FAMILIESUSA
THE VOICE FOR HEALTH CARE CONSUMERS

September 20, 2026

The Honorable Robert F. Kennedy, Jr.
Secretary
Department of Health and Human Services
200 Independence Ave. SW
Washington, DC 20201

Submitted electronically via regulations.gov

Re: Response on Request for Information: Categories Used in Federal Vaccine Recommendations and the Role of Shared Clinical Decision-Making

Dear Secretary Kennedy,

On behalf of Families USA, thank you for the opportunity to respond to this Request for Information, "Categories used in Federal Vaccine Recommendations and the Role of Shared Clinical Decision-Making." As the longtime national, non-partisan health care consumer advocacy organization, Families USA is committed to ensuring that all Americans have access to the high-quality health care and health they deserve, including comprehensive evidence-based vaccines proven to protect the health of families and communities. We are deeply concerned about efforts by the administration, including through this RFI, that undermine access to evidence-based vaccines and spread false information about their safety and efficacy. **We urge HHS to change course and re-assert its commitment to science and evidence-based medical interventions including vaccinations.**

In particular, we strongly oppose the recommendations to move routine vaccines to the Shared Clinical Decision-Making category, muddying the definition, resulting in less coverage and more cost and confusion. Additionally, reinstating the Task Force to provide recommendations exceeds its statutory mandate and undermines ACIP's independence. We urge the Administration to reverse course and rebuild vaccine trust, using science-based communication, not political interference.

Vaccines are one of the most significant evidence-based public health interventions in modern history, successfully mitigating the severity of illnesses and spread of diseases such as the flu and measles, and have reduced mortality and eradicated infectious diseases such as polio and smallpox.[i] Vaccinations serve as the bedrock of any high-value health care system.[ii] In the United States alone, routine childhood immunizations prevented 508 million cases of illness, 32 million hospitalizations, and 1.13 million deaths over the lifetime of the roughly 117 million children born between 1994-2023.[iii] Those vaccinations also produced a net $540 billion in direct savings to payers through reduced

treatment costs and fewer complications from vaccine-preventable disease and $2.7 trillion in societal savings including averted lost wages and missed school days.[iv] Ensuring that every child, regardless of zip code or background, can easily access the evidence-based vaccines they need without financial barriers is foundational to preventing infectious disease outbreaks, and helps to keep families out of the emergency room – the most expensive care settings – and ultimately helps to hold health care costs down.[v] At a time when health care costs are out of control with families being increasingly exposed to rising premiums and out-of-pocket costs, preventing the spread of illness and disease is not only good for the health of the public but also can be an effective cost-containment strategy.[vi]

Given the importance of maintaining access to evidence-based vaccines, we are deeply concerned that this RFI and Executive Order 14420 "Delivering Gold Standard Childhood Vaccine Recommendations for Americans,"[vii] are promoting misinformation about the safety and effectiveness of vaccines that will ultimately jeopardize access to these essential health care interventions for children and families. The attacks on vaccines through this RFI and the Executive Order run contrary to long-standing academic evaluation and evidence of the safety and efficacy of immunizations and directly undermine medical and clinical best-practices that are continually reinforced by experts across U.S. medical societies and associations[viii]. On behalf of the American people, we reaffirm what researchers have found for decades:

Vaccines are safe, effective and are an essential evidence-based tool for protecting the health of American communities by reducing morbidity and mortality of vaccine-preventable illnesses.[ix] As a result, we urge **HHS to change course and instead work to preserve and support independent, evidence-based bodies – including ACIP – so they can continue to make vaccine recommendations based on the best science and medical evidence available, and help ensure those vaccines are covered without cost for children, families and patients across the country.**

Specific to this RFI, we offer additional detailed comments on the following sections:

- C. Shared Clinical Decision-Making: Meaning, Risks and Benefits
- D. Considerations in Setting Recommendations
- E. Trust and Communication

C. Shared Clinical Decision-Making (SCDM): Meaning, Risks and Benefits

Overall Recommendation: HHS should rescind the redesignation of six vaccines from routine to SCDM, preserving SCDM recommendations for the narrow, risk-based purpose intended by ACIP, and not establishing any new vaccine recommendations without new evidence to support their introduction.

Q. 8 What does, or what should, "shared clinical decision-making" mean in the vaccination context?

In a clinical setting, Shared Clinical Decision Making (SCDM) is a collaborative process in which a health care provider, together with patients, family members, or caregivers weighs the benefits and risks of a medical intervention, including vaccination and together reaches a decision that reflects both the clinical evidence and the patient's circumstances.[x] Importantly, SCDM describes a process that most providers already do every day when they counsel patients and families about immunizations.

