



September 20, 2026

Cynthia Goss
Deputy Assistant for Planning and Evaluation
200 Independence Ave, SW
Washington, DC 20201

Re: Docket No. HHS-OS-2026-0332

Dear Ms. Goss:

The Biotechnology Innovation Organization (BIO) thanks the Department of Health and Human Services (HHS) for the opportunity to submit comments on the request for information (RFI) regarding *Categories Used in Federal Vaccine Recommendations and the Role of Shared Clinical Decision-Making*.¹

BIO is the premier biotechnology advocacy organization representing biotech companies, industry leaders, and state biotech associations in the United States and more than 35 countries around the globe. BIO members range from biotech start-ups to some of the world's largest biopharmaceutical companies – all united by the same goal: to develop medical and scientific breakthroughs that prevent and fight disease, restore health, and improve patients' lives.

I. Overview

BIO supports efforts to improve public understanding of vaccine recommendations, strengthen communication, and maintain and increase public trust in vaccination to support vaccine uptake. In BIO's view, these objectives are best advanced by strengthening the existing federal vaccine policy framework and its established scientific and policy processes, rather than creating parallel structures that could introduce uncertainty, fragment decision-making, or undermine years of carefully crafted processes. Reforms should be built upon, rather than circumvent, the existing processes and the role of a fair and balanced Advisory Committee on Immunization Practices (ACIP) within them.

It is imperative that any reforms start with a clear understanding of why the existing framework was created, the objectives it was designed to achieve, and a clear understanding of a need for change. The current vaccine recommendation categories were developed to translate ACIP's scientific assessment into clear clinical guidance about which populations could be considered for a vaccine and under what circumstances, while supporting consistent implementation, coverage, and access. The categories were not intended to signal different standards of evidence or different levels of confidence in vaccine safety and effectiveness. Rather, they distinguish how the expected benefits of vaccination apply across populations: broadly across a defined population for routine recommendations, primarily among individuals with identifiable risk factors for risk-based recommendations, or variably depending on individual circumstances.

¹ 91 Fed. Reg. 54724 (Aug. 24, 2026).

Any effort to revise this framework should therefore preserve these foundational purposes and carefully evaluate whether proposed changes would improve clarity and decision-making without creating unintended consequences for vaccine access, coverage, uptake, or public confidence.

BIO's comments in response to the RFI, outlined in greater detail below, address the following key issues:

Changes to the recommendation categories are not needed; if any change is made, it should be led by ACIP and include opportunity for meaningful public comment. BIO believes the current recommendation categories provide an appropriate framework to support vaccination decisions. BIO also sees opportunities to improve communication and support informed vaccination decisions without creating additional recommendation categories. Individuals should be able to readily understand what is recommended, why it is recommended, and how a recommendation applies to their circumstances. Achieving this clarity and strengthening public trust can be accomplished through clear, consistent communication, rather than introducing additional complexity to the recommendation framework. Any consideration of additional or modified categories or terminology must therefore be supported by a clear need, policy rationale, and robust evidence, and be carefully evaluated for potential downstream effects on vaccine access, coverage, uptake, and implementation. Changes in nomenclature should not alter or diminish the rigorous evidentiary standards applied to vaccines, regardless of the recommendation category under which they fall. HHS should also maintain a clear distinction between federal vaccine recommendations and legal requirements to vaccinate. Recommendations are not requirements, and state and local vaccination requirements likewise operate independently of the federal recommendation process and should not be conflated with it.

The Shared Clinical Decision-Making (SCDM) recommendation type remains an important way to reflect the need for individual-level decision-making in consultation with providers. All vaccination decisions should involve meaningful communication between the healthcare professional and the patient or caregiver, including discussion of the vaccine's benefits and risks, the individual's health circumstances and preferences, and any questions necessary to support informed consent. The SCDM category does not indicate that clinical discussion or individual choice is absent or unnecessary for routine or risk-based recommendations. Rather, it identifies vaccines for which the expected benefit may vary among individuals based on their specific circumstances and for which an individualized assessment is particularly important in determining whether vaccination is appropriate. HHS should clearly distinguish this population-level *recommendation* category from the shared decision-making *process* that appropriately underlies all clinician-patient conversations about vaccination.

