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November 21, 2025

Comments Submitted for the Record
Docket # CDC-2025-0783-0001
Advisory Committee on Immunization Practices (ACIP)

The hepatitis B vaccine prevents hepatitis B virus (HBV) infection. HBV can cause a chronic infection which can be asymptomatic and hidden and yet cause progressive and serious chronic liver disease, cirrhosis, liver failure, liver cancer and death. According to the CDC, “Each of the HepB vaccines are highly effective in preventing infection. Studies indicate that immunity persists for at least 30 years among healthy people who initiate HepB vaccination at less than 6 months of age.” HBV can be transmitted by very minute amounts of infected blood, genital fluids and sometimes saliva. Approximately 90% of babies infected with HBV during delivery to a person with an HBV infection develop a lifelong infection, compared to only 5% of infected adults.

The hepatitis B vaccine provides protection when given as a series of doses, starting with a dose given shortly after birth, according to the CDC and Children's Hospital of Philadelphia. While hepatitis B screening is standard during prenatal care, many, especially mothers from poor and underserved communities, deliver without having received prenatal care. We also emphasize that almost half of all births in the United States are funded by Medicaid. This indicates that these families live in an environment of insecurity, uncertainty, and stress about basic life resources. We recognize that as a corollary, unlike some other families, many people at risk of transmitting HBV to their babies are unlikely to have the freedom, health literacy and medical knowledge necessary to actively make the best decisions for their child and to effectuate them. Historically our public health system was created to support and provide necessary health services for these families, initially providing milk and nutrition as well as health guidance. Our national public health system must continue to make vaccine guidance with these most needy American families in mind.

Worldwide, liver cancer is the second most common cause of cancer death. **We recognize that the hepatitis B vaccine is the first proven, safe and effective anti-cancer vaccine**. Since 1986, a second generation of genetically engineered (or DNA recombinant) synthetic hepatitis B vaccines are being used. These do not contain human cells, other organisms or blood products and are proven to be extremely safe. More than a billion doses have been administered globally since the 1980s, and serious adverse events and allergic reactions have rarely been reported. The most common

side effects are mild transient pain at the injection site in fewer than 10% of children, occasionally with also transient mild complaints of fatigue, headache and irritability in up to 20% of children. A low-grade brief fever may occur in up to 6%.

Without widespread prevention through hepatitis B vaccination and early intervention, the United States is projected to spend more than $44.8 million yearly by 2050 on hepatitis B-related medical care.

As recounted in a detailed MMWR report, initially, hepatitis B vaccination was recommended only for those at “high risk”, such as newborns of known infected mothers or people in a household with an infected person. However, immunization of only high-risk groups failed to stop transmission of hepatitis B virus because about one-third of patients with active disease were not in identifiable risk groups. In 1991, the Advisory Committee on Immunization Practices (ACIP) recommended immunizing all infants to address these failed attempts to control hepatitis B and its attendant morbidity, mortality and health care costs that resulted from only immunizing high-risk groups. Following this recommendation, which was widely implemented by 1996, hepatitis B disease was virtually eliminated in children less than 18 years of age in the United States.

Defend Public Health emphasizes that for over 30 years, hepatitis B vaccination, with the first dose given in the delivery room, has been proven to be a safe and effective preventive public health measure. We emphasize that cases of potential harms cited in the Vaccine Adverse Event Reporting System (VAERS) are all based on clinically unevaluated and unverified reports; the safety of the hepatitis B vaccine, including its administration shortly after birth, is well established.

There is no scientific or epidemiologic data or evidence that would support a revision of the current protocol. Specifically, and inevitably, making hepatitis B vaccination at birth optional will result in a rise in neonatal hepatitis B infections across the United States and be detrimental to the health of American families.

Defend Public Health strongly supports the current hepatitis B vaccination birth dose protocol and opposes any changes. This is one of the proven ways we have made, and can continue to make, America healthy.

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Defend Public Health (DPH) is a volunteer-led network of public health practitioners, researchers, healthcare workers, advocates and allies fighting to protect the health of all from attacks on proven, science-based public health policies. We believe that everyone has the right to what they need for a healthy life, regardless of race, ethnicity, religion, disability, sexual orientation, gender or gender identity.