To that end, this administration's recent decision to move six vaccines — hepatitis A, hepatitis B, meningococcal, rotavirus, influenza, and COVID-19 — from a routine recommendation to a SCDM designation is unnecessary and unsupported by the evidence, and is ultimately counterproductive, and sends misleading and mixed messages to the public.[xi] Pediatricians and primary care physicians already engage their patients in shared clinical decision making about vaccines.[xii] Efforts by HHS to redesignate certain vaccines do not strengthen SCDM between clinicians and patients. Instead, it undermines the scientific consensus on vaccine safety and efficacy, casts doubt on the clinical judgement of CDC, ACIP and the broader medical community, lends credibility to vaccine misinformation, and leaves patients uncertain about interventions supported by decades of rigorous evidence.[xiii]

ACIP's SCDM definition is distinct from the clinical definition and is used in specific contexts. Within ACIP's framework, SCDM carries a specific and narrow meaning: it is a risk-based designation, reserved for vaccines where particular individuals may benefit but broad vaccination of the group is unlikely to produce a population-level impact.[xiv] Importantly, no new scientific evidence justifies redesignating these six vaccines under the SCDM standard set by ACIP, and no evidence suggests that adding this new SCDM category will change the public's understanding of vaccines. **We therefore urge HHS to rescind the redesignation of these six vaccines, restore their routine recommendations, and preserve SCDM for the narrow, risk-based purpose ACIP intended.**

Q11. What are the risks of an SCDM category, including confusion, reduced access or uptake, and time burdens in practice, and what evidence supports them?

Families USA opposes converting routine vaccine recommendations to the shared clinical decision-making (SCDM) category. The SCDM category should be reserved for the risk-based purpose ACIP intended: vaccines for which individual risk factors, rather than population-level benefit, determine whether a patient should be vaccinated. Shared decision-making as a clinical best-practice is already part of every vaccination encounter—to move vaccines from routine recommendations sends a signal about individual risk factors unsupported by evidence.

Converting a routine recommendation to SCDM as seen in the Executive Order 14420 creates risks and harms in three concrete ways that undermine access to care: it invites coverage denials, it strips away standing orders, and it shifts cost and burden onto consumers, providers, and rural communities. These results will add cost, complexity, and confusion to our health system, taking the time of patients and providers, adding costs and further burdening an overstretched primary care system, but not for any reason supported by science. This means less coverage and less access, and more inconvenience and costs.

Coverage Failures

Research shows that plans diverge sharply in how they treat SCDM recommendations: while some insurers cover routine and SCDM vaccines alike, others state explicitly that coverage extends only to vaccines subject to directive ACIP language ("should," "shall," "is") for routine use, and not to permissive ("may") recommendations.[xv] Adding categories to this flawed system will increase confusion and likely result in more care denials.

Undermining standing orders

Standing orders allow nurses, pharmacists, and other non-physician health care professionals to assess, prescribe, and administer vaccines without a separate physician visit. Standing orders serve as a central mechanism for removing barriers to care and reaching patients where they are. Most state standing-order authorities are written to track "an immunization that is recommended by the federal CDC and ACIP," so when a vaccine moves out of the routine category, the standing order can lapse with it. At least 27 states and the District of Columbia reference authorities other than CDC and ACIP for vaccine recommendations, which generally allow for continued administration via standing orders.[xvi]

Undue burden for consumers, providers and rural communities

Proposals to unnecessarily spread vaccine administration across multiple office visits including recommendations for only one vaccine per appointment and splitting MMR into three separate injections, create significant new barriers to access. The current childhood schedule rests on evidence, and no new research supports these changes.[xvii] What they would produce is more appointments — and every additional appointment comes with an inherent set of costs. Under a one-vaccine per visit rule, a family would go from five vaccine appointments in a child's first year of life to *twenty-six*.[xviii]

Twenty-six visits in the first year would be a near impossible schedule for most families to be able to reasonably maintain. Each additional visit means time away from work and school.[xix] Appointment availability is already constrained, with average wait times of 31

days and more than 100 million Americans lacking access to primary care providers.[xx] A prolonged schedule also leaves infants unprotected for longer. With no national paid family leave, many families place children in child care between six weeks and three months of age, before a delayed schedule would confer the protection they need.[xxi] For example, rotavirus spreads easily in group care, on toys, books, and the hands of child care providers.[xxii] Before the vaccine, it caused roughly 3 million episodes of gastroenteritis, 410,000 physician visits, 55,000–70,000 hospitalizations, and 20–60 deaths each year among children under 5.[xxiii] The timing is narrow: the first dose must be given before 15 weeks of age, and no dose may be given after 8 months, even if the series is incomplete.[xxiv] Limiting infants to one vaccine per visit puts that window at risk. These changes would upend not just our health system, but would also disrupt our childcare system and providers.