BIO supports maintaining SCDM recommendations as a component of the recommendation framework. The choice of a vaccine recommendation as routine, risk-based, or SCDM should be based on the nature and distribution of the expected benefit as demonstrated by the evidence: a routine recommendation where benefit is broadly applicable across a defined population, a risk-based recommendation where benefit is concentrated among persons with identifiable risk factors, and shared clinical decision-making recommendation where the magnitude of benefit may meaningfully vary based on individual circumstances. *Importantly, the use of SCDM should not diminish vaccine confidence or create the perception that these vaccines are less valuable or less appropriate for patients who may benefit from them.*

While clinical judgement should be individualized, recommendations for populations, as made through ACIP, must be as clear as possible to facilitate uptake for the intended population. HHS should ensure that the recommendation framework supports, rather than impedes, meaningful clinician-patient discussions and access to vaccination. Further, HHS should consider whether additional guidance may be useful from the agency to clarify that -- for the purposes of coverage in commercial insurance, Medicare, and Medicaid -- all ACIP recommendation types, including risk-based, SCDM, or any similar successor category, must be covered.

All policymaking should reflect that ACIP is tasked with making vaccine recommendations, while other entities are tasked with different and specific areas of vaccine policy. The process by which recommendations are developed is equally important to the terminology and categories themselves. Grounded in its statutory role, decades of experience rigorously evaluating vaccine evidence through a transparent and deliberative process, and its critical ties to vaccine coverage, access, and the broader public health system, ACIP remains the appropriate federal entity for developing vaccine recommendations, consistent with the distinct responsibilities established by Congress. An additional strength of the existing framework also derives from the complementary roles of the Food and Drug Administration (FDA), ACIP, and the Centers for Disease Control and Prevention (CDC). FDA's regulatory review, ACIP's evidence-based deliberations and recommendations, and CDC's implementation and communication functions represent distinct but interconnected components of the federal vaccine system. Specifically:

- FDA is tasked with reviewing applications for the licensure of vaccines, including a review of safety and effectiveness and licensing them for use.
- ACIP, under the auspices of CDC, is tasked by the Secretary with developing clinical and population-level vaccine utilization recommendations. Congress has codified this role in various statutes that import ACIP's usage recommendations into policies on vaccine coverage, injury compensation, and other areas, as described further below.
- Separate from these efforts, the role of the Task Force on Safer Childhood Vaccines is to make recommendations in specific areas to minimize the risk of adverse events associated with pediatric vaccines, which is distinct from ACIP's role in making recommendations for use.

BIO encourages HHS to preserve these distinct roles as well as the transparent, evidence-based processes through which vaccine recommendations have historically been developed, reviewed, and updated.

Patient access must be maintained. Finally, any changes to the federal vaccine recommendation framework should preserve meaningful and affordable access to vaccination. Americans who want to receive vaccines should be able to do so without cost-sharing, regardless of how a vaccine recommendation is categorized. In particular, HHS should provide clear guidance regarding coverage of vaccines subject to risk-based recommendations and SCDM, including consideration of approaches used by Medicare and Medicaid, to promote consistent access and avoid creating financial barriers to vaccination.

We address each of these issues as relevant to the questions posed in the RFI below.

II. Responses to Requests for Information

A. Adequacy of the Current Categories

BIO appreciates HHS' interest in assessing the current categories, how they are understood by clinicians, patients, parents, and other stakeholders, and potential misunderstanding around the meaning of current categories of recommendations. Our comments on these questions focus on the following points:

- The current categories are appropriate and adequate for the role of conveying federal vaccination recommendations. If any changes are made, they should be led by ACIP and proposed for meaningful public comment before adoption.
- ACIP recommendations play an important role in various statutory authorities that support access for patients who wish to receive vaccinations, distinct from other efforts HHS undertakes regarding vaccines like the recommendations made by the Task Force on Safer Vaccines.
- More clarity is likely needed to ensure it is well understood that the three current ACIP recommendation categories all constitute recommendations that trigger insurance coverage requirements to ensure vaccine access.
- HHS should consider whether additional guidance is needed to underscore that the existing ACIP recommendation categories all constitute recommendations with important implications for other policy frameworks at both the federal and state levels.

