National Vaccine Information Center

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U.S. Department of Health and Human Services
Advisory Committee on Immunization Practices Secretariat
Centers for Disease Control and Prevention
US Department of Health and Human Services
1600 Clifton Road NE
Atlanta, Georgia 30329-4027

Re: Docket No. CDC-2025-0454-0001
ACIP Meeting Sept. 18-19, 2025 Request for Public Comment
Federal Register Citation: 90 FR 42245

On behalf of the non-profit charitable National Vaccine Information Center (NVIC), this comment is being submitted to the federal Advisory Committee on Immunization Practices (ACIP) of the U.S. Centers for Disease Control and Prevention (CDC) by Barbara Loe Fisher, co-founder and president of NVIC and a former consumer member of the National Vaccine Advisory Committee (1988-1992) and FDA Vaccines and Related Biological Products Advisory Committee (1999-2003).

In November 1991, when the ACIP published new recommendations for the use of hepatitis B vaccine in the *Morbidity and Mortality Weekly Report* (MMWR), CDC officials announced that they were "making hepatitis B vaccine a part of routine vaccination schedules for all infants" - whether the mother was hepatitis B positive or not - in order to provide "the rationale for a comprehensive strategy to eliminate transmission of hepatitis B virus in the United States."[1] Not counting smallpox vaccine discontinued in 1971 as a routinely recommended childhood vaccine,[2] hepatitis B vaccine was the ninth vaccine to be included in the federally recommended childhood vaccine schedule (diphtheria, tetanus, pertussis, polio, measles, mumps, rubella, haemophilus influenza type B) and the first vaccine CDC officials directed doctors to inject into infants on the first day of life.

Thirty-three years ago, a small number of parents were voicing concerns about DPT and oral polio vaccine reactions, vaccines that were given beginning at age two months, but most parents did not question the safety and effectiveness of primarily giving children vaccines that prevented diseases communicated in a public setting. However, parents were not begging for a vaccine to be administered to their newly born babies to

“eliminate” an infection that, according to the CDC, “is not spread through kissing or sharing utensils” and “also is not spread through sneezing, coughing, hugging, breastfeeding, or food or water” and is primarily transmitted by older teenagers and adults who are injecting drug users or have a history of sexually transmitted diseases or multiple sexual partners.[3] [4]

In fact, in the 1980s and 1990s, few parents even knew what hepatitis B was because there was a very low rate of hepatitis B infections in the U.S. general population.[5] Today the disease still disproportionately infects people living Asia and Africa and other economically disadvantaged countries.[6]

In 1985, the population of the U.S. was approximately 239 million people[7] and the number of reported cases of hepatitis B peaked at 26,611 and subsequently declined annually. [8] By 1991, when the ACIP recommended all infants receive a birth dose of the hepatitis B vaccination, the number of reported cases of hepatitis B had decreased to 18,003. [9]

In the Oct. 21, 1994 *MMWR*, CDC officials stated:[10]

> *“The reported incidence of hepatitis B decreased 59% from 1985 through 1993. This decline was caused by decreases in the number of cases reported among homosexual men between 1985 and 1989 (61%) and in the number reported among injecting-drug users from 1989 through 1992 (51%). These decreases are thought to result from an increase in AIDS awareness, which has resulted in behavioral changes (e.g., safer sex and needle-using practices).”*

By 1996, there were 10,637 cases of hepatitis B reported in the U.S. with 279 cases reported in children under the age of 14 and the CDC stated that *"Hepatitis B continues to decline in most states, primarily because of a decrease in the number of cases among injecting drug users and, to a lesser extent, among both homosexuals and heterosexuals of both sexes."*[11]

Notably, the significant decline in hepatitis B disease in the U.S. occurred *before* ACIP’s 1991 recommendation that all infants be administered a birth dose of hepatitis B vaccine before being discharged from the hospital newborn nursery.