The cost of this effort needs to be better considered — adding unnecessary costs to an already overpriced system. Further, at the average Medicare rate for an evaluation and management visit for $61.11, the necessary 11 additional conversations with a provider would translate to $672.21 in new costs per child in the first year of life and would result in up to $2.4 billion in added annual costs to the health care system.[xxv] These changes would add increased counseling time, documentation demands, and liability exposure under an unclear standard of care.[xxvi] These new requirements would only exacerbate the already growing administrative and staffing burdens facing primary care providers.[xxvii] SCDM requires a genuine two-way conversation; a portal message to a patient does not satisfy that requirement.[xxviii]

The impact of these burdens is amplified in rural communities. Patients living in rural areas utilize less care and travel farther when they do seek care, so scheduling an additional twenty-one appointments would dramatically exacerbate an existing access gap and expand risk for missed doses.[xxix] This would also compound the rural health primary care crisis. “Health Resources and Services Administration (HRSA) projects that by 2037 only 68 percent of the demand for rural primary care physicians will be met.”[xxx]

To that end, Families USA urges HHS not to establish any additional recommendation categories. SCDM recommendations must be used only as ACIP intended — for vaccines whose benefit varies from person to person and never as a device to cast doubt on vaccines whose benefit is clearly established. The introduction of shared clinical decision-making has already generated significant confusion and new administrative burden across the health care system, for clinicians determining eligibility, for pharmacists and other vaccinators, for payers adjudicating coverage, and most consequentially for the families attempting to understand which vaccines they can access and at what cost. Every additional vaccine in this category multiplies these friction points and creates one more juncture at which a patient can be turned away or billed unexpectedly. Rather than layering

on further complexity, HHS should stabilize the framework that providers, payers, and consumers already rely on.

D. Considerations in Setting Recommendations

Overall recommendation: As set forth by Congress, any vaccine recommendations for the civilian population must be made by ACIP. Separate recommendations cannot and should not come from the HHS Task Force, which will only result in further confusion.

Q14. What considerations should be relied upon in establishing vaccine recommendations and assigning categories, and under what conditions should each predominate? Commenters are specifically invited to address the availability, quality, and strength of evidence; the appropriate approach where randomized controlled trial evidence is absent, infeasible, or unethical to obtain; disease severity and epidemiology; individual versus population benefit; a presumption in favor of individual autonomy, informed consent, and religious freedom; and feasibility and programmatic consequences

Protecting and preserving the role of the Advisory Committee on Immunization Practices (ACIP)

Notably absent from this RFI is any discussion on the role of ACIP, the current advisory committee whose recommendations Congress has tied to vaccine coverage requirements. ACIP's charge has been consistent since 1964: to advise the Director of the Centers for Disease Control and Prevention (CDC) on the use of vaccines and related agents for the effective control of vaccine-preventable diseases in the civilian population of the United States.[xxxi] In the six decades since, under administrations of both parties, ACIP's purpose has remained unchanged while the committee's independence and scientific rigor have been strengthened by Congress and ACIP itself. ACIP's designation under the Federal Advisory Committee Act (FACA) in 1972 brought open meetings and strict federal ethics rules.[xxxii] In 1978 the chair became an elected position filled by the committee instead of the CDC Director, a deliberate decision to guard against political interference. The unanimous adoption of Grading of Recommendations Assessment, Development and Evaluation (GRADE) in 2010 and the Evidence to Recommendation framework (EtR) in 2018 made the committee weigh certainty of evidence, benefits versus harms, evaluation cost effectiveness, equity and feasibility.[xxxiii]

Congress has ratified ACIP's role repeatedly, through the Vaccines for Children provisions of the Social Security Act, section 2713 of the Public Health Service Act, and provisions in the Affordable Care Act and the Inflation Reduction Act that tie ACIP recommendations to coverage obligations. In doing so, Congress incorporated ACIP's evidence standards, including the GRADE and EtR framework, and recommendation categories into federal law. Departing from those standards deviates from what Congress enacted.

- The Advisory Committee on Immunization Practices (ACIP) was established in 1964 to give the U.S. Public Health Service (USPHS) standing expert advice on the use of vaccines in the civilian population.[xxxiv] Executive Order (EO) 14420 signed on August 10, 2026 reconstitutes the HHS Task Force on Safer Childhood (the Task Force) vaccines which was disbanded in 1996 due to completing its Congressional statutory mandate to improve the safety of vaccines for children. Under this EO, the Task Force is to assess the "ideal timing and sequencing of all core childhood vaccines and adjust the Federal childhood and adolescent vaccine schedule as appropriate based on gold-standard science;" [xxxv]
- This Task Force should not be reinstated for three major reasons:
    - It exceeds the statutory charge. Congress originally directed the Task Force to improve vaccine safety, not to advise on the vaccine schedule.
    - It contradicts the Task Force's own prior conclusion that schedule review and vaccine safety are part of an interagency process, and not the responsibility of a single body.
    - It removes this work from the public view and reduces transparency. Unlike ACIP, the Task Force is not governed by FACA. There are no open meeting requirements, no public docket, no published evidence review, and no conflict-of-interest disclosures.[xxxvi] Moving schedule decisions from ACIP to the Task Force does not resolve questions about transparency. It forecloses the public's ability to ask them.