1. The Current Categories Are Appropriate for the Purposes of ACIP Recommendations and Other Purposes.

BIO believes the current and longstanding vaccine recommendation categories are appropriate and adequate as they stand to convey the applicability of federal vaccine recommendations. Beyond indicating whether a vaccine is recommended, recommendation categories serve an important role in conveying the population for whom vaccination is recommended, and the expected benefit, framed through the lens of rigorous benefit and risk assessments and a careful assessment of the available evidence and the strength and certainty of that evidence. Maintaining clear, consistent, and coherent terminology and categorization is critical to ensuring access, preserving trust, and enhancing understanding by patients and stakeholders, appropriate implementation across the health care system, and consistency in vaccine coverage by payers.

Regarding HHS' interest in how levels of evidence should affect formulation of recommendation categories or choice of category for a given vaccine, ACIP should apply a common, rigorous, and transparent evidentiary framework across all recommendation categories. The choice of a vaccine recommendation as routine, risk-based, or SCDM should not be based on different levels of evidence, but rather the nature and distribution of the expected benefit demonstrated by the evidence. ACIP can and should consider certainty of evidence within its recommendations, but the certainty of evidence should not mechanically determine the recommendation category.

Where opportunities exist to make recommendations easier for patients and clinicians to understand, HHS should first consider improvements to the explanation and communication of existing categories rather than adding complexity. BIO encourages HHS to focus its efforts on improving communication around vaccine recommendations to support informed vaccination decisions and subsequent uptake of appropriate vaccines. The documented challenges with the current framework are primarily implementation challenges, rather than structural ones, and should be addressed through targeted education, integration into clinical decision-support

systems, and improvements in provider and patient communications rather than through categorical restructuring. Clear and consistent communication is vital at every level, from ACIP to the public and clinicians, and from clinicians to individuals, regardless of the type of recommendation. Simply changing the name or definition of a recommendation category will not, on its own, improve communication, understanding, or trust.

While BIO does not believe changes to the existing categories are warranted, in the event HHS does decide, based on responses to the RFI, that changes may be appropriate, the process for updating the categories should be led by ACIP and provide meaningful opportunity for public comment on any proposed changes. Specifically, such a process should be led by ACIP, in consultation with the Secretary, because the recommendation categories represent forms of recommendations within the advisory committee authority under which the Secretary has constituted ACIP. Further, while BIO appreciates that HHS has sought public comment through this RFI, any changes to the recommendation categories should occur only after the publication of any proposed changes and opportunity for public comment. The process for any changes to the recommendation categories must be transparent and follow ACIP's own processes.

2. ACIP's Authority to Make Vaccine Recommendations Is Separate and Distinct from Authorities of the Task Force and Other Entities.

In assessing the role of ACIP's recommendations, it is important to clarify the role of ACIP alongside other federal authorities and policies relating to vaccine access. As noted previously, ACIP, the Task Force on Safer Childhood Vaccines (the "Task Force"), and other entities have different authorities and distinct roles. Specifically, ACIP has been tasked by the Secretary with formulating recommendations with respect to specific use of vaccines in the context of population health and the vaccine schedule, which are given important legal effect through other federal and state authorities, while the Task Force is authorized to provide more general policy recommendations regarding vaccine safety.

ACIP is currently constituted under the Secretary's advisory-committee authority under section 222 of the Public Health Service Act.² ACIP was established by the Surgeon General of the U.S. Public Health Service in 1964 as a technical advisory committee, replacing the Public Health Service's prior reliance on ad hoc vaccine-specific committees as the number of licensed vaccines and federal immunization programs expanded. Following enactment of the Federal Advisory Committee Act in 1972, ACIP was formally constituted as a federal advisory committee and is now authorized under the Secretary's PHS Act advisory committee authority.³ The ACIP's authority, under its charter, is to make recommendations concerning which populations should receive vaccines, at what ages, on what schedules, and under what circumstances, which must be adopted by the CDC Director to take effect.⁴ Congress has given legal force to ACIP recommendations in multiple statutes affecting access, including the Public Health Service Act's preventive-services requirement for commercial health insurance, the Vaccines for Children program, and the VICP provisions governing addition of vaccines to the Vaccine Injury Table.⁵ It is also critical that any changes do not interfere with the ability for patients to seek

² 42 U.S.C. § 217a.

