 2026 Executive Order purports to direct the Task Force to address “the timing and sequencing of the Federal immunization schedule and the continuous evaluation of the risk-benefit profile of recommended vaccines.” But ACIP—not the Task Force—is the body empowered to help develop federal vaccine policy and modify the federal immunization schedules described above. Said differently, ACIP—not the Task Force—is the body that Congress has chosen to guide the type of critical vaccine recommendations and standards the Executive Order seeks to accomplish.

The Task Force’s narrow and long-ago fulfilled statutory mandate to improve upon vaccine products and manufacturing processes existing “on the market on December 22, 1987,” 42 U.S.C. § 300aa-27(a)(1), contemplates no role comparable to ACIP. Any attempt to have the Task Force serve as a general vaccine policymaking body would therefore far exceed the Task Force’s limited statutory mandate while usurping ACIP’s role. This is unlawful.

¹⁵ The Advisory Commission on Childhood Vaccines specifically advises the Secretary on the National Vaccine Injury Compensation Program. *See* Health Res. & Serv. Admin., *Advisory Commission on Childhood Vaccines* (last rev. Jan. 2025), <https://www.hrsa.gov/advisory-committees/vaccines>.

¹⁶ *See, e.g.,* Ctrs. for Disease Control and Prevention, *About CDC’s Vaccine Safety Monitoring Program* (Aug., 2024), <https://www.cdc.gov/vaccine-safety-systems/about/cdc-monitoring-program.html>.

¹⁷ *See* Press Release, note 15, *supra*.

Further, because State Medicaid plans, CHIP coverage, VFC systems, and other health infrastructure¹⁸ are tied to ACIP, any transfer of vaccine policymaking responsibilities away from ACIP and to the Task Force would have serious consequences for state healthcare systems. The Department's recent vaccine policy actions have already caused significant confusion, disruption, and harm to those systems and the state agencies that operate them. The Department's future actions should work to repair and prevent further damage. Pushing ACIP aside in favor of a legally unaccountable Task Force would further exacerbate that disarray.

3. Using the Task Force to develop federal vaccine policy will further impair HHS's credibility and undermine States' reliance on HHS for its assistance with public health matters.

ACIP has historically operated transparently through open meetings, evidence-based decision-making, and strict conflict-of-interest safeguards in line with FACA's obligations to maintain "fairly balanced" membership and avoid "inappropriate[] influence[] by the appointing authority or by any special interest." 5 U.S.C. § 1004(b)(2)–(3).

By contrast, the Task Force is comprised solely of three political appointees from NIH, FDA and CDC leadership—and the Department has given no assurance that it will operate with independence or transparency. Rather, President Trump's August 10, 2026 Executive Order and the RFI indicate that the Task Force will operate at political direction with no democratic systems or procedures to guide its work. Indeed, its activities thus far have been entirely opaque.

The revival of the Task Force is further colored by HHS's recent conduct, which has already prompted States to form their own health alliances, establish their own expert advisory committees, change their laws, and expend resources combatting misinformation about vaccines coming from HHS leadership, starting with Secretary Kennedy. If HHS now takes vaccine policy guidance from a Task Force that is, by design, subject to political influence, it will further undermine credibility with States, medical providers, and other stakeholders, resulting in incoherent and fractured vaccine policy across the country.

III. The current federal vaccine recommendation categories are well-established and should be retained.

The current vaccine recommendation categories—routine, risk-based, and SCDM—have historically provided clear, efficient, and evidence-based policy to guide States' administration of their public health and Medicaid programs. Until June 2025, States relied almost exclusively on the CDC's vaccine recommendations.¹⁹ These categories have enabled States to implement robust immunization programs and deliver clear, consistent, and evidence-based immunization guidance to the public and providers.

¹⁸ See 42 U.S.C. § 1396s(a)(1) ("In order to meet the requirement of 1396a(a)(62) of this title, each State shall establish a pediatric vaccine distribution program (which may be administered by the State department of health), consistent with the requirements of this section . . .").

¹⁹ See, e.g., Ass'n of State and Territorial Health Offs, note 9, *supra*.

While the RFI appears to signal HHS’s skepticism about the current recommendation categories, it does not identify any update in scientific consensus that supports changing them. And because there is significant value for States in the continuity of reliable vaccine recommendations, the Department should bear a heavy burden before departing from them, which it clearly fails to meet.

