

InformedCHOICEWA.org

September 14, 2020

RE: FDA-2020-P-1857-0001, Citizen Petition from SIRI & GLIMSTAD LLP

To the UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES AND THE FOOD AND DRUG ADMINISTRATION:

We, the Board and Members of Informed Choice WA, support the above named petition which requests “that the Commissioner of Food and Drugs (the “Commissioner”) withdraw or suspend the approval granted by the Food and Drug Administration (“FDA”) for Engerix-B and Recombivax HB for infants and toddlers until a properly controlled and adequately powered double-blind trial of sufficient duration is conducted to assess the safety of these products as required pursuant to applicable federal statutes and regulations for licensing these products.”

We add the additional reasons:

1. The vast majority (99.4%¹) of newborns, infants, and toddlers in the United States are at zero risk of contracting Hepatitis B. Routine screening of mothers before giving birth effectively identifies children who may be at risk during the birth process². Post-exposure immune globulin is available for infants at risk.
2. Administering a vaccine to a child who is at virtually zero risk of infection, and who may not enter a potential time of risk for years, decades, or ever, makes that vaccine exposure all risk and no benefit to the child.
3. Administering a drug that is “not medically indicated” for the patient is a violation of medical ethics as well as potential insurance fraud.
4. The CDC did not begin recommending Hepatitis B vaccination of newborns for the child’s direct benefit, but in hopes of many years later reducing infections in high-risk adults³.
5. Exposing one person to the risks of a medical intervention that has no benefit for them, for the purported benefit of others at some future time, violates long-standing ethical standards. Medical ethicist Henry K. Beecher wrote in 1966: “there is no right to risk an injury to one person for the benefit of others.”⁴

We ask that you fulfill the request of the petitioners.

Sincerely,

Bernadette Pajer
ICWA Public Policy Director
on behalf of our Board and Members

¹ About 25,000 out of ~ 4million births, for a risk rate of .625% and non-risk rate of 99.4% in U.S. annually are to women infected with HVB; maternal infection is the major risk factor for newborn and early childhood risk <https://pediatrics.aappublications.org/content/135/5/e1141>

² <https://www.cdc.gov/hepatitis/hbv/HBV-RoutineTesting-Followup.htm>

³ <https://www.cdc.gov/mmwr/preview/MMWRhtml/00033405.htm>

⁴ <https://www.forbes.com/sites/leahrosenbaum/2020/06/12/willowbrook-scandal-hepatitis-experiments-hideous-truths-of-testing-vaccines-on-humans/#34040945279c>