³ Smith et al., *History and Evolution of the Advisory Committee on Immunization Practices—United States, 1964–2014*, 63 MMWR 955, 955–56 (2014)).

⁴ Advisory Committee on Immunization Practices, *Charter*, effective June 24, 2026, <https://www.cdc.gov/acip/about/acip-charter.html>.

⁵ 42 U.S.C. § 300gg-13(a)(2), 1396s(e), 300aa-14(e)(2).

compensation in the patient centered VICP program. As described in greater detail later in this section, state statutes have given legal force to ACIP recommendations as well.

It is worth underscoring the important role that a balanced ACIP, as an advisory committee on vaccine use, plays in conjunction with determinations by the FDA. ACIP issues its recommendations only after a vaccine has received licensure from the FDA under the Public Health Service Act, with such licensure based on a showing that the vaccine is “safe, pure, and potent.”⁶ Through this licensure process, vaccine sponsors conduct extensive preclinical and clinical trials, including randomized controlled clinical trials, in accordance with FDA requirements. These clinical trials are designed by sponsors to demonstrate safety and efficacy based on product characteristics, clinical needs, disease burden, and epidemiology. FDA explains that, in Phase 3 vaccine studies, “the vaccine is generally administered to thousands of people” to demonstrate effectiveness and gather additional safety data, representing substantially larger trials than typical Phase 3 studies for other types of products.⁷ ACIP makes recommendations regarding how a marketed vaccine should be used in various populations and circumstances. ACIP’s categories of recommendations represent different ways of recommending the vaccine for different populations in different circumstances and represent recommendations with respect to specific vaccines.

By contrast, the Task Force has a separate role that does not relate to recommendations regarding specific vaccines or their use. The Task Force is authorized to “prepare recommendations to the Secretary” regarding the Secretary’s policy with respect to two issues:

- “promot[ing] the development of childhood vaccines that result in fewer and less serious adverse reactions than those vaccines on the market on December 22, 1987, and promote the refinement of such vaccines”⁸ and
- “mak[ing] or assur[ing] improvements in, and otherwise us[ing] the authorities of the Secretary with respect to, the licensing, manufacturing, processing, testing, labeling, warning, use instructions, distribution, storage, administration, field surveillance, adverse reaction reporting, and recall of reactogenic lots or batches, of vaccines, and research on vaccines, in order to reduce the risks of adverse reactions to vaccines.”⁹

The two bodies therefore have distinct functions: The Task Force’s statutory authority is to make recommendations to the Secretary regarding how to promote “the development” and “refinement” of childhood vaccines with fewer and less serious adverse events and regarding the Secretary’s policy efforts—not including HHS recommendations—to reduce the risks of such adverse reactions. ACIP’s mandate from the Secretary is to make recommendations concerning the clinical use of particular vaccines. The Task Force’s authority to make recommendations on policies to promote vaccine safety is not an alternative to ACIP’s role in making recommendations for specific vaccines that have legal effect regarding insurance coverage and other issues, nor a substitute for statutory processes assigned to other agencies or advisory bodies.

3. HHS Should Consider Steps to Clarify the Meaning of ACIP’s Existing Recommendation Categories.

⁶ 42 U.S.C. § 262(a).

⁷ Food & Drug Admin., *Vaccine Development – 101*, <https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/vaccine-development-101>.

⁸ 42 U.S.C. § 300aa-27(a).

⁹ 42 U.S.C. § 300aa-27(b)

Potentially, the most significant area of confusion around the existing ACIP categories is the lack of clarity around the meaning of each of the three categories as ACIP recommendations. In any policymaking and communications that HHS undertakes around categories of ACIP recommendations, **HHS should underscore and clarify that each of the three ACIP recommendation categories constitutes ACIP recommendations.** Specifically, while maintaining the existing categories, HHS could consider the following specific actions regarding ACIP practice:

- **Updated Guidance:** Regardless of whether the ACIP categories are updated, HHS, through CMS and other relevant agencies, should issue new or updated guidance or FAQs clarifying that all ACIP categories constitute recommendations for both public and private insurance coverage or other purposes.
- **Terminology Clarification:** HHS should consider whether the formal name for each category should itself include the term “Recommendation,” to further clarify that all three categories are, in fact, recommendations—i.e., “Routine Recommendation,” “Risk-Based Recommendation,” and “Shared Clinical Decision-Making Recommendation.”

