



**HEPATITIS B VACCINE
VAXELIS VACCINE
PRETERM AND LOW BIRTHWEIGHT BABIES
TROUBLING ISSUES**

My Child, My Choice

Issue 2



INFORMATION...YOU MAY HAVE MISSED

DID YOU KNOW that the primary reason the CDC recommended Hepatitis B vaccination for all newborns in the United States in 1991 was because public health officials and doctors could not persuade adults in high risk groups (primarily IV drug users and persons with multiple partners) to get the vaccine?

DID YOU KNOW that Hepatitis B is primarily an adult disease transmitted most frequently through blood and other body fluids, but that it is NOT transmitted through sneezing, kissing, sharing food or utensils, or breastfeeding?

DID YOU KNOW that if a mother does not have Hepatitis B infection (patients are tested for this when pregnant), then her newborn baby (scheduled to get the Hepatitis B vaccine within 12 hours of birth) is not at risk?

DID YOU KNOW that there is no recommended medicine for the treatment of Hepatitis B acute infections and that 95% of adults recover fully from acute Hepatitis B infections?

DID YOU KNOW that in clinical trials before licensure, adverse reactions from the Hepatitis B vaccines were monitored for only 4-5 days?

DID YOU KNOW that children who will get the new (six-in-one) VAXELIS vaccine may end up receiving an unnecessary extra (fifth) dose of polio and an unnecessary extra (fourth) dose of Hepatitis B?

DID YOU KNOW that the new adult Hepatitis B vaccine, HEPLISAV-B, showed a signal for heart attacks in its clinical trials?

DID YOU KNOW that a NICU hospital nurse revealed, “The step-down units are calling the NICU’s and saying ‘Hey, we’re going to go ahead and give these four babies their two-month shots today, make sure you have beds ready because we all know they’re going to have increased breathing difficulties, feeding and digestion difficulties, apnea, and bradycardia.’”?

DID YOU KNOW that a 2018 report stated that American babies are less likely to survive their first year than babies in other rich countries?

DID YOU KNOW that a study showed that boys vaccinated with the Hepatitis B vaccine as neonates had threefold greater odds for an autism diagnosis compared to boys never vaccinated or vaccinated after the first month of life?

DID YOU KNOW that the editor of the medical journal *Lancet* wrote, “Journals have devolved into information laundering operations for the pharmaceutical industry”?

DID YOU KNOW that in 1983 the CDC was authorized to accept external “gifts” from industry and other private parties through its CDC Foundation, and has received millions of dollars from vaccine manufacturers?



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HEPATITIS B VACCINE



FACTS ON HEPATITIS B INFECTION

WHAT IS HEPATITIS B?

Hepatitis B (HBV) is a viral infection that infects the liver and **requires direct contact with infected blood or other body fluids for transmission.** Symptoms of hepatitis B generally appear in 90 days and last a few weeks. Symptoms include fever, fatigue, loss of appetite, nausea, vomiting, abdominal pain, dark urine, discolored (clay) bowel movements, joint pain and jaundice (yellowish skin or eyes).

About half of infected adults and children over the age of five will have symptoms of the disease, while many children who are under the age of five will not.

<https://www.nvic.org/vaccines-and-diseases/Hepatitis-B/what-is.aspx>

HOW COMMON IS HEPATITIS B?

The significant decline in hepatitis B disease in the U.S. occurred prior to the CDC's Advisory Committee on Immunization Practices' (ACIP) 1991 recommendation that all infants be administered a birth dose of hepatitis B vaccine before being discharged from the hospital newborn nursery.

In 1985, the number of cases of hepatitis B peaked at 26,611 and subsequently declined annually. When childhood vaccination campaigns for hepatitis B vaccination were introduced in 1991, the number of reported cases of hepatitis B had already decreased to 18,003 (U.S. population then about 235 million). By 1996, there were only 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."

By 2006, the number of hepatitis B cases decreased to 4,713 with only 14 cases reported in children less than 14 years of age. In 2016, there were 3,218 reported cases of acute hepatitis B in the U.S.

<https://www.nvic.org/vaccines-and-diseases/hepatitis-b/history.aspx>

IS HEPATITIS B CONTAGIOUS?

