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Safety Data for Hep B Vax for Newborns Exposed

Analysis by Dr. Joseph Mercola Fact Checked | February 28, 2023

STORY AT-A-GLANCE

- The safety data on Recombivax HB, the hepatitis B vaccine for newborns, are sadly lacking, as the FDA approved the shot based on clinical trials performed on only 147 infants and children and followed for only five days
- There are four hepatitis B vaccines, two of which are approved for infants; the second approved for infants is Engerix-B, and clinical safety data show infants and children were followed for only four days in these trials
- Most infants are not at high risk for hepatitis B. It makes better financial and health sense to test mothers before birth and vaccinate only those infants born to mothers with an active or chronic hepatitis B infection, putting off vaccination in other infants until they are older
- The current childhood vaccination schedule includes 19 potential doses of vaccines and one mRNA experimental injection by the time an infant is 6 months old. Many of these contain aluminum, which raises a child's risk of persistent asthma in childhood

As the pandemic years have made abundantly obvious, the results of politically and financially driven public health policies can be devastating. And, as more and more vaccines get added to both child and adult schedules, it's becoming clear there needs to be an open and rational discussion about how vaccines fit into public health policy and what they offer in protection against infectious diseases.

One thing that is certain is we all want our children to be healthy and safe from unnecessary harm. However, as lead attorney for Informed Consent Action Network

(ICAN), Aaron Siri explains,[1] just one example of the negligence in regulations is the sadly lacking safety data on the hepatitis B vaccine for newborns.

Newborns Given Hepatitis B Vax Without Proper Safety Data

Before a newborn leaves the hospital, they're given one vaccine for hepatitis B, even though the safety data for it is scant, if that. According to Siri,[2] the clinical trials designed to protect newborns included only 434 doses of Recombivax HB given to 147 healthy infants and children up to 10 years of age, and these children were monitored for only five days after each dose.[3]

In other words, the testing was done not only on infants, but also on older children whose immune system is vastly different than a newborn's. Additionally, there were only 147 infants and children, total, involved in three clinical studies, which means there were far fewer infants who received the shot before it was released and approved in the childhood vaccine schedule.

If you'd like a closer look at the clinical trials and information on all vaccines, you can search "FDA vaccines licensed for use in the United States." That will bring you to a page[4] on the FDA website with a list of all the product names and the trade name. When you click on a specific vaccine link it will take you to the FDA's page for the vaccine on which you'll find a link for the package insert.

As Siri describes, section 6.1 of each package insert includes information about clinical trials the FDA used to approve a vaccine. In total there are four hepatitis B vaccines approved for use, but only two are approved for use in infants — Recombivax HB made by Merck and Engerix-B made by GlaxoSmithKline Biologicals.

According to the package insert, the most frequently reported adverse reactions included a fever of over 101 Fahrenheit, diarrhea, fatigue and weakness, diminished appetite and rhinitis.

Siri also notes, there is no indication there was a control group in the studies. He compares the paucity of data in the clinical trials for Recombivax HB given to newborns

to the warp speed COVID jab.[5] Comparatively, the studies on the COVID jab, which we know were not adequate, would appear admirable.

For example, Siri notes the COVID jab had six months of safety data while the Recombivax HB shot followed children for just five days. Pfizer's COVID trials[6] enrolled 46,331 participants in a Phase 3 clinical trial while Recombivax HB tested just 147 infants and children.

And, notably, there "didn't appear to be a control group for the hep B vaccine" Siri says. "And even if there was, what are you going to do with 147 kids' data?"[7]

Believing this may have been an error, Siri's group submitted a Freedom of Information Act request for the studies the FDA used to approve Recombivax HB. The data confirmed that safety monitoring only occurred for five days after injections were given to newborns, 1-month-old and 6-month-old babies. GlaxoSmithKline Biologicals was even worse, as the Engerix-B shot only tracked safety data for four days:

> *"These are the only two shots that a newborn can get in America,"* Siri says. *"That's the first shot they get in life. So, I'd say ridiculous might be too soft of an adjective to describe that safety review period."*

On behalf of ICAN, Siri's firm has filed a petition with the FDA requesting either a proper clinical trial to ascertain side effects and efficacy or withdrawing the licensure from Merck. By law, the FDA has six months to respond to such a request which, according to Siri, has expired. Having not received a formal response from the FDA, the plan is to sue the FDA in federal court over this issue.

