CDC Advisers May Nix Hepatitis B Vaccine for Newborns

The HBV vaccine prevents liver cancer and saves lives, but critics contend that most infants don't need the first dose immediately after birth.

September 19, 2025 By Liz Highleyman

[Update: On Friday, the Advisory Committee on Immunization Practices put off a vote on delaying the birth dose of the hepatitis B vaccine. After hearing data and testimony on Thursday, committe members' comments suggest that they have not reached agreement.]

A Centers for Disease Control and Prevention (CDC) vaccine advisory committee, newly reconstituted by Health Secretary Robert F. Kennedy, Jr., meets today in Atlanta to discuss childhood vaccines, and the hepatitis B vaccine birth dose is in the crosshairs.

The CDC currently recommends that all infants receive their first dose of the hepatitis B vaccine within 24 hours after birth, followed by two more doses at age 1 to 2 months and at 6 to 18 months. The vaccine prevents serious complications of chronic hepatitis B virus (HBV) infection, including cirrhosis and liver cancer.

"The birth dose provides a safety net preventing a terrible outcome that we can't count on our system of health care to otherwise prevent, with minimal or no risk to the newborn," Demetre Daskalakis, MD, MPH, who until recently headed the CDC's National Center for Immunization and Respiratory Diseases, told Hep.

The Advisory Committee on Immunization Practices (ACIP) develops national recommendations for vaccines for children and adults, which are typically approved by the CDC director. In June, Kennedy removed all members of the committee and replaced them with allies, some of whom share his skepticism towards vaccines. This week, he announced five new members.

In late August, Kennedy ousted CDC director Susan Monarez, PhD, after the two clashed over vaccine policy. At a Senate hearing yesterday, Monarez testified that she was fired for refusing Kennedy's demand that she give prior approval of ACIP recommendations and fire key staff. High-level agency officials, including Daskalakis, resigned in protest.

Monarez noted that Kennedy said he frequently spoke to President Donald Trump about changing the childhood vaccine schedule and told her it would be changed in September, suggesting that

ACIP's decision may already be determined. Without a permanent CDC director, the current interim director—Kennedy's deputy Jim O'Neill—or Kennedy himself may give the final approval.

ACIP is scheduled to discuss the combination measles/mumps/rubella/varicella (chickenpox) vaccine Thursday morning and the hepatitis B vaccine in the afternoon. On Friday, the committee will discuss COVID-19 vaccines. The Food and Drug Administration approved three updated COVID shots last month, but limited their authorization to people over 65 and those with underlying health conditions. In May, Kennedy announced that COVID vaccines would no longer be recommended for healthy children or pregnant women.

Do Newborns Need the Hep B Vaccine?

While surveys show that most parents favor long-standing childhood vaccines, such as those that prevent measles, mumps and polio, they are less confident about newer vaccines, like those for hepatitis B, chickenpox and COVID.

HBV is a blood-borne virus that can spread through direct contact with blood and via objects that come in contact with blood, such as shared needles for injecting drugs or tattooing, or shared household items like razors. It can also be transmitted during sex and from pregnant women to their babies. About 90% of infants infected at birth will develop chronic hepatitis B—much higher than the 10% rate for those who acquire the virus as adults.

Many people with hepatitis B have no obvious risk factors, however, and in about a third of cases, the transmission route is unknown. In the United States, HBV prevalence is highest among Asian, Black and Native populations. Hepatitis B can be treated with antivirals, such as tenofovir, but there is no cure.

The consequences of chronic hepatitis B are grave. While the virus typically does not cause symptoms at early stages, over time it can lead to liver fibrosis (scarring), cirrhosis, hepatocellular carcinoma (the most common type of liver cancer), liver failure and the need for a liver transplant. Hepatitis B is a leading cause of liver cancer worldwide, along with hepatitis C, heavy alcohol use and fatty liver disease. Around 25% of people with chronic infection will die from its complications.

