Advisory Committee on Immunization Practices (ACIP)

Written Comment

June 20, 2025

Public Comment for June 25-26, 2025 ACIP Meeting

The Hepatitis B Foundation is deeply concerned by the removal of all 17 members of the Advisory Committee on Immunization Practices (ACIP) and the recent announcement by Secretary Kennedy that longstanding vaccine recommendations may be revisited and revised. These abrupt actions inject uncertainty into a process that has long been defined by scientific rigor, public trust, and transparency.

Since its founding in 1964, ACIP has served as an independent advisory body dedicated to protecting public health through evidence-based vaccine policy. Undermining this independence not only weakens public confidence but risks disrupting access to vaccines that save lives, especially for vulnerable infants and children.

We are particularly alarmed by the potential impact on access to the hepatitis B birth dose, a cornerstone of hepatitis B prevention and liver cancer elimination. Hepatitis B is a leading cause of liver cancer worldwide [1]. The birth dose, administered within 12–24 hours of birth, is the only way to prevent mother-to-child transmission and is the first step in lifelong protection. Without it, up to 90% of infants who contract hepatitis B at birth will develop a chronic liver infection, placing them at a significantly increased risk of developing liver cancer in their lifetime [2]. There is no cure. Liver cancer prevention is essential, and it starts at birth.

History has shown us that risk-based approaches are ineffectual and will eventually fail. In the early 1980s, perinatal transmission continued despite targeted screening of pregnant women. That is why, in 1988, the Centers for Disease Control and Prevention (CDC) recommended universal hepatitis B vaccination at birth, in addition to HBIG when appropriate, for babies born to mothers who tested positive for hepatitis B, and later expanded it to all infants regardless of maternal hepatitis B status [3].

Further, when a temporary precautionary recommendation in 1999 led some hospitals to delay the birth dose due to concerns (that have now been thoroughly addressed) about thimerosal, hepatitis B vaccination rates for high-risk infants plummeted. Even after thimerosal was removed by 2000, birth dose coverage did not fully recover in many hospitals [4]. This proved that risk-

based recommendations are not only difficult to implement, but they fail to protect the infants who need it most, especially when maternal screening systems are overburdened or incomplete [5].

Today, the hepatitis B vaccine given at birth contains no thimerosal [6], and ACIP's universal hepatitis B birth dose recommendation remains the best safeguard against hepatitis B transmission, pediatric liver disease, and liver cancer. It also ensures infants are protected in cases of maternal screening errors, which occur quite frequently, or when babies are born into households, knowingly or unknowingly, with other infected family members [7].

The U.S. is one of more than three dozen countries around the world that recommend the birth dose for infants [8]. Evidence-based science has shown that anyone can get hepatitis B - regardless of age, background, or risk category. Accidents happen: an accidental blood spill or unrecognized household exposure can lead to deadly, lifelong consequences for children. Vaccination is the best tool we have to protect our loved ones and our communities. Universal birth dose vaccination creates a safety net that protects all children, especially those whose exposure risk may not be obvious at birth.

Years of meticulous, peer-reviewed research show that universal birth dose leads to higher completion of the full hepatitis B series and better protection for children overall [9]. Weakening or revisiting this recommendation would turn back decades of progress and place millions of newborns at risk each year.

This is not the time for confusion or regression. It is a time to stand firmly behind science, prevention, and the protection of our youngest and most vulnerable.

References:

1. World Health Organization. (2024). *Hepatitis B*. https://www.who.int/news-room/fact-sheets/detail/hepatitis-b
2. Centers for Disease Control and Prevention. (2022). *Clinical overview of perinatal hepatitis B.* https://www.cdc.gov/hepatitis-b/hcp/perinatal-provider-overview/index.html
3. Centers for Disease Control and Prevention. (1991). *Hepatitis B virus: A comprehensive strategy for eliminating transmission in the United States through universal childhood vaccination*. https://www.cdc.gov/mmwr/preview/mmwrhtml/00033405.htm
4. Centers for Disease Control and Prevention. (2002). *Impact of the 1999 thimerosal statement on hepatitis B vaccination coverage*. https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5006a3.htm

5. Clark, S. J., Cabana, M. D., Malik, T., Yusuf, H., & Freed, G. L. (2001). H*epatitis B vaccination practices in hospital newborn nurseries before and after changes in vaccination recommendations.* Archives of pediatrics & adolescent medicine, 155(8), 915–920. https://doi.org/10.1001/archpedi.155.8.915
6. Centers for Disease Control and Prevention. (2021). *Thimerosal in vaccines*. https://www.cdc.gov/vaccine-safety/about/thimerosal.html
7. Centers for Disease Control and Prevention (1988). *Recommendations of the Immunization Practices Advisory Committee Prevention of Perinatal Transmission of Hepatitis B Virus: Prenatal Screening of all Pregnant Women for Hepatitis B Surface Antigen.* https://www.cdc.gov/mmwr/preview/mmwrhtml/00000036.htm
8. World Health Organization. (2024) – processed by Our World in Data. *Which countries include hepatitis B birth dose vaccines in their national vaccination programs?* WHO Immunization Data – Vaccine Introductions. https://ourworldindata.org/grapher/hepatitis-b-birth-dose-vaccine-immunization-schedule
9. Lernout, T., Hendrickx, G., Vorsters, A., Mosina, L., Emiroglu, N., & Van Damme, P. (2014). *A cohesive European policy for hepatitis B vaccination, are we there yet?.* Clinical microbiology and infection : the official publication of the European Society of Clinical Microbiology and Infectious Diseases, 20 Suppl 5, 19–24. https://doi.org/10.1111/1469-0691.12535