Biotechnology Innovation Organization
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September 13, 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-2025-0454; Advisory Committee on Immunization Practices (ACIP)

Dear Dr. Zadeh and Members of the ACIP:

The Biotechnology Innovation Organization (BIO) is appreciative of the opportunity to provide comments to the Advisory Committee on Immunization Practices (ACIP) in advance of the September 18-19th, 2025 meeting. BIO submits this comment to reaffirm the importance of ACIP's established evidence-based processes and their critical role in safeguarding American health and vaccine access. In short, BIO encourages continued excellence in the work done by ACIP by adhering to the established steps that lend weight and legitimacy to ACIP's recommendations. These steps are part of a system that has contributed to decades of progress in protecting Americans against deadly infectious diseases.

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 30 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 vaccine policy developed through a transparent and predictable process. At the center of this success is ACIP, whose recommendations have been trusted by the public and medical community because of their legacy of being informed by the best available evidence, subject-matter experts, and deliberate procedures, including GRADE and the Evidence to Recommendations (EtR) framework. Continuous consistency and predictability in vaccine guidance from ACIP allows the U.S. to accelerate the delivery of life-saving vaccines to those wanting and needing them and support the ongoing development of new vaccines.

The ACIP provides a model of integrity and transparency. Its success lies in structured evidence reviews conducted over multiple public meetings supported by dedicated workgroups, which involve experts from across public health, academia, and clinical practice. The scientific data presented to ACIP is the product of coordination among top experts, coupled with 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 and understand how decisions affecting their health are made. Following these principles is not merely following administrative procedures, but 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 determinations. We look forward to seeing this tradition of rigor and transparency continue to be upheld by the current ACIP through its future work.

Given what ACIP's deliberations mean for vaccine access for Americans, it is crucial that this principled approach and these processes are maintained. Just as vaccines take years to develop, ACIP processes require careful time and attention to develop and implement. 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, voting language and public communications. For example, unexpected changes in recommendations for a vaccine could lead to supply shortages in the marketplace thus impacting the ability of Americans to get vaccines that have been recommended by medical providers.

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. For example, there are already some access barriers to vaccines with shared clinical decision making (SCDM) recommendations that could be further strained by additional requirements such as a prescription. Many Americans do not have a primary care provider and the vast majority of Americans receive COVID-19 and influenza vaccines in the pharmacy setting. Should the committee choose to apply the SCDM recommendation, we encourage the committee not to apply any additional requirements that further impede access.

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
Biotechnology Innovation Organization