...hepatitis B is not common in childhood and is not highly contagious in the same way as chicken pox and pertussis. Hepatitis B is primarily an adult disease transmitted most frequently through blood but can also be transmitted through other body fluids. Hepatitis B is NOT transmitted through sneezing, kissing, sharing food or utensils or breastfeeding.

Those most at risk of hepatitis B include needle using drug addicts (illegal IV drug users); those who have sexual contact with a person infected with hepatitis B; sexually promiscuous heterosexual and homosexual adults; residents and staff of custodial institutions such as prisons; health care workers exposed to blood; hemodialysis patients; and infants born to infected mothers.

Transmission of hepatitis B from infected mother to infant has always been uncommon and continues to be uncommon in the U.S., primarily due to routine prenatal screening of all pregnant women for hep-

atitis B infection, which, in many states, is required by law. Infants of mothers who are found to be positive for hepatitis B or whose hepatitis B status is unknown are treated by immunoprophylaxis with hepatitis B immune globulin (HBIG) to prevent transmission from mother to baby.

<https://www.nvic.org/vaccines-and-diseases/hepatitis-b/contagious.aspx>

CAN HEPATITIS B CAUSE INJURY AND/OR DEATH?

For most people hepatitis B is not a deadly disease....Fifty percent of adults infected with hepatitis B will have no symptoms. Hospitalization for acute hepatitis B is low and limited to the elderly, individuals with pre-existing medical conditions and those who require treatment for dehydration from severe nausea and vomiting. On very rare occasions, acute hepatitis B infections can lead to liver failure and death.

There is no recommended medicine for the treatment of acute infections and 95 percent of adults recover fully from acute hepatitis B infection and acquire life-long immunity. Eating well, drinking plenty of fluids and avoiding alcohol and drugs assist in recovery.

Of the approximately five percent who do not recover completely and become chronic carriers of the virus, only 20 to 30 percent will develop life threatening liver disease such as cirrhosis or liver cancer. Chronic infection requires monitoring and avoidance of alcohol to avoid liver damage.

Those who recover completely from hepatitis B infection acquire life-long immunity. Of those who do not recover completely, fewer than five percent become chronic carriers of the virus with only 20 to 30 percent developing liver cancer or cirrhosis.

<https://www.nvic.org/vaccines-and-diseases/hepatitis-b/injury-death.aspx>

BABY'S FIRST VACCINE!

Babies are given Hepatitis B vaccine on their first day of life, usually within 12 hours of birth. According to the CDC, how would a newborn baby possibly acquire Hepatitis B?

Hepatitis B is spread when blood, semen, or other bodily fluid infected with the hepatitis B virus enters the of a person who is not infected. People can become infected through:

- *Birth (if a mother has hepatitis B, her baby can become infected)*
- *Sharing items such as razors or toothbrushes with an infected person*
- *Contact with the blood or open sores of an infected person*
- *Sex with an infected partner*

- *Sharing needles, syringes, or other drug-injection equipment*
- *Exposure to blood from needlesticks or other sharp instruments*

<https://www.cdc.gov/hepatitis/hbv/bfaq.htm#bFAQc01>

QUESTION:

Since pregnant women are tested for Hepatitis B, and babies in hospital nurseries are not likely at risk from the scenarios above, why do babies of mothers who do not have Hepatitis B still get the vaccine in the hospital?

ANSWER:

ACHIEVEMENTS IN PUBLIC HEALTH: HEPATITIS B VACCINATION – UNITED STATES, 1982–2002

<https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5125a3.htm>

In June 1982, the Advisory Committee on Immunization Practices (ACIP) published the first official recommendations on the use of hepatitis B vaccine. ACIP recommended pre-exposure vaccination initially for groups with a high risk for HBV infection. However, by 1989, it had become evident that members of these groups were not being vaccinated in substantial numbers.

In 1991, recognizing the difficulty of vaccinating high-risk adults, ACIP recommend-

ed a comprehensive strategy to eliminate HBV transmission in the United States. The strategy focused on universal childhood vaccination, including infants.

NEWBORN HEPATITIS B VACCINATION COVERAGE AMONG CHILDREN BORN JANUARY 2003-JUNE 2005 – UNITED STATES

<https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5730a3.htm>

In 1991, the first dose was recommended to be administered at birth before hospital discharge or at age 1-2 months. In 2002, ACIP indicated a preference for the first dose to be administered before hospital discharge.

