Sanofi
Morristown, New Jersey

November 24, 2025

Advisory Committee on Immunization Practices (ACIP)
US Centers for Disease Control and Prevention
Atlanta, Georgia

Dear Dr. Kulldorff and ACIP members,

Sanofi appreciates the opportunity to provide comment and share our perspective on the upcoming discussions regarding the U.S. immunization schedule and related recommendations.

We share a commitment to public health, transparency, and evidence-based medicine. Our priority remains ensuring access to, and the availability of safe and effective immunizations. Sanofi immunizations approved by FDA and recommended by CDC benefit the health of children, families, communities and health systems by helping to reduce the burden and severity of vaccine-preventable diseases. We adhere to high scientific values and uphold rigorous standards under which our immunizations have and continue to be developed, tested, evaluated, approved, and monitored.

Sanofi immunizations aim to maximize protection with the fewest doses to meet the medical needs of all Americans. Across all our products, we monitor their lifecycle from pre-licensure through post-licensure to ensure safety and efficacy. Each ingredient in our immunizations plays a specific and necessary role in protection, either by stabilizing the formulation, enhancing immune response, or ensuring safety during storage and administration. These components are carefully selected and used in the lowest effective quantity, based on decades of evidence and regulatory oversight by FDA, to maximize benefit and minimize risk.

The current U.S. childhood immunization schedule is based on robust data that demonstrate safety and optimizes protection for infants when they are most at risk. Delaying vaccination increases the time that a child is susceptible to vaccine-preventable diseases, as most infant immunizations require a second or third dose for full protection.

Combination vaccines are given to approximately 80% of U.S. infants and reduce the number of injections, minimize discomfort for children, and improve workflow for healthcare providers so they can administer vaccines safely and effectively. Parents generally prefer combination vaccines to reduce the number of injections a child receives in a visit and the overall number of office visits. Changes to recommendations for any component within a combination vaccine risk reducing options for families and could disrupt vaccine supply and limit access for years. These supply challenges would extend beyond combination vaccines to include stand-alone vaccines that prevent diphtheria, tetanus, pertussis, *Haemophilus influenzae* type b, and polio.

If high-quality evidence were to show a safety concern with any of our immunizations, we would act immediately to address it and develop a safer alternative. At present, there is no credible evidence indicating a safety risk with today's immunizations. Making changes to these immunizations would require extensive research, testing, and regulatory review, and there are long lead times required for manufacturing and production. This would leave patients without access to the protection today's vaccines provide.

Sanofi values informed consent and supports families in making decisions based on the best available data regarding risks and benefits with their healthcare provider. We are proud to play a role in making those choices available, which aligns with HHS Secretary Kennedy's strong support for families to have access to immunizations. Removing options limits parents' ability to decide what is best for their families.

We look forward to our continued partnership to maintain recommendations that protect infants early in life when they are most vulnerable and to preserve access. Together, we can continue to prevent serious diseases and safeguard public health.

Thank you for your consideration.

Sincerely,

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