Most Infants Are Not at High Risk for Hepatitis B

According to the CDC,[8] the leading means of transmission include spread when infected blood, semen or other bodily fluids are transferred to an uninfected person. This happens through shared needles or other drug equipment, sexual contact, or from mother to baby at birth.

In other words, the likelihood of a child contracting hepatitis B except at birth is extremely low. For many people, it's a short-term Illness, but it can become chronic and lead to liver cirrhosis or liver cancer. There is a simple blood test[9] that detects the presence of the virus, called the surface antigen. If that test is positive, further testing is necessary to determine if the infection is acute or chronic.

The surface antigen test costs between $24 and $69.99 depending on the area of the country and the lab that draws the test.[10] In comparison,[11] each hepatitis vaccine for infants costs the provider (pediatrician) between $26 and $27 per shot — but the markup they charge is well over four times their cost. You may pay from $118[12] to $140[13] per shot depending on your provider.

Data[14] show that the risk of an unvaccinated infant acquiring hepatitis B during birth can be up to 100% when they're born to a hepatitis B antigen-positive mother. However, since a newborn's immune system doesn't function in the same way as an older child's or an adult's, wouldn't it make more sense to spend $25 to test mothers before birth and vaccinate only those infants whose mothers have an acute or chronic hepatitis B infection?

Childhood Shot Schedule: 20 Shots Before 6 Months

In the precious early months of life, when an infant's brain and immune system are continuing to grow, most receive up to 20 injections of vaccines that parents are told will protect their child.[15] Beyond the hepatitis B newborn shot, at 2 months old they get six vaccine doses including a second hepatitis B, diphtheria, tetanus, pertussis, Haemophilus influenzae type b, pneumococcal conjugate and inactivated poliovirus.

Some are repeated at 4 months and 6 months, when they also receive their first flu and COVID-19 shot. All told, there are potentially 19 doses of vaccine and one dose of an experimental mRNA injection an infant could receive by 6 months of age.

According to every vaccine's package insert in Section 6.1, the clinical trial data don't offer parents a strong indication of what could happen when their newborn and infant

receives these doses:[16]

> *"Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a vaccine cannot be directly compared with rates in the clinical trials of another vaccine and may not reflect the rates observed in practice."*

Aluminum in the Hepatitis Vaccine Exacerbates Asthma

According to the CDC, one cost of following the childhood vaccination schedule is persistent asthma linked to **aluminum exposure**. Aluminum is the most common vaccine adjuvant, and the hepatitis B vaccine is one that contains it.[17,18] Despite its neurotoxicity,[19] manufacturers add aluminum to vaccines to create an enhanced inflammatory response that theoretically generates higher protective antibodies.

However, an increasing number of parents say that repeated exposure to vaccines with aluminum may be harming their children. Indeed, previous animal studies demonstrated that aluminum increases the risk of allergy by inducing a T helper 2 cell-biased immune response.[20]

In other words, the aluminum causes the T cells to be overactivated, which then exacerbates allergic responses.[21] This is known to affect airway inflammation and the hyperresponsiveness that occurs in children with allergic asthma.

In a January 2023 study with 326,991 children born from 2008 to 2014, they set out to assess "the association between cumulative aluminum exposure from vaccines before age 24 months and persistent asthma at age 24 to 59 months."[22]

They found there was a 1.26- and 1.19-times higher risk of persistent asthma for each additional milligram of vaccine-related aluminum exposure. The observational study stopped short of saying that it proves a link between aluminum-containing vaccines and asthma.

The CDC also stated that it has no intention of altering its vaccine recommendations based on this study alone.[23] However, the researchers pointed out that rates of asthma in U.S. children steadily increased in the 1980s and 1990s, then remained steady since 2001.