These actions could be taken as part of a public process led by or in direct coordination with ACIP, with further opportunity for public comment regarding any potential changes or updates.

Clarity around the fact that all ACIP categories represent ACIP recommendations is essential to ensuring that ACIP’s recommendations have their intended legal effect through other laws Congress and states have passed that each rely on ACIP recommendations to establish insurance coverage—each of which are essential to vaccine access. Trump Administration leaders have made clear that updates to ACIP recommendations are not intended to affect access to or coverage of recommended vaccines, and additional clarity from HHS specifically regarding the meaning of ACIP categories will support this goal.

President Trump directed that changes to the childhood vaccine schedule occur “while preserving access to vaccines currently available to Americans,” and subsequently ordered federal agencies to ensure that vaccines remaining in any recommendation category continue to be covered without cost sharing by private insurance and covered by Medicaid, CHIP, and the Vaccines for Children Program.¹⁰ Similarly, following the January 2026 update to the childhood immunization schedule, CMS Administrator Mehmet Oz explained that “[a]ll vaccines currently recommended by CDC will remain covered by insurance without cost sharing” and that “[n]o family will lose access.”¹¹ As these statements recognized, clarifying that all three ACIP categories constitute ACIP recommendations from a legal perspective is important across a number of programs that support vaccine access, including the following:

Federal Insurance Coverage Requirements: Vaccine coverage requirements under federal law, across the major forms of health insurance coverage (commercial insurance, Medicare,

¹⁰ Presidential Memorandum, *Aligning United States Core Childhood Vaccine Recommendations with Best Practices from Peer, Developed Countries* (Dec. 5, 2025), <https://www.whitehouse.gov/presidential-actions/2025/12/aligning-united-states-core-childhood-vaccine-recommendations-with-best-practices-from-peer-developed-countries/>; Exec. Order No. 14,407, *Realigning United States Core Childhood Vaccine Recommendations with Best Practices from Peer, Developed Countries* (May 29, 2026), <https://www.whitehouse.gov/presidential-actions/2026/05/realigning-united-states-core-childhood-vaccine-recommendations-with-best-practices-from-peer-developed-countries/>.

¹¹ HHS, *CDC Acts on Presidential Memorandum to Update Childhood Immunization Schedule* (Jan. 5, 2026), <https://www.hhs.gov/press-room/cdc-acts-presidential-memorandum-update-childhood-immunization-schedule.html>.

and Medicaid), are all based on ACIP recommendations. Generally speaking, commercial health plans must cover without cost sharing, immunizations that “have in effect a recommendation from” ACIP “with respect to the individual involved.”¹² Medicare Part D plans have no deductible and cost sharing obligations for adult vaccines that are “administered in accordance with recommendations” of ACIP.¹³ State Medicaid programs must cover vaccines recommended by ACIP, and their administration, without cost sharing, for all “full benefit” populations.¹⁴

Even if HHS makes no changes to the existing ACIP categories, as BIO recommends, the administration's goal of protecting vaccine access for patients who want vaccines would benefit from additional guidance around the meaning of the ACIP categories in relation to the statutory references discussed above. CMS (potentially in collaboration with the Departments of Labor and Treasury) should reinforce that all three categories of ACIP recommendations represent recommendations that trigger coverage of vaccines as preventive services under 42 U.S.C. § 300gg-13, and CMS should also reissue detailed guidance or FAQs reinforcing this point with respect to Medicare and Medicaid coverage.

Vaccines for Children (VFC): The VFC program is an important program to ensure that all parents who wish to vaccinate their children can access the vaccines they choose regardless of insurance coverage status. In establishing VFC, Congress expressly tied the scope of vaccines that may be purchased under the program to “the list” of vaccines “established and periodically reviewed” by ACIP (42 U.S.C. § 1396s(e)). This “list” includes all recommendations made by ACIP, and HHS should ensure, in any communications or policymaking around ACIP categories, that all categories of recommendations fall within the “list” described by the VFC statute.