In 1988, the ACIP prudently recommended that all pregnant women be screened for hepatitis B infection during every pregnancy so infants born to hepatitis B positive mothers could receive hepatitis B immune globulin (HBIG) and/or hepatitis B vaccine to help prevent development of a chronic hepatitis B carrier state that can be asymptomatic and may progress to cirrhosis or liver cancer later in life.[12] CDC officials stated, “It is now evident that routine screening of all pregnant women is the only strategy that will provide acceptable control of perinatal transmission of HBV infection in the United States.”[13]

Today as in the 1990s, it is estimated that less than one percent of pregnant women in the U.S. are chronically infected with hepatitis B and at risk for transmitting the infection to their newborns, with about 25,000 babies born annually to hepatitis B infected mothers at risk for developing chronic infections.[14]

After more than 30 years of injecting millions of newborn infants weighing as little as 4.5 pounds (2,000 grams) with hepatitis B vaccine on the first day of life,[15] in 2023 CDC officials estimated there were 14,400 cases of acute hepatitis B infections and 17,650 cases of newly reported chronic hepatitis B infections in the U.S.[16] in a population of about 335 million people.[17]

ACIP Recommends First Recombinant DNA and Virus-Like Particle Vaccine for All Newborns Even If Mother Is Hepatitis B Negative

In 1991, when ACIP made the at-birth universal use recommendation, it meant that the first genetically engineered vaccine using recombinant DNA technology, Merck's RECOMBIVAX HB vaccine licensed by the U.S. Food and Drug Administration (FDA) in 1986,[18] and the first genetically engineered virus like particle vaccine GlaxoSmithKline's ENGERIX-B licensed in 1989, [19] routinely would be given to infants in hospital nurseries within a day of birth – whether the mother tested hepatitis B positive or not. Doctors and medical personnel were instructed to give a hepatitis B shot to all newborns, even though virtually nothing is known about the immune or neurological status or genetic or epigenetic history of a 12 to 24-hour old baby and whether an individual infant is more susceptible to suffering injury or death from vaccination.[20] [21] [22]

ACIP's universal use recommendation for every baby born in America to get a hepatitis B shot meant that the first immunological challenge an infant who had just emerged from the womb[23] would be forced to experience would be the injection of a genetically engineered biological product that stimulates the immature immune system to provoke a strong inflammatory response to recombinant proteins[24] and ingredients like *Saccharomyces cerevisiae* yeast protein;[25] [26] a neurotoxic aluminum hydroxide adjuvant[27] [28] (amorphous aluminum hydroxyphosphate sulfate); and a neurotoxic mercury preservative (Thimerosal),[29] [30] which was replaced by 2002 with another toxin - formaldehyde.[31] [32]

The following statements by Merck & Co. are made in the product insert Highlights of Prescribing Information regarding RECOMBIVAX HB:

- "*The duration of the protective effect of RECOMBIVAX HB in healthy vaccinees is unknown at present and the need for booster doses is not yet defined."* (Merck)

- "*In three clinical studies, 434 doses of RECOMBIVAX HB, 5 mcg, were administered to 147 healthy infants and children (up to 10 years of age) who were monitored for 5 days after each dose. Injection site reactions and systemic adverse reactions were reported following 0.2% and 10.4% of the injections,*

respectively. The most frequently reported systemic adverse reactions (>1% injections), in decreasing order of frequency, were irritability, fever (101F oral equivalent), diarrhea, fatigue/weakness, diminished appetite and rhinitis." (Merck)

- "*RECOMBIVAX HB has not been evaluated for its carcinogenic or mutagenic potential or its potential to impair fertility"*

Merck also states that "In healthy adults, injection site reactions and systemic adverse reactions were reported following 17% and 15% of the injections, respectively." Among the adverse reactions reported among 1,252 healthy adults in clinical trials were: fatigue/weakness; headache; fever (.100F), malaise, nausea, diarrhea, upper respiratory infection; abdominal pain/cramps, vertigo/dizziness, paresthesia, puritis, rash, angioedema, urticaria, arthralgia including monoarticular, myalgia, back, neck and shoulder pain, lymphadenopathy, insomnia, dysuria, hypotension.