The majority of vaccines that appear on the current three-tiered recommendation structure are categorized as “routinely recommended,” which promotes vaccine uptake and the suppression of vaccine-preventable disease. Routine recommendations are made only when the scientific evidence clearly establishes that the population-level benefits of receiving a vaccine (within a recommended age group) substantially outweigh its risks. Routine recommendations therefore provide an evidence-based clinical default that is foundational to how vaccines are discussed and delivered—which ultimately influences individuals’ vaccination choices.²⁰ The RFI itself confirms that “[u]nder a *routine* (universal) recommendation, the default is to vaccinate all persons in an age group absent contraindications.” RFI at 54724. Evidence from prior instances where ACIP moved *towards* routine recommendations demonstrates that those changes increased vaccine uptake and decreased rates of vaccine-preventable disease.²¹ Routine recommendations therefore remain a critical and highly effective public health tool.

IV. SCDM is appropriate only in limited circumstances and its misuse threatens public health.

Prior to June 2025, SCDM was narrowly defined and used in limited circumstances. No evidence supports changing that practice now.

At times, the RFI appears to conflate SCDM with informed consent—two materially distinct concepts—to push for further expansion of the SCDM designation. Most notably, the RFI asks whether the current vaccine categories “unintentionally imply” that “individual consent” applies only to SCDM or that only SCDM confers the “benefits” of “informed consent.” RFI at 54727-28. These questions—purposefully or otherwise—contribute to the inaccurate impression that SCDM is the only kind of recommendation that allows for patient autonomy and consent. In reality, consent is a universal principle of medical ethics, while vaccine recommendations, including SCDM, communicate what is scientifically known about the population-level risk-benefit profile of receiving a vaccine.²² A provider’s legal and ethical obligations to obtain informed consent from a patient or a parent before providing medical care apply regardless of whether a vaccine is routinely recommended or recommended based on SCDM.²³ Expanding

²⁰ See Jake Scott, *CIDRAP Op-Ed: Quiet dismantling: How ‘shared decision-making’ weakens vaccine policy and harms kids*, CIDRAP (Jan. 6, 2026), <https://www.cidrap.umn.edu/childhood-vaccines/cidrap-op-ed-quiet-dismantling-how-shared-decision-making-weakens-vaccine-policy>.

²¹ See Emily Lawler, *Effectiveness of vaccination recommendations versus mandates: Evidence from the hepatitis A vaccine*, *Journal of Health Economics*, Vol. 52, 45–62 (2017); Emily Lawler, *Giving teens a boost? Effects of adolescent meningococcal vaccine recommendations*, *American Journal of Health Economics*, Vol. 6(2), 251–287 (2020).

²² Scott, J., *When the Default is Inaction*, note 6, *supra*.

²³ As the preamble to the RFI correctly recognizes, informed consent “principles apply across all vaccine recommendations, including routine ones,” and that informed consent is not “confined” to the SCDM category. RFI at 54725-26.

SCDM, therefore, does not alter those obligations. Rather, expanding SCDM to vaccines that are routinely recommended based on this misleading premise and without a valid evidentiary basis for doing so would only undermine federal vaccine policy and diminish vaccine uptake.

Indeed, the SCDM designation is intended for situations in which there is “genuine clinical equipoise,” meaning that “individual factors meaningfully shift the risk-benefit assessment” and the “population-level benefit is uncertain.”²⁴ Thus, HHS has historically, and appropriately, reserved this recommendation category for vaccines falling within this narrow scope—(1) hepatitis B vaccination for certain adults aged sixty years or older, (2) serogroup B meningococcal vaccination for adolescents and young adults, (3) human papillomavirus (HPV) vaccination for certain adults, and (4) conjugate pneumococcal vaccination for patients aged sixty-five or older.²⁵ Notably, before June 2025, CDC had never used SCDM when recommending vaccines for young children.

Since June 2025, however, HHS has repeatedly attempted to redefine and expand SCDM beyond its intended scope, including by changing the decades-long routine hepatitis B birth dose recommendation to “individual-based decision-making” for hepatitis B-negative mothers and by stripping seven childhood vaccines of their routinely recommended status.²⁶ These actions are currently the subject of litigation. *See Arizona v. Kennedy*, No. 26-cv-01609-VC (N.D. Cal. 2026); *AAP v. Kennedy*, 823 F.Supp.3d 141 (D. Mass. 2026).

The RFI itself makes a strong case against the overuse of SCDM. It acknowledges that the SCDM designation eliminates any default vaccine recommendation. RFI at 54725-26. As a result, SCDM “requires more time [to implement] than routine recommendations,” generates confusion over insurance coverage, is incompatible with “electronic health record and immunization forecasting tools,” creates confusion for patients, and leads to lower vaccine uptake than routine recommendations. RFI at 54725. But even as the Department acknowledges the tangible negative impacts from SCDM, the RFI indicates that HHS intends to further expand its improper use of this recommendation category. RFI at 54727-28. Doing so would unquestionably exacerbate these harms. CDC’s own experience confirms that uptake for vaccines recommended based on SCDM is lower than routinely recommended vaccines, by orders of magnitude.²⁷ Lower vaccine uptake for vaccines that have long been established as safe, effective, and beneficial for public health—and remain so—will predictably result in higher rates of vaccine-preventable disease.