State Law References: Clarification that all categories of ACIP recommendations are themselves recommendations is also crucial because numerous state statutes similarly refer to whether a vaccine is “recommended” by ACIP or has a “recommendation” in place. The state statutes that support access based on ACIP recommendations fall into a number of categories, all of which are important in supporting patients’ ability to access vaccines when they choose. For instance, beyond federal requirements for coverage of ACIP-recommended vaccines, states often also have their own requirements to clarify and reinforce federal requirements. For instance, Maine requires coverage for immunizations that “have a recommendation from” ACIP with respect to the insured individual.¹⁵ Neither ACIP nor the federal government has a role in setting vaccination requirements (for school or daycare entry, employment or otherwise). States and private entities have responsibility for establishing those requirements. Changes in the recommendation categories should not be made in an effort to infringe on those authorities. Further states often incorporate ACIP recommendations into professional scope-of-practice laws, such as to define the vaccines that pharmacists or other non-physician practitioners may administer without an individual prescription, which can represent an important channel for easy access to vaccination for those who choose it. For instance, North Carolina authorizes pharmacists to administer to adults “the vaccines or immunizations recommended by” ACIP.¹⁶ Finally, states also use ACIP recommendations to define hospitals’ and other health-care facilities’ obligations to offer or provide vaccines to patients or residents, which can represent a

¹² 42 U.S.C. § 300gg-13(a)(2); 45 C.F.R. § 147.130(a)(1)(ii).

¹³ 42 U.S.C. § 1395w-102(b)(8)

¹⁴ 42 U.S.C. §§ 1396a(a)(10), 1396d(a)(13)(B) & (r)(1)(B)(iii), 1396u-7(b)(5).

¹⁵ Me. Rev. Stat. tit. 24-A, § 4320-A(1)(B)

¹⁶ N.C. Gen. Stat. § 90-85.15B(a1).

convenient opportunity for these individuals to receive vaccines. For instance, Illinois requires every hospital to adopt an influenza and pneumococcal immunization policy providing for vaccination of specified patients “in accordance with the recommendations” of ACIP.¹⁷

While the federal government does not have authority to interpret state law, communications regarding the current ACIP recommendation categories, or any new categories, should underscore that the range of recommendation categories all represent ACIP recommendations for the purposes of state laws.

B. Potential Additional or Modified Categories and Timing and Frequency Recommendations

As noted above, BIO does not believe changes are needed to the existing recommendation categories and supports existing education and clarification around the meaning of the existing categories rather than changes to them. However, if HHS does decide to reconsider or alter existing recommendation categories, any consideration of such modifications should be grounded in a clear policy rationale and supported by robust evidence demonstrating that the proposed changes would improve decision-making, communication, and public understanding. Further, any changes must incorporate a transparent and public process for the publication of proposed changes, discussion, review, and consideration prior to finalization.

Recommendation terminology can have significant downstream effects on how recommendations are interpreted and operationalized, including by health care providers, health plans, pharmacists, government programs, and patients. Accordingly, HHS should consider how changes could affect implementation beyond clinical decision-making, including vaccine coverage, uptake, access, and affordability. Prior to initiating any changes, HHS should establish objective criteria, plain-language definitions, and clear implementation guidance including, as discussed above, establishing any new categories in the ACIP charter with clear explanations of each recommendation category.

Retaining the existing categories would also allow HHS, and ACIP in particular, to focus on educating providers, patients, and other stakeholders about the standards and meaning of the existing categories, as well as evidence underlying the recommendations for specific vaccines including their timing. Recommendations for specific vaccines may change within existing categories over time, as new strong and reliable evidence at times may support the revision of recommendations, especially when the level of disease burden changes. Communicating such changes in vaccine recommendations is an important challenge even assuming HHS maintains the existing categories. Without clear translation and explanation of evolving science, providers and patients may incorrectly associate changing recommendations with shifting messaging as opposed to increased evidence. Further, significant changes to the underlying structure of ACIP recommendations can have significant implications for scientific evidence generation, including creating new uncertainty around how to design clinical trials and studies to provide the highest quality, clearest evidence regarding vaccine safety and efficacy.

