Biotechnology Innovation Organization
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November 24, 2025

ACIP Secretariat
Centers for Disease Control and Prevention
Attention: Docket No. CDC-2025-0454
1600 Clifton Road NE
Mailstop H21-12
Atlanta, Georgia 30329-4027

For electronic submission

Re: Docket No. CDC-2025-0783; Advisory Committee on Immunization Practices (ACIP) Meeting

Dear Dr. Zadeh and Members of the ACIP:

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to provide comments to the Advisory Committee on Immunization Practices (ACIP) in advance of the December 4-5, 2025 meeting. BIO encourages the reinstatement of several long-standing practices that have historically supported ACIP's application of high-caliber science and transparent evidence-based decision making to safeguard Americans' ability to protect against deadly infectious disease and avoid unintended disruptions to vaccine supply and patient access.

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 35 other nations. BIO membership includes vaccine developers and manufacturers who have worked closely with the public health community to support policies that help ensure access to innovation and life-saving vaccines for all individuals.

For decades, the U.S. has been a global leader in scientific rigor and health innovation in vaccines, exemplified by policy developed through a transparent and predictable process. The Committee's recommendations have earned trust because they have been consistently informed by structured evaluations that used the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) system and the Evidence to Recommendation (EtR) processes. Continuous consistency and predictability in vaccine guidance from ACIP allows the U.S. to accelerate the delivery of vaccines to those wanting and needing them and to support the ongoing development of new vaccines.

The longstanding ACIP process provides a model of integrity and transparency. Its success lies in structured reviews of the full body of evidence related to a vaccine conducted over multiple public meetings supported by dedicated workgroups, which involve experts from across public health, academia, patient organizations, and clinical practice. Maintaining transparency around ACIP's workgroup membership, remits, and deliberations is a critical part of this model. Historically, this information has been publicly available on the CDC website, and a return to this would support continued confidence and clarity for stakeholders. The scientific data presented to ACIP is the product of coordination among leading experts on the epidemiology and clinical implications of disease, immunology and vaccinology, and the implementation of immunizations with a U.S. specific lens. This expertise is strongly supported by scientific presentations from industry research leaders. This principled approach enables evidence to be made publicly available ahead of each meeting, giving the public and

stakeholders the opportunity to engage. Following these principles is not merely following administrative procedures; it is an essential safeguard that helps ensure that recommendations are rooted in high-caliber science, reflect the expertise of diverse professionals, and inspire confidence among providers and the public in the final recommendations that are tailored specifically for the American population. We look forward to seeing this tradition of rigor and transparency continue to be upheld by the current ACIP through its future work.

ACIP's recommendations are foundational to vaccine access in the United States, shaping which vaccines patients can receive and when. Because ACIP recommendations directly determine coverage under the Vaccines for Children (VFC) program and strongly influence private-sector coverage, any shifts in those recommendations can have immediate and significant consequences for whether patients are able to access vaccines. Americans can only have real choice in protecting themselves and their families when they have access to, and options among, available vaccines. Given these impacts, it is crucial that ACIP's principled approach and processes are maintained, with the careful time and attention they demand. As ACIP moves forward, it is important that it continues to help ensure new members are thoroughly prepared in the science, data is rigorously and continuously examined with balanced consideration, workgroups are effectively engaged, and that transparency is maintained through the timely and advanced sharing of agendas, meeting slides, scientific data, workgroup membership, voting language and public communications.

BIO also wishes to emphasize that vaccine supply is highly sensitive to recommendation changes and the realities of long production timelines risk creating new unintended barriers to access for patients. Unexpected changes, without an immediate safety concern, in recommendations could lead to supply shortages in the marketplace. Vaccines are complex biologics with exceptionally long production timelines, often at least 12 to 18 months from start to finish, and substantially longer when changes to licensing requirements are made. Even seemingly modest changes, such as modifications to dosing schedules or shifts that affect combination vaccine configurations, can have far-reaching impact. Changes to ingredients, antigens, or components can necessitate entirely new clinical development timelines. New development timelines typically span 8–10 years and much longer if new clinical and regulatory requirements for successful licensure and recommendation are necessitated. We encourage ACIP to consider these practical implementation implications carefully when engaging in discussions or contemplating shifts in recommendations with immediate or near-term impact on the marketplace and patients' ability to get vaccines that have been recommended.

We encourage continued excellence by adhering to the established steps that lend weight and legitimacy to ACIP's recommendations, while being mindful to avoid rushed, delayed, confusing, or premature changes to vaccine recommendations that could unintentionally weaken reliance on a system that has contributed to decades of progress in protecting Americans against deadly infectious diseases. The Committee has various recommendation types at their disposal that can, if used properly, help facilitate discussions between patients, parents, and healthcare providers. It is vital that the recommendations made do not add any additional barriers to access for those who want to receive vaccines.

The weight of ACIP's historic role in vaccine access cannot be overstated: its recommendations have been the cornerstone of vaccine access in the U.S. They provide the legal and clinical framework for providers to counsel and administer vaccines in accordance with state laws. For Americans to truly have the choice to protect themselves from serious diseases, ACIP's recommendations must be clear, reliable, and grounded in the best available scientific evidence.

Sincerely,

/s/
Phyllis A. Arthur
EVP & Head, Healthcare Policies and Programs