²⁴ Scott, J., *Quiet Dismantling*, note 21, *supra*.

²⁵ See Allison Kempe, et al., *Shared Clinical Decision-Making Recommendations for Adult Immunization: What Do Physicians Think?*, 36 J. Intern. Med. 2283-91 (2021), doi:10.1007/s11606-020-06456-z.

²⁶ Press Release, Ctrs. for Disease Control and Prevention, *ACIP Recommends Individual-Based Decision-Making for Hepatitis B Vaccine for Infants Born to Women Who Test Negative for the Virus* (Dec. 5, 2025), <https://www.cdc.gov/media/releases/2025/2025-acip-recommends-individual-based-decision-making-for-hepatitis-b-vaccine-for-infants-born-to-women.html>; Decision Memo, Ctrs. for Disease Control and Prevention, *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>.

²⁷ See Jeffrey Vietri, et al., *Pneumococcal vaccine uptake among Medicare beneficiaries aged ≥65 years following the shared clinical decision-making recommendation for 13-valent pneumococcal conjugate vaccine in 2019*, Vaccine, 41(36), 5211–5215 (2023).

V. Ongoing ad hoc changes to federal vaccine recommendations will impair public health and further diminish States’ reliance on the Department.

The Departments’ weakening of vaccine recommendations in recent months has not been grounded in the science, procedure, or transparency that has guided federal vaccine policy for decades. Thus, HHS’s recent actions have upended States’ reliance on CDC and ACIP as an authoritative source of evidence-based vaccine policy. CDC’s weakening of the childhood immunization schedule, for example, has had a significant operational, public health, and financial impact on States. *See generally, Arizona*, Complaint, 3:26-cv 01609 (N.D. Cal. Feb. 24, 2026), Dkt. 1.

The RFI alludes to various proposals that, if adopted, would harm States, patients, and providers—further impairing public health and undermining States’ reliance on federal vaccine policy. RFI at 54727-28. The Department, for example, suggests that providers spread out the administration of vaccines—including MMR—across multiple medical appointments, without providing any evidence as to the necessity or efficacy of this approach. RFI at 54728. The suggestion is both unreasonable and dangerous. The MMR vaccine used today²⁸.⁷ Additionally, administering vaccines over multiple visits would needlessly burden parents, patients, and providers—with especially acute impacts on low-income families and communities with limited access to medical care. Thus, splitting up the administration of the MMR vaccine would foreseeably suppress the uptake of yet another safe, effective, and life-saving vaccine that has been routinely recommended for decades.

* * *

Absent recommendations backed by robust and transparent scientific evidence, the Secretary cannot effectively advise and assist States in the prevention and suppression of communicable diseases. If the Secretary continues along the present path, States will be forced to continue untethering their reliance from HHS, CDC, and ACIP at significant expense. The States, therefore, urge the Department to restore its commitment to the rigorous scientific analysis and independent expertise that has historically enabled strong federal-state cooperation in safeguarding the public health through coherent vaccination recommendations.

²⁸ “Individual components of MMR vaccine are not available in the U.S.” Children’s Hosp. of Philadelphia Vaccine Educ. Ctr., *Measles, Mumps and Rubella (MMR): The Diseases & Vaccines* (last rev. Jun. 26, 2025), <https://www.chop.edu/vaccine-education-center/vaccine-details/measles-mumps-and-rubella-vaccines>. The recognized benefits of the combined vaccine over three different vaccines include: fewer shots, fewer office visits, less time to be susceptible to [the] three diseases (measles, mumps and rubella), and a lower change for vaccine administration errors. *Id.*

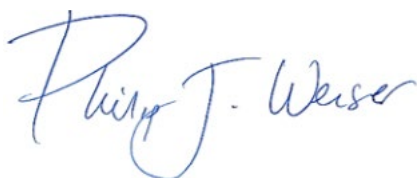
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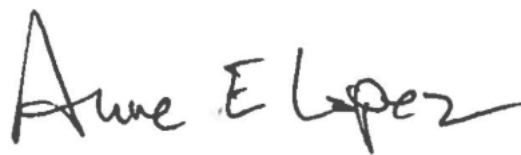
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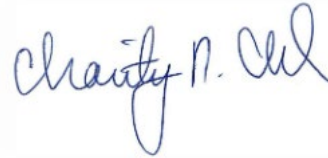
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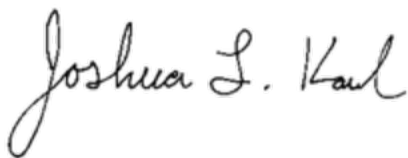
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