Merck also states that in post-marketing experience:

> *"An apparent hypersensitivity syndrome (serum-sickness-like) of delayed onset has been reported days to weeks after vaccination, including arthralgia (usually transient), fever, and dermatologic reactions such as urticaria, erythema multiforme, ecchymoses and erythema nodosum. Autoimmune diseases including systemic lupus erythematosus (SLE), lupus-like syndrome, vasculitis, and polyarteritis nodosa have also been reported."*

Other post-marketing adverse events that have been reported following receipt of RECOMBIVAX HB include Guillain Barre syndrome (GBS), multiple sclerosis and exacerbation of multiple sclerosis, myelitis including transverse myelitis, seizure, febrile seizure, peripheral neuropathy including Bell's Palsy, radiculopathy, herpes zoster, migraine, muscle weakness, hypesthesia, encephalitis, Stevens-Johnson syndrome, alopecia, eczema, arthritis, thrombocytopenia, agitation, somnolence, optic neuritis, tinnitus, conjunctivitis, visual disturbance, uveitis, syncope and tachycardia.

The following statements by GlaxoSmithKline are made in the product insert Highlights of Prescribing Information for ENGERIX-B:

- "*In 36 clinical studies, a total of 13,495 doses of ENGERIX-B were administered to 5,071 healthy adults and children who were initially seronegative for hepatitis B markers, and healthy neonates. All subjects were monitored for 4 days post-administration…. The most frequently reported adverse reactions were injection-site soreness (22%) and fatigue (14%)."*

- *"ENGERIX-B has not been evaluated for carcinogenic or mutagenic potential, or for impairment of male fertility in animals."*

GlaxoSmithKline also stated that in post-marketing experience:

"An apparent hypersensitivity syndrome (serum-sickness-like) of delayed onset has been reported days to weeks after vaccination, including arthralgia/arthritis (usually transient), fever and dermatologic reactions such as urticaria, erythema multiforme, ecchymoses and erythema nodosum."

Other post-marketing adverse reactions reported following ENGERIX-B include meningitis, thrombocytopenia, encephalitis, encephalopathy, migraine, multiple sclerosis, neuritis, neuropathy including hypoesthesia, paresthesia, Guillain Barre syndrome (GBS) and Bell's palsy, optic neuritis, paralysis, paresis, seizures, syncope, transverse myelitis; conjunctivitis, keratitis, visual disturbances, tinnitus, vertigo, palpitation, tachycardia, vasculitis, apnea, bronchospasm including asthma-like symptoms, dyspepsia, alopecia, angioedema, eczema, erythema multiforme including Stevens-Johnson syndrome, erythema nodosum, lichen planus, purpura, arthritis, muscular weakness, abnormal liver function tests.

In 1994, the Institute of Medicine, National Academy of Sciences, published a report *Adverse Events Associated with Childhood Vaccines* and the IOM Vaccine Safety Committee that included evaluation of adverse event reports following the relatively new recombinant hepatitis B vaccines.[33] The IOM committee concluded that there were with no or too few biological mechanism or epidemiological studies in the medical literature to determine whether the evidence was inadequate to accept or reject a causal relationship between hepatitis B vaccine and:

- Guillain Barre syndrome
- multiple sclerosis
- optic neuritis
- transverse myelitis
- arthritis
- acute or chronic arthropathy
- Sudden Infant Death Syndrome (SIDS)

The only adverse event that the IOM committee acknowledged to be causally associated with hepatitis B vaccines was death from anaphylaxis.

In 1998, a special report *Hepatitis B Vaccine: The Untold Story* was published by the National Vaccine Information Center (NVIC) as more parents across the U.S. were protesting the mandating of hepatitis B vaccine for daycare and school attendance and reporting that they were being coerced into giving their newborns hepatitis B vaccine before hospitals would agree to discharge the mother and newborn after birth - even though the mother tested hepatitis B negative. [34] In the report, I pointed out that the hepatitis B vaccines were only studied in a few thousand children followed up for four or five days, but that there were already many reports published in the medical literature describing immune system and brain damage following hepatitis B vaccination and deaths in infants under age one month, with most of the newborn deaths being classified as sudden infant death syndrome (SIDS) - even though SIDS is not

historically recognized in the medical literature as occurring in babies under two months of age.[35]

