670 Maine Avenue, SW • Suite 1000, Washington, DC 20024 • PHRMA.ORG

September 20, 2026

VIA ELECTRONIC FILING – http://www.regulations.gov

Cynthia Goss
Deputy Assistant Secretary for Planning and Evaluation (Health Policy)
Performing the Delegable Duties of the Assistant Secretary for Planning and Evaluation
Office of the Secretary
Department of Health and Human Services
Attention: HHS-OS-2026-0332
200 Independence Ave SW
Washington, DC 20201

Re: Request for Information: Categories Used in Federal Vaccine Recommendations and the Role of Shared Clinical Decision-Making (HHS-OS-2026-0332)

Dear Deputy Assistant Secretary Goss:

Thank you for the opportunity to provide comments in response to the Department of Health and Human Services' ("HHS" or the "Department") request for information regarding federal vaccine recommendation categories and shared clinical decision-making (the "RFI").[1] The Pharmaceutical Research and Manufacturers of America ("PhRMA") represents the country's leading innovative biopharmaceutical research companies, which are focused on developing innovative medicines that transform lives and create a healthier world. Together, we are fighting for solutions to ensure patients can access and afford medicines that prevent, treat and cure disease. PhRMA member companies have invested more than $900 billion in the search for new treatments and cures over the last decade, supporting nearly five million jobs in the United States.[2]

PhRMA appreciates the Department's stated focus on strengthening public trust in vaccine recommendations and ensuring that federal recommendations are meaningful, transparent, and understandable to patients, parents, and clinicians. PhRMA believes it is imperative that stakeholders work together with HHS, the Centers for Disease Control and Prevention ("CDC"), the Advisory Committee on Immunization Practices ("ACIP"), and others to help ensure the continued availability of and access to vaccines.

As the Department considers whether changes to the current framework are warranted, two overarching principles should guide this effort. First, both the development of federal vaccine recommendation

---

[1] HHS, *Request for Information: Categories Used in Federal Vaccine Recommendations and the Role of Shared Clinical Decision-Making*, 91 Fed. Reg. 54724 (Aug. 24, 2026).
[2] Jocelyn Ulrich, PhRMA, *Biopharmaceutical Companies in America Hit New Investment Milestone* (Aug. 14, 2026).

categories and the issuance or modification of individual vaccine recommendations should occur through an evidence-based, transparent, and public process that preserves the central role of a properly constituted and fairly balanced ACIP. Second, consistent with federal law, the category of vaccine recommendation should not affect patients' eligibility for compensation under the National Vaccine Injury Compensation Program ("VICP"). Any framework that weakens patient access to compensation or creates uncertainty regarding liability protections could undermine patient interests, discourage investment in new and improved vaccines, and risk recreating the conditions that led Congress to establish the VICP in the first place.

* * *

I. Changes to Recommendation Categories or Individual Recommendations Should Be Developed Through an Evidence-based, Transparent, and Public Process.

While continuous evaluation and refinement are important, any changes to the federal vaccine recommendation categories or individual vaccine recommendations should begin from the recognition that the current United States childhood and adolescent immunization schedule is the product of decades of rigorous scientific research, ongoing safety monitoring, epidemiologic analysis, and expert review. It reflects extensive evaluation by public health experts, clinicians, and scientific advisory bodies and has been developed specifically to address the disease risks, health care infrastructure, and population needs of the United States.

For this reason, modifications to existing vaccine recommendation categories, the creation of new categories, and all decision-making regarding individual vaccine recommendations should be supported by robust scientific evidence, accompanied by a clear public health rationale, and evaluated by a properly constituted and fairly balanced ACIP in public deliberations. Supporting analyses, scientific evidence, and proposed rationales should be made publicly available sufficiently in advance of any ACIP meeting or vote to allow meaningful review and participation by stakeholders. Changes to recommendation categories or individual vaccine recommendations should be considered extremely carefully and take account of implementation considerations, including implications for clinical workflows and inventory management.

Further, the timing and frequency of recommendations should be tailored to reflect the best available data on vaccine safety, effectiveness, duration of protection, disease burden, and the needs of high-risk populations. This is particularly important for annually updated seasonal vaccines. HHS should evaluate the practical and cascading implications of any category changes, and who might be better positioned to evaluate the need for any changes, given that revisions, while well-intentioned, can create confusion and complicate implementation.

