NATIONAL CONSUMERS LEAGUE
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September 20, 2026

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

Re: Request for Information: Categories Used in Federal Vaccine Recommendations and the Role of Shared Clinical Decision-Making; Docket No. HHS-OS-2026-0332

Dear Secretary Kennedy:

The National Consumers League (NCL) appreciates the opportunity to comment on the Department of Health and Human Services' (HHS) Request for Information regarding categories used in federal vaccine recommendations and the role of shared clinical decision-making (SCDM). For more than a century, NCL has advocated for policies that protect consumers and promote access to safe and effective healthcare. Vaccines are among our most important public health tools, protecting communities from serious and preventable disease. At a time of declining vaccine confidence and falling childhood vaccination rates, NCL believes changes to federal vaccine policy should be guided by two overarching goals: strengthening public trust and increasing uptake of FDA-approved vaccines. Changes that unnecessarily complicate vaccine recommendations, make vaccination less convenient, or create unwarranted doubt about vaccines will move us in the wrong direction.

Questions 5 and 14: Scientific evidence and evidentiary standards

Federal vaccine recommendations should reflect the totality of the best available scientific evidence, including evidence regarding vaccine safety and effectiveness, disease severity and epidemiology, and individual and population-level benefits. Where the scientific evidence supports routine vaccination, federal recommendations should communicate that conclusion clearly. Randomized controlled trials (RCTs) are an important source of scientific evidence, but they are not the only scientifically valid source of evidence and may not be appropriate or ethical for every research question.[1] For example, once substantial evidence establishes that a

[1] Chapter 12: Integrating Randomized and Non-randomized Studies in Evidence Synthesis | ACIP GRADE Handbook | CDC; Should we recategorize vaccine recommendations? | Voices For Vaccines

vaccine protects against serious disease, it may be unethical to withhold that protection from individuals solely to create a control group. RCTs should continue to be used when appropriate, but federal vaccine recommendations should also consider other rigorous sources of evidence, including large-scale health data, real-world studies, disease surveillance, post-licensure studies, and vaccine safety monitoring.

In addition, while the United States should learn from the experiences of other countries, international approaches should not determine U.S. vaccine policy. Countries differ substantially in population size and diversity, disease epidemiology, healthcare delivery, access to care, and immunization infrastructure. Federal recommendations should reflect the evidence and public health needs of the U.S. population, and should not be driven by the recommendations of other countries without considering important differences between their populations and healthcare systems and those of the United States.

Question 7: Vaccine timing and administration

NCL is concerned about approaches that encourage families to separate vaccines or receive recommended vaccines over multiple visits without a scientifically supported clinical reason. Research using U.S. vaccination data has found that children receiving combination vaccines were more likely to complete recommended vaccinations and receive them on time than children receiving only single-antigen vaccines.[2] Requiring or encouraging additional visits creates additional opportunities for children to miss or delay recommended vaccines because of scheduling difficulties, transportation, work and caregiving obligations, or simply failure to return for another appointment. Parents and caregivers should receive accurate information about their options, but flexibility should not be communicated in ways that suggest that separating vaccines is safer or medically preferable when the evidence does not support that conclusion.

Questions 11 and 12: Shared clinical decision-making, communication, and access

NCL is concerned that expanding the use of SCDM where the scientific evidence supports routine vaccination could have unintended consequences for vaccine confidence and uptake. Moving vaccines from routine recommendations to SCDM can imply that those vaccines are less important and create confusion for parents and clinicians.[3] CDC has similarly reported concerns that SCDM recommendations can appear to reflect lower confidence in a vaccine and can be difficult and time-consuming to communicate to patients.[4]

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[2] Effect of combination vaccines on completion and compliance of childhood vaccinations in the United States - PubMed

[3] 'A steady hand and a voice of reason': Experts equip pediatricians with tools to address vaccine confusion | AAP News | American Academy of Pediatrics

[4] Advisory Committee on Immunization Practices (ACIP) Evidence to Recommendations (EtR) for Use of Additional Doses of 2024-2025 COVID-19 Vaccines in Older Adults and People who are Moderately or Severely Immunocompromised | ACIP | CDC

For vaccines subject to SCDM, HHS should make clear that the designation does not mean that a vaccine is no longer covered by insurance. As the RFI recognizes, vaccines recommended through SCDM are subject to the same federal coverage requirements as routinely recommended vaccines, including coverage without cost-sharing under the Affordable Care Act and availability through the Vaccines for Children Program. HHS should clearly communicate these coverage requirements to providers and patients so that concerns about cost do not become an additional barrier to vaccination.

Questions 17 and 18: Public trust, communication, and evaluation

Strengthening public trust must be a central goal of federal vaccine policy. Vaccines are among the greatest public health successes, and HHS should pursue policies and communications that build confidence in vaccines and the institutions responsible for protecting public health. This requires clear, consistent, transparent, and scientifically accurate communication about vaccine benefits and risks and the evidence underlying federal recommendations. HHS should avoid changes to recommendation categories that lack a scientific basis or could unnecessarily undermine vaccine confidence, create confusion about the benefits of vaccination, or signal scientific uncertainty where the evidence does not support it. At the same time, HHS should undertake robust consumer education efforts aimed at increasing vaccine confidence and uptake, including providing clear information about why vaccines are recommended, where consumers can receive them, and insurance coverage requirements.

In addition, HHS should evaluate any new recommendation framework by its real-world effects. Measures should include vaccination uptake, timely completion of recommended vaccine series, disparities in vaccination rates, consumer understanding and confidence, access to recommended vaccines, and rates of vaccine-preventable disease.

The United States has achieved extraordinary public health gains through vaccination. NCL urges HHS to ensure that any changes to federal vaccine policy build on that success. Federal recommendations must reflect the best available science and advance the public health goal of helping Americans protect themselves and their families from preventable disease.

Sincerely,

Lisa Bercu
Senior Director of Health Policy