

November 24, 2025

Advisory Committee on Immunization Practices Centers for Disease Control and Prevention 1600 Clifton Road NE Atlanta, Georgia 30329

Re: Docket No. CDC-2025-078

## Dear ACIP Voting and Liaison Members:

Trust for America's Health (TFAH) appreciates the opportunity to provide comments as part of the December 4-5, 2025 meeting of the Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP). TFAH is a nonpartisan, nonprofit public health policy, research, and advocacy organization dedicated to promoting optimal health for every person and community and making the prevention of illness and injury a national priority. For more than 20 years, our annual report, *Ready or Not: Protecting the Public's Health from Diseases, Disasters, and Bioterrorism*, has emphasized the role of routine vaccination in promoting the country's national, health, and economic security. Given the overwhelming body of evidence on its safety and effectiveness, we urge the ACIP to maintain the existing recommendation for the universal hepatitis B birth-dose recommendation.

The ACIP plays a unique role in protecting the public from vaccine-preventable diseases. Its recommendations shape insurance coverage, guide healthcare providers and public health practitioners, and inform the public. The childhood and adolescent immunization schedule is not a mandate, instead offering parents the choice of if or when to vaccinate their child(ren) by ensuring vaccines are accessible and affordable. Narrowing or removing existing recommendations would create barriers to care that could have lifelong impacts on infants and their families.

The universal hepatitis B birth-dose vaccine recommendation remains essential for preventing infection and saving lives. Hepatitis B can be transmitted perinatally or through household or community exposures. The risk of developing chronic infection is highest in infancy, with approximately 90 percent of infected infants developing chronic hepatitis B, placing them at increased risk for cirrhosis, liver cancer, liver failure, and premature death.<sup>2</sup> Since being implemented in 1991, the universal hepatitis B birth-dose has reduced hepatitis B cases among

<sup>&</sup>lt;sup>1</sup> McKillop, Matt, Farberman, Rhea K., Lieberman, Dara A. "Ready or Not: Protecting the Public's Health from Diseases, Disasters, and Bioterrorism." *Trust for America's Health*. <a href="https://www.tfah.org/wpcontent/uploads/2025/03/2025-ReadyOrNot-FINALr.pdf">https://www.tfah.org/wpcontent/uploads/2025/03/2025-ReadyOrNot-FINALr.pdf</a>. Accessed November 19, 2025.

<sup>&</sup>lt;sup>2</sup> U.S. Department of Health and Human Services. "Hepatitis B Basic Information." <a href="https://www.hhs.gov/hepatitis/learn-about-viral-hepatitis/hepatitis-b-basics/index.html">https://www.hhs.gov/hepatitis/learn-about-viral-hepatitis/hepatitis-b-basics/index.html</a>. Accessed November 19, 2025.

children and adolescents by 99 percent and prevented an estimated 90,100 childhood deaths. 3,4

Decades of research and surveillance have demonstrated that hepatitis B vaccines are safe for newborns. There is no evidence linking the birth-dose to neonatal death or to increased risks of medical conductions such as allergies or multiple sclerosis. Common side effects are mild and temporary, such as injection site pain, headache, and fatigue.<sup>5</sup> As with all vaccines administered in the United States, the hepatitis B vaccine underwent rigorous testing before being approved for use, and it continues to be monitored through multiple systems to allow public health officials and researchers to quickly identify and investigate potential safety signals.<sup>6</sup>

Changes to ACIP's hepatitis B vaccine recommendations would also impact other components of the child and adolescent immunization schedule. Later doses of the hepatitis B vaccine series are often administered in combination vaccines that may protect against polio, diphtheria, tetanus, pertussis, and haemophilus influenzae type B, depending on the specific product. These combination vaccines allow children to receive fewer shots while protecting against the same number of diseases. Changing the administration of the hepatitis B vaccine could impact the routine vaccination against the other vaccine-preventable diseases included in these combination shots, delaying disease protection and increasing the number of shots a child receives.

Accessible vaccines promote optimal health for every person and community. TFAH urges the ACIP to maintain the current childhood and adolescent immunization schedule in order to preserve decades of progress against vaccine-preventable diseases. Should the Committee have any questions about our comments, please contact Emily Horowitz, Senior Government Relations Manager, at ehorowitz@tfah.org.

Sincerely,

J. Nadine Gracia, MD, MSCE

President and CEO

Trust for America's Health

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<sup>&</sup>lt;sup>3</sup> Bixler, Danae, Roberts, Henry, Panagiotakopoulos, Lakshmi, et al. "Progress and Unfinished Business: Hepatitis B in the United States, 1980-2019." *Public Health Reports*. June 2023. https://journals.sagepub.com/doi/10.1177/00333549231175548. Accessed November 19, 2025.

<sup>&</sup>lt;sup>4</sup> National Foundation for Infectious Diseases. "Why We Give Hepatitis B Vaccines to Infants." https://www.nfid.org/why-we-give-hepatitis-b-vaccines-to-infants/. Accessed November 19, 2025.

<sup>&</sup>lt;sup>5</sup> U.S. Centers for Disease Control and Prevention. "Hepatitis B Vaccine Safety." <a href="https://www.cdc.gov/vaccine-safety/vaccines/hepatitis-b.html">https://www.cdc.gov/vaccine-safety/vaccines/hepatitis-b.html</a>. Accessed November 19, 2025.

<sup>&</sup>lt;sup>6</sup> Michaud, Josh and Kates, Jennifer. "How Does the Federal Government Monitor Vaccine Safety?" *KFF*. https://www.kff.org/other-health/how-does-the-federal-government-monitor-vaccine-safety/ Accessed November 19, 2025.

<sup>&</sup>lt;sup>7</sup> U.S. Centers for Disease Control and Prevention. "Combination Vaccines." <a href="https://www.cdc.gov/vaccines-children/about/combination-vaccines.html">https://www.cdc.gov/vaccines-children/about/combination-vaccines.html</a>. Accessed November 19, 2025.