Measles and other vaccine-preventable diseases are at their highest levels in decades.[xxxvii] At exactly this moment, providers and families need one clear, evidence-based source of guidance.[xxxviii] Instead, patients are being given competing expert bodies, shifting standards, and a schedule under review behind closed doors.[xxxix] Parents' desire to protect their children is being met with confusion rather than clarity.[xl] The path forward should be the restoration of the one Congress already built. ACIP's role and charter must be restored to its original scope.

ACIP already has a clear process for how to evaluate and weigh certainty of evidence, how to account for adverse effects, how to assess benefit relative to harm, through the GRADE and EtR framework. New pathways to recommendation are not necessary and not supported.

Families USA strongly recommends that ACIP be restored and allowed to work free from political influence and that no parallel system of recommendations is set up through the HHS Task Force. We further urge HHS to revert the ACIP charter back to reflect the committee's core functions and ensure the Task Force's role remains within its statutory lane. Specifically, the charter should:

- **Restore the original statement of purpose** by striking the "and/or decreased symptomatology" and "gaps in vaccine safety research including adverse effects following vaccination" language from the committee's stated goal.
- **Preserve ACIP's authority over its own evidence-review process.** The process by which the committee evaluates evidence and formulates recommendations should not be modified except by ACIP itself.
- **Maintain membership qualification requirements focused on** vaccine expertise.

Section E. Trust and Communication

Q17. What communication practices should accompany vaccine recommendations so that they earn and keep public trust?

The public supports clear, evidence-based vaccine recommendations, and mandates remain a necessary tool to protect the health, safety, and security of our nation. The work isn't finished; considerably more is needed to rebuild public confidence. The actions this Administration have taken undermine what trust remains. To that end, we strongly encourage HHS to adopt the following practices:

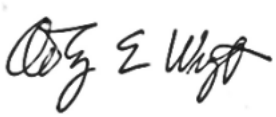
- **Insulate independent, evidence-based and peer-reviewed science from political interference:** The Administration must remove political interference from NIH, CDC, and other science agencies, including through the grant review and award decisions. The Administration must rescind the proposed OMB rule and reinstate the 33 terminated studies on vaccine hesitancy at NIH, a direct effort to understand the very problem exacerbated by this RFI.[xli]
- **Confine the Task Force to its statutory role.** The Task Force should not issue recommendations on changes to the immunization schedule. All Task Force members should be subject to the same conflict-of-interest requirements that govern ACIP members, and the Task Force should meet the same transparency standards ACIP is held to: open meetings, public comment periods, and publicly available minutes.
- **Restore staffing for CDC and its partner agencies:** Ensuring the agencies have the funding and experienced personnel to staff them is pivotal in rebuilding trust within these agencies.
- **Retire the autism framing.** Vaccines do not cause autism. Continuing to raise a scientifically settled question erodes trust and displaces the safety communication families actually need.[xlii] The Administration must state unequivocally that vaccines do not cause autism and must remove language on the CDC's website that states, "the claim 'vaccines do not cause autism' is not an evidence-based claim because studies have not ruled out the possibility that infant vaccines cause autism. Studies supporting a link have been ignored by health authorities."[xliii]

- **Invest in trusted local messengers.** Clinicians, state and local health departments, and community-based organizations carry credibility that federal communications alone cannot substitute for. Resource them accordingly by ensuring no budget is passed that does not include **at least $11.581 billion in funding for the CDC** to distribute grants and reinstate previously rescinded grant funding.[xliv]

Families USA has long fought for coverage and to control costs. These recommendations recognize that these proposed changes would undermine access and coverage to lifesaving vaccines, contribute to more disease and less public health, as well as a more costly and confusing health system.

Our children's health, the stability of our health care system, and the strength of our economy all depend on vaccine policy that follows the evidence. HHS should abandon this course and instead protect the independent bodies, ACIP among them, that make science-based recommendations and ensure clear coverage without cost sharing. Thank you for the opportunity to respond to this RFI and for your time and consideration of our recommendations. Please contact Sophia Tripoli, Managing Director of Health Policy (STripoli@familiesusa.org) with any questions.

Sincerely,



Anthony Wright
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