With respect to timing and frequency, HHS should focus on ensuring that vaccination timing reflects relevant clinical and epidemiologic considerations, such as risk of illness exposure, rather than creating new recommendation categories. Existing recommendations also already provide flexibility through broad vaccination timing windows reflected in vaccine labels and the schedule. This flexibility allows vaccination to occur at different points within an appropriate

¹⁷ 210 Ill. Comp. Stat. 85/6.26(a)(2)).

timeframe, providing patients with choice within an evidence-based clinical recommendation. HHS should consider improving communication about this existing flexibility to help address provider and parent questions about scheduling. This could include provider education materials explaining the evidence underlying recommended age ranges and the clinical considerations associated with delaying vaccination beyond those ranges, as well as patient-facing materials explaining the distinction between flexibility within a recommended window and delaying or declining a recommended vaccine.

As described further above, changes to vaccine categories would also undermine efforts to ensure that the existing recommendations help patients access vaccines where appropriate. Congress has repeatedly tied vaccine access protections to ACIP recommendations, reflecting a broader federal policy, supported by the Trump Administration, of ensuring access to recommended vaccines.. States also rely on ACIP recommendations for insurance coverage, vaccine purchasing, scope-of-practice rules, and other key policies that support patient access.

Creating uncertainty through changes to the existing categories also risks undermining the meaning of existing ACIP recommendations, which are essential to providers and patients understanding vaccine use that is appropriate for different patients in different circumstances. Having an FDA-approved vaccine on the market without any ACIP recommendation can create significant practical access barriers even though the product remains legally available, which would be inconsistent with the Administration's stated goal of avoiding disruptions in vaccine access. Specifically, ACIP recommendations serve an important informational function for providers and patients that FDA-approved labeling and manufacturer communications cannot fully replace.

Finally, in relation to ensuring that ACIP recommendations have their intended effect, especially given ACIP's increased use of SCDM as a recommendation category, HHS should ensure that payment policy adequately compensates clinicians for the time they spend educating and counseling patients regarding vaccines.

Overall, BIO supports retaining the current recommendation categories unless HHS can identify a demonstrated need for change and establish, through an evidence-based and transparent process, that modifications would meaningfully improve the clarity of the vaccine recommendation framework and support patient access to vaccines.

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

Recommendations that allow for SCDM are critical to maintaining access to and coverage for vaccines for which the magnitude of the benefit may meaningfully vary based on individual circumstances. Importantly, a SCDM recommendation should not diminish vaccine confidence or create the perception that these vaccines are less valuable or less appropriate for patients who may benefit from them.

Any effort to modify or replace the terminology used to describe shared clinical decision-making should be informed by additional research and meaningful stakeholder engagement. Changes in nomenclature could have implications beyond the language used in a recommendation itself, including for patient-level guidance, clinical decision support tools, electronic health record systems, and the prompt logic used to guide healthcare professionals and patients. HHS should therefore carefully evaluate how any changes would be operationalized across the healthcare system before adopting new terminology.

If SCDM recommendations are retained, as BIO recommends, HHS should clearly reinforce that vaccines recommended under SCDM remain federally recommended vaccines and that coverage for these vaccines therefore remains available. This clarification is important for a number of access policies—insurance coverage requirements, programs such as the VFC program, and other areas—where ambiguity regarding the status of SCDM vaccines could create barriers to access or lead to inconsistent implementation.

In addition, HHS should also emphasize that there is still significant and meaningful benefit to vaccination for SCDM vaccines, such as reducing the risk of illness and helping to prevent avoidable disruptions such as missed school or work and unnecessary healthcare utilization. Clear communication about these benefits will be important to ensuring that the use of SCDM supports informed, patient-centered decision-making without inadvertently undermining confidence in vaccination.

To support these goals, HHS should develop and disseminate clear, coordinated provider- and patient-facing materials to better explain SCDM-recommended vaccination. Communication efforts should also be coordinated across HHS, CDC, and CMS to provide clear guidance to payers and other relevant stakeholders on coverage and access, including applicable cost-sharing protections, to promote consistent implementation and minimize barriers to vaccination.