The 2001 date is significant, as most aluminum-containing vaccines were added to the childhood vaccine schedule before 2001. This includes, for example, diphtheria, tetanus, and acellular pertussis (DTaP), hepatitis B, some formulations of Haemophilus influenzae type b (Hib) and pneumococcal conjugate vaccines.

It's Time for Rational Discussions on Vaccine Safety

Unofficial surveys[24,25] have suggested that highly vaccinated children may have more chronic health problems than unvaccinated children, and that unvaccinated children have a far lower incidence rate of autism. A 2014 study[26] published in the Journal of Public Health and Epidemiology found that increases in autistic disorder correspond with the introduction of vaccines using human fetal cell lines and retroviral contaminants.[27]

When you also consider that the U.S. was the first country to grant emergency use authorization (EUA) for COVID jabs to children as young as 6 months,[28] and that the CDC Advisory Committee on Immunization Practices just added them to the child vaccine schedule[29] even though children have the lowest risk of COVID and therefore the least need for the shots,[30] it's clear that it's time for some rational dialogue on vaccine safety.

But to have rational discussions, we cannot ignore signs that mandatory use of multiple vaccinations in early childhood is NOT a safe preventive strategy, especially since we have no idea how many children's lives are sacrificed in the name of "the greater good."

From my point of view, there's little doubt we need to review the safety and effectiveness of the current vaccination program, especially since there has never been a large, prospective, well-designed study to evaluate whether children who are unvaccinated or

who received fewer vaccines are more or less healthy than children who receive all federally recommended vaccines.

These discussions must include methodologically sound investigative studies that are not compromised by conflicts of interest within industry and government. The good news is that there is much more historical data available today about the vaccine program and the effect it has on children and families. Just one study comparing the health outcomes of vaccinated versus unvaccinated children could shed light on the childhood vaccine schedule.

COVID Jab Added to Secure Indemnification

In yet another display of sacrificing children for Big Pharma and profits, the U.S. became the first country in the world to grant emergency use authorization (EUA) for Pfizer's and Moderna's **COVID jabs to toddlers** and children as young as 6 months. The FDA issued the EUA on June 17, 2022,[31] and the next day the CDC recommended all toddlers get the shot as soon as possible.[32]

However, as with the Hepatitis B vaccine, the pediatric EUA was based on extremely weak evidence, even after the FDA lowered the efficacy requirements for the pediatric population and even though children have the lowest risk of COVID and therefore have the least need for the shots.[33]

The addition of the unlicensed COVID-19 shots to the child, adolescent and adult vaccine schedules was approved in a unanimous 15-0 vote at the CDC Advisory Committee on Immunization Practices (ACIP).[34]

Dr. Robert Malone, inventor of the mRNA and DNA vaccine core platform technology said the move was likely to shatter whatever remaining trust Americans had in the CDC, "as it should. I am shocked by the malfeasance. I have no trust left at all in our public health system. It is broken," he said.

"Why the Rush for Toddler Vaccines?" asks Wall Street Journal editorial board member Allysia Finley in a July 4, 2022, op-ed.[35] Indeed, asked that same question, and I'm glad

the legacy media's WSJ had the courage to print it.

The stark truth is that the FDA and CDC are no longer in the business of protecting public health. They are securing profits for the drug industry, and the EUA for infants and young children was the first crucial step toward securing permanent legal indemnity for the drug makers.

By adding the shots to the vaccine schedule, it paves the way for U.S. schools to require them for attendance. The shots were also added to the Vaccine for Children (VFC) program, which provides vaccines to children at no or low cost using federal funding.[36]

Pfizer and Moderna, the shots' makers, will also be granted permanent legal indemnity, which otherwise would have disappeared once COVID-19 shots were no longer protected under emergency use authorization (EUA).[37]

You can learn more about this indemnification process in "**The Real Reason They Want to Give COVID Jabs to Kids**," which features my interview with Alix Mayer, board president of the Children's Health Defense's California chapter.

So, the reason the FDA and CDC have acted and continue to act so irrationally and ignore safety signals is that they are not working to protect you. They're working for the drug industry, and they've just sold out our children.