Vaccinating babies born to women with hepatitis B immediately after birth can prevent chronic infection. Administering hepatitis B immunoglobulin (injected antibodies) to the infant, if available, and treating the mother with antivirals provides additional protection. The World Health Organization recommends the vaccine birth dose for all infants, and the U.S. and many other countries have adopted this policy.

"As the first anti-cancer vaccine, the hepatitis B vaccine plays an invaluable role in helping children and adults lead long, healthy lives," Hepatitis B Foundation president Chari Cohen, DrPH, MPH, said in a February statement. "Prior to the universal infant hepatitis B vaccination

recommendation in 1991, nearly 18,000 children in the U.S. were infected each year before they reached the age of 10, and half of these children were infected during childbirth. With universal birth dose and infant vaccination, childhood and adolescent hepatitis B infections have dramatically decreased by 95%.”

More than 1 billion hepatitis B vaccine doses have been administered worldwide since the early 1980s. Numerous studies and real-world experience have shown that the vaccine is safe and generally well tolerated. The most common side effects are soreness at the injection site, fatigue, fever and irritability in children. In rare cases, it can cause Guillain-Barré syndrome, a neurological disorder. Case reports of post-vaccine autoimmune conditions have not been confirmed in systematic reviews of medical research.

Before the Hepatitis B vaccine in 1982, 200k-300k Americans were infected annually, including 20k children. Rates have plummeted.

Hep B infection at birth and in early childhood can lead to debilitating illness and liver cancer for the rest of a person’s life. The vaccine is…

pic.twitter.com/TsWFuM70Ym

— U.S. Senator Bill Cassidy, M.D. (@SenBillCassidy)

September 9, 2025

At yesterday’s and previous hearings—and on X—Senator Bill Cassidy, MD (R–La.), a liver specialist, argued for the importance of the HBV vaccine birth dose, sparring with Sen. Rand Paul, MD (R–Ky.), an ophthalmologist. In February, Cassidy cast the deciding vote to confirm Kennedy as health secretary after extracting promises that he would not limit vaccine access.

CDC guidelines recommend that women should be screened for hepatitis B during each pregnancy, and there is little debate that babies born to those who test positive should get the vaccine birth dose. But opponents of infant vaccination contend that babies born to HBV-negative

mothers do not face this risk, so vaccination can be deferred until later in life. Some insiders suggest that ACIP might delay recommended vaccination until age 4.

“Unless the mother is hepatitis B positive, an argument could be made to delay the vaccine for this infection, which is primarily spread by sexual activity and intravenous drug use,” ACIP chair Martin Kulldorff, PhD, said at the committee’s June 25 meeting.

However, some pregnant women do not receive prenatal care, some may be in the acute phase of HBV infection when the test doesn’t detect the virus and some acquire the virus after testing negative. The previous policy of only vaccinating people considered to be at risk was not adequate, leaving many children vulnerable.

“With the fragmented health care system in the U.S., pregnant women may not get prenatal care, or the results of testing may not make it to the birth hospital. With cuts to Medicaid, this will get worse,” Daskalakis told Hep. “The risk/benefit of the vaccine is such that the birth dose addresses that issue as well as starting a series that may prevent infection further downstream. ACIP should not close that window to avoid preventable outcomes using a vaccine that is extremely low risk and generates good protection at birth.”

Daskalakis emphasized that the HBV vaccine birth dose is just a clinical recommendation, not a mandate. However, most states do require hepatitis B vaccination for children to attend daycare and school, and these mandates are often legally tied to ACIP recommendations. Florida has already moved to rollback vaccine mandates, even as hepatitis B cases among children in the state are rising.

Another consideration is that keeping the CDC’s birth-dose recommendation means the vaccine must be covered by insurance and it is included in the federal Vaccines for Children program, which provides childhood vaccines for free to low-income families. Without insurance, the HBV vaccine can cost upwards of $100 per dose.

If the committee rescinds the current recommendation, “parents who want to get the vaccine for their child at birth will not be able to as a covered service,” Daskalakis said. “Physicians should discuss this with parents to make their decision on timing—ACIP should not be the decider, the parent should be.”

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