D. Considerations in Setting Recommendations

A key strength of the current vaccine recommendation framework is the complementary role of FDA, ACIP, CDC, CMS, and HRSA. Prior to licensure, vaccine manufacturers must demonstrate safety and efficacy through robust clinical development programs. This is supported by large clinical trials, extensive safety monitoring, and FDA review of manufacturing quality and consistency. FDA determines whether a vaccine is safe and effective for its intended use based on the totality of available evidence. In cases where placebo-controlled trials are infeasible or unethical, evidence may also come from other forms of controlled trials, immunobridging studies, observational research, real-world effectiveness data, and pre- and post-licensure safety monitoring. FDA's role is to determine whether a vaccine may be licensed, while ACIP's role is to assess and recommend how that vaccine can and should be used in the context of protecting public health.

In developing vaccine recommendations, the primary considerations should remain a transparent assessment of the benefits and risks informed by evidence quality, disease burden, epidemiology, implementation considerations, and public health impact. Vaccines for diseases associated with significant morbidity, mortality, long term sequelae or outbreak potential warrant attention and careful consideration even when evidentiary limitations exist. Decisions should reflect the totality of available scientific evidence through a structured and transparent framework.

The existing GRADE and Evidence-to Recommendation (EtR) frameworks used by ACIP were specifically designed to support these assessments. The processes systematically evaluate the quality of evidence, benefits and risks, certainty, feasibility, equity, resource needs, and public health impact. Importantly, they also clearly identify areas of uncertainty, which allow for transparent re-review and evaluation. BIO supports the continued use and improvements on these methodologies to make recommendations and appropriately reassess vaccine recommendations as new data emerges. When evidence is limited or evolving, uncertainty should be explicitly acknowledged. Any recommendation changes should be considered only with adequate underlying evidence to inform decisional changes to recommendations for

vaccine use. The existing ACIP framework allows for recommendations to reflect varying levels of evidentiary uncertainty. Clear communication of the established benefits, remaining uncertainties, and post-licensure evidence supports informed, individual decision making, public trust, and allows the recommendations to evolve over time. BIO encourages HHS to preserve the distinct and complementary roles of FDA, ACIP, CDC, CMS, HRSA, and the Task Force, recognizing the separate statutory authorities that underlie each.

E. Trust and Communication

Evidence demonstrates that state school-entry vaccination requirements are effective in maintaining high vaccination coverage and preventing outbreaks of vaccine-preventable diseases. Public opinion data also indicate continued support for routine childhood immunization requirements. States with well-established vaccination policies, including appropriate exemption frameworks, generally maintain high vaccination coverage rates. BIO believes these policies should continue to support public health goals, while preserving choice and public confidence.

Notably, there are no states that currently require COVID-19 vaccination for employment or school attendance. Historically, states have considered school-entry requirements for a vaccine only after they have been approved and recommended for several years—allowing for accumulated safety, effectiveness, and real-world use data. This approach allows for ongoing evaluation of risks and benefits, refinement of clinical recommendations, and clear communication with patients and families that helps establish public confidence prior to being considered for school entry requirements.

BIO believes that transparency is essential to maintaining trust in vaccines and vaccine communication. The rationale for recommendations and what data is used in recommendation setting should be clear and transparent at all levels. As evidence evolves, HHS should clearly explain how evidence is evaluated, any uncertainty of new or existing evidence, and remaining knowledge gaps for continued evidence generation. These messages must be carried through, and tailored appropriately, for the intended audience—states and jurisdictions, providers, policy makers, and most importantly the American people. Public trust is strengthened when HHS communicates decisions transparently, acknowledges uncertainty, and provides consistent, plain-language definitions for providers and patients to make health decisions. Further, as noted above, maintaining the existing ACIP categories will help advance these efforts to communicate recommendations transparently and clearly, because it will allow HHS to build on existing work rather than introducing new confusion and uncertainty.

III. Conclusion

BIO appreciates the opportunity to submit comments in response to this RFI and looks forward to partnering with HHS as the agency takes steps to improve public understanding of vaccine recommendations, strengthen communication, and maintain and increase public trust in vaccination to support vaccine uptake.

Sincerely,

/s/

Phyllis Arthur
Executive Vice President, Chief of Global Health