In evaluating potential changes to recommendation categories or individual vaccine recommendations, the Department should rely on transparent and replicable evidence review processes, including the Grading of Recommendations, Assessment, Development, and Evaluation ("GRADE") approach and the accompanying Evidence to Recommendations ("EtR") framework. These processes provide a consistent and structured means of evaluating the burden of vaccine-preventable disease, the balance of the benefits and risks of vaccination, the strength and certainty of evidence, and the potential individual and population-level impacts of the vaccine.[3] Any departure from these established approaches should be

[3] *Id.* at 54725.

publicly explained and supported by a compelling scientific rationale. Transparent review through a properly constituted and fairly balanced ACIP and adherence to established evidence-based frameworks are essential not only to sound policymaking, but also to maintaining public confidence and trust in federal vaccine recommendations.

II. In Order to Protect Patients and Preserve the Integrity of the VICP, Changes to Recommendation Categories or Individual Vaccine Recommendations Should Not Diminish Patient Access to No-Fault Compensation.

As HHS acknowledges, maintaining public confidence and trust requires considering the "downstream legal and programmatic consequences of category assignment."[4] The RFI correctly recognizes that insurance coverage requirements and eligibility under the Vaccines for Children Program ("VFC") do not depend on the specific recommendation category assigned to a vaccine.[5] HHS should likewise make clear that patients retain access to compensation under the VICP regardless of the recommendation category assigned to a vaccine.

Such clarification is important not only to preserve public confidence and continued access to longstanding federal vaccine programs, but also to maintain the integrity of the VICP itself. Established by Congress through the National Childhood Vaccine Injury Act of 1986 ("NCVIA"), the VICP was created to provide a stable and predictable framework for compensating vaccine-related injuries while supporting a robust national immunization program. It reflects a longstanding social compact: Individuals and communities benefit from widespread vaccination, while the federal government commits to providing a mechanism to fairly and efficiently compensate very rare, serious injuries. Vaccines are one of the most effective public health tools we have, and the overwhelming benefits of vaccination outweigh the risks, as shown by thousands of peer-reviewed studies involving hundreds of thousands of people and by continuous monitoring after approval.[6] But no medical intervention is entirely without risk and, while most side effects related to vaccines are mild and short-lasting, in very rare instances, patients experience severe injuries. The VICP ensures that these patients are fairly and rapidly compensated—without needing to prove fault or undergo a lengthy civil trial. Moreover, preserving VICP coverage not only helps patients directly, but also encourages investment in the research, development, and improvement of vaccines, thereby expanding patient access to safe and effective vaccination options.

Any potential changes to vaccine recommendation categories or individual recommendations should preserve full patient access to the VICP for vaccines recommended for use in children and pregnant women. By statute, coverage under the VICP flows from inclusion of a vaccine on the Vaccine Injury Table and imposition of an excise tax by Congress.[7] Regulations promulgated by the Health Resources & Services Administration ("HRSA"), which administers the VICP, confirm that presence on the table and imposition of the tax govern coverage under the VICP. The Secretary adds vaccines newly recommended for "routine administration" to children and pregnant women.[8] Under current policy, population-based, risk-based, and shared clinical decision-making-based recommendations *all* fall within the framework of routine recommendations. The January 2026 memorandum adopted by the former Acting Director of the

---

[4] *Id.* at 54724.
[5] *Id.* at 54725, 54728.
[6] Children's Hospital of Philadelphia, *Vaccine Science: Common Questions about Vaccine Liability* (Jan. 24, 2024).
[7] *See* Public Health Service Act ("PHSA") § 2133(5) (defining a "vaccine-related injury or death" to "an illness, injury, condition, or death associated with one or more of the vaccines set forth in the Vaccine Injury Table"); 26 U.S.C. § 4131 (providing for imposition of the excise tax); *see also* 42 C.F.R. § 100.3.
[8] *See* PHSA § 2114(e); 42 C.F.R. § 100.3.

CDC stated that the "current CDC schedule . . . categorizes routine immunization recommendations into three general categories: (1) population-based (i.e., age-based, including catch-up), (2) risk-based (i.e., immunosuppression, other underlying medical conditions, work-related, or other special circumstances that increase risk of illness), and (3) shared clinical decision-making-based."[9] And HRSA states that "even if a covered vaccine is administered 'off-label' or contrary to CDC or [ACIP] recommendations[,]" claims associated with that vaccine are still eligible for VICP compensation.[10] Furthermore, eligibility for compensation is not limited to children or pregnant women—*any* person who alleges an injury resulting from a listed vaccine is permitted to file a claim.[11] It is inconsistent with this broad eligibility framework to deny VICP coverage simply because the wording or categorization of a recommendation has been adjusted.