In January 1999, NVIC released data that showed the number of hepatitis B associated serious adverse event and death reports in American children under the age of 14 outnumbered the reported cases of hepatitis B disease in that age group, calling government mandated hepatitis B vaccination of all children "a dangerous and scientifically unsubstantiated policy." At the same time, NVIC released the results of a national poll of 1,000 registered voters in December 1998 that showed 68 percent of Americans support a parent's right to be informed of the risk of diseases and vaccines and be able to choose whether or not their children receive certain vaccines.[36]

On May 18, 1999, a congressional hearing was held in the Criminal Justice, Drug Policy and Human Resources Subcommittee of the House Government Reform Committee chaired by Rep. John Mica (R-FL) with testimony offered by parents of children who had been injured or who had died following hepatitis B vaccination. I testified about the hundreds of reports that NVIC had received of children regressing into chronic poor health after being vaccinated with a clear pattern of hepatitis B vaccine reaction symptoms occurring within days or weeks of vaccination and deaths in newborns under age two months. I pointed out that:[37]

> "*The information sheet on hepatitis B produced by the Centers for Disease Control in compliance with safety provisions in the National Childhood Vaccine Injury Act does not come close to meeting the "informed" part of informed consent. Parents who want to make educated hepatitis B vaccine decisions for their children often are threatened when they even ask to delay vaccination if the child is sick. The lack of informed consent protections in mass vaccination programs is leading to fear and mistrust of the whole vaccination system."*

In 2011, the Institute of Medicine, National Academy of Sciences, published a report *Adverse Effects of Vaccines: Evidence and Causality* that included a summary of epidemiologic assessments, mechanistic assessments and causality conclusions for reported adverse events associated with hepatitis B vaccines. The IOM committee concluded that there were either no or too few biological mechanism or epidemiological studies in the medical literature to determine whether the evidence was adequate to accept or reject a causal relationship between hepatitis B vaccine and 26 reported serious adverse health conditions marked by acute or chronic immune or brain dysfunction, including:[38]

- encephalitis
- encephalopathy
- seizures
- acute disseminated encephalomyelitis
- transverse myelitis
- optic neuritis
- neuromyelitis optica

- multiple sclerosis onset in adults
- multiple sclerosis onset in children
- multiple sclerosis relapse in adults
- multiple sclerosis relapse in children
- first demyelinating event in adults
- first demyelinating event in children
- Guillain Barre syndrome
- chronic inflammatory disseminated polyneuropathy
- brachial neuritis
- erythema nodosum
- onset or exacerbation of systemic lupus erythematosus
- onset or exacerbation of vasculitis
- onset or exacerbation of polyarteritis nodosa
- onset or exacerbation of psoriatic arthritis
- onset or exacerbation of reactive arthritis
- onset or exacerbation of rheumatoid arthritis
- onset of exacerbation of juvenile idiopathic arthritis
- type 1 diabetes
- fibromyalgia.

The only reported adverse event associated with hepatitis B vaccine for which the IOM Committee to Review Adverse Effects of Vaccines could find sufficient scientific evidence to make a causality conclusion for in 2011 was anaphylaxis after vaccination in individuals who are yeast-sensitive.

In 2024, an article was published in *Vaccines* that evaluated the safety of hepatitis B vaccination of pre-term infants, most of which are being given a hepatitis B shot on the day of birth if they weigh at least 4.5 pounds. The authors stated:[39]

> "*We found no publications investigating the timing of the birth dose of hepatitis B vaccine, and AEFI reporting was exclusively short-term (hours to days following administration). Research focusing on the safety of hepatitis B vaccine in preterm infants specifically within 7 days of birth is lacking, particularly regarding long-term morbidity risk. Further research in this area is required.*"

The 1991 ACIP recommendation for universal use of hepatitis B vaccine on the day of birth by all infants, regardless of whether or not the mother is infected with hepatitis B, was misguided. It is a classic case of public health policy preceding the science and, in retrospect, caused significant harm to public perception of the wisdom of federal vaccine use recommendations for infants and children.

It is time to remove the recommendation and emphasize screening of all pregnant women for hepatitis B infection so a more science-based and personalized hepatitis B vaccine policy can take its place. At the same time, priority should be given to funding biological mechanism research that will close long-standing scientific knowledge gaps

about how and why hepatitis B vaccine can cause injury and death and who is more susceptible to suffering harm from vaccination.

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