To the extent HHS makes modifications to such recommendations or proposes new categories, HHS should expressly affirm that *all* vaccines included on the Vaccine Injury Table are covered under the VICP and that recommendations for use in children and pregnant women that are issued by ACIP and adopted by the CDC constitute recommendations for routine use in these populations for purposes of VICP coverage. In other words, the availability of no-fault compensation should not hinge upon whether a particular vaccine recommendation has been classified as risk-based, shared clinical decision-making ("SCDM"), or some other category. This result is consistent with both the text and purpose of the statute, which links coverage under the VICP with inclusion on the Vaccine Injury Table and does not define "routine" use in a manner that would exclude recommendations based on individualized clinical assessment or risk factors. Indeed, both the SCDM and risk-based categories contemplate routine use, either after consultation with a clinician (in the case of SCDM) or in certain subpopulations (in the case of risk-based recommendations).

A contrary result—where some types of recommendations are considered routine for purposes of VICP coverage and others are not—is untenable as a matter of public policy. Recommendation categories are intended to communicate nuanced clinical guidance and advice, not to alter the compensation available to individuals in the case of injury. Furthermore, any recommendation framework that limits compensation or creates uncertainty regarding VICP eligibility harms patients by making it more difficult to obtain compensation and erodes the public trust that HHS identifies as a central objective of the vaccine recommendation framework. Public trust is strengthened when the government recognizes both the benefits and the risks of vaccination and maintains mechanisms to address the uncommon cases in which injuries occur. Preserving access to compensation therefore advances the Department's stated goal of maintaining confidence in vaccine recommendations and the institutions responsible for developing them.

Preserving VICP coverage is important not only for patients and families seeking compensation, but also for the continued development of vaccines and the improvement of vaccines currently on the market. Vaccine research, development, and manufacturing require substantial long-term investment by academic institutions, biotechnology companies, and manufacturers. A stable and predictable no-fault

---

[9] Decision Memorandum, Adopting Revised Childhood and Adolescent Immunization Schedule, at 2 (Jan. 5, 2026). Implementation of this memorandum has been stayed by the U.S. District Court of the District of Massachusetts. *See* Memorandum and Order on Plaintiffs' Motion for Preliminary Injunction, *American Academy of Pediatrics v. Kennedy*, No. 1:25-cv-11916 (Mar. 16, 2026).

[10] HRSA, *Covered Vaccines* (Sept. 2026).

[11] Indeed, a non-pregnant adult can file a paralytic polio claim under the VICP, even if that adult did not personally receive the oral polio vaccine, since vaccine-derived polio can be linked to community transmission (e.g., it can be contracted by changing the diaper of a baby who received the vaccine). *See* PHSA § 2114(a).

compensation system helps support those investments by reducing litigation uncertainty and enabling vaccine developers to focus resources on innovation. These concerns are not merely theoretical. In the 1980s, escalating litigation costs and liability exposure contributed to manufacturers exiting the market and concerns about the continued availability of essential vaccines.[12] Congress created the VICP to address these challenges by providing an alternative compensation system that protects injured individuals while helping ensure a stable vaccine supply and maintaining incentives to continue to develop and improve vaccines. Since then, vaccine manufacturers have continued to invest in research and development, and numerous new vaccines have been brought to market. But it is important to understand that progress is not preordained. Excluding vaccines intended for use in children and pregnant women from the scope of the VICP would undermine the carefully balanced framework Congress established, reducing incentives for investment in next-generation vaccines and potentially destabilizing a fragile market and risking a return to the conditions that led Congress to establish the VICP in the first instance.

* * *

As the Department evaluates potential changes to recommendation categories and individual vaccine recommendations, it should ensure that any potential reforms remain grounded in strong scientific evidence, are developed through a transparent and public process, and preserve the longstanding protections and stability provided by the VICP. These principles will help sustain public confidence in vaccine recommendations, protect patients, and support the continued development and availability of safe and effective vaccines.

Please do not hesitate to contact Carolyn Ha (cha@phrma.org) or Kelly Goldberg (kgoldberg@phrma.org) if we can provide additional information or answer any questions related to our comments.

Sincerely,

/s/

Carolyn Ha
Deputy Vice President, Policy & Research

/s/

Kelly Falconer Goldberg
Vice President, Law/Senior Counsel for Biopharmaceutical Regulation

[12] *See* Institute of Medicine, *Vaccine Supply and Innovation* (1985); *see also Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 226 (2011) (discussing this history).