ELIMINATION OF PERINATAL HEPATITIS B: PROVIDING THE FIRST VACCINE DOSE WITHIN 24 HOURS OF BIRTH (COMMITTEE ON INFECTIOUS DISEASES, COMMITTEE ON FETUS AND NEWBORN)

Pediatrics September 2017

<https://pediatrics.aappublications.org/content/140/3/e20171870>

...approximately 1,000* new cases of perinatal hepatitis B infection are still identified annually in the United States....To reduce the incidence of perinatal hepatitis B transmission further, the American Academy of Pediatrics endorses the recommendation of ACIP of the CDC that all newborn infants with a birth weight of greater than or equal to 2000 g (4 lbs 6 oz) receive hepatitis B vaccine by 24 hours of age.

**2017 U.S. population about 325 million*

(NOTE: Only 5 of Europe's 31 countries recommend a dose of hepatitis B vaccine for newborns whose mothers are Hepatitis-B negative: Estonia, Lithuania, Poland, Portugal, and Romania.)

ARE THERE ROBUST SAFETY STUDIES FOR THIS NEWBORN POLICY?

The Informed Consent Action Network (ICAN) asked the Dept. of Health and Human Services (HHS) to show them safety studies on this protocol. HHS referred them to the vaccine insert (which stated that vaccine adverse effects were studied

for 4 or 5 days post immunization – see chart below) and to an ACIP report, which cited seven studies to support recommending this vaccine at 1-day, 1-month and 6-months of life. Two of these studies included adult homosexual males; a third study did not use either of the Hep B vaccines licensed for infants in the U.S., excluded children who did not complete the vaccine series, and lacked a placebo control; and a fourth study involved “virtually all” adults and did not provide any separate results for infants or children. The remaining three studies were clinical trials that did not have a placebo control group and that did not assess safety for longer than 7 days after vaccination.

<https://www.docdroid.net/03pUhlM/icanreply-december312018.pdf>

Recommended Age (First Dose)	Vaccine/Manufacturer	Safety Review Period Prior to Licensure	Subject Group	Placebo Group
1 Day Old	Hep-B (Engerix)/ GlaxoSmithKline	4 Days	Hep-B	No Placebo
1 Day Old	Hep-B (Recombivax)/ Merck	5 Days	Hep-B	No Placebo

HOW LONG DOES IMMUNITY LAST?

Anti-HBs levels after vaccination decline over time. The persistence of detectable anti-HBs levels varies by age at vaccination. By 18 years after vaccination, approximately 16% of persons vaccinated at age (younger than) <1 year have detectable antibody levels of (more than) ≥ 10 mIU/mL, compared with 74% for those vaccinated at age (older than) ≥ 1 year.

<https://www.cdc.gov/mmwr/preview/mmwrhtml/rr6210a1.htm>

NOTE: Manufacturers' inserts for Hepatitis B vaccines (HEPLISAV-B, Recombivax-HB, and Engerix-B) do not provide information on long-term effectiveness of their vaccine. (They have also not been studied for carcinogenic or mutagenic potential, or for impairment of fertility.)

INDUSTRY INSIDER SPEAKS

Trained chemist Jorge Araujo was working for Merck (hepatitis B manufacturer) in the vaccine sterile quality operations business unit as a supervisor in their biochemistry lab. His wife (a nurse) was due to have a baby soon and they started to look into vaccines. One of their first concerns was about the hep B vaccine given to infants. Jorge realized that “virtually every medical scholar acknowledges that the immune system of a newborn infant is nowhere near developed” and **vaccinating a newborn with hep B “is a medical intervention to boost an immune system about which we know very little.”**

He asked his colleagues within the industry questions about vaccine safety and efficacy, and also did his own research. He concluded that many vaccine

safety studies are “shabby” and “rushed,” there is “shoddy” data in some studies, there is a “lackadaisical attitude” when it comes to the process of investigating, developing, and releasing vaccine products to the market (which is not the case with other medical products), and pharmacokinetics work (the study of the movement of a drug into, through, and out of the body) in vaccines is “terribly lacking.” He says, **“My belief is that vaccine safety science is flawed and incomplete.”**

The Araujos did not vaccinate any of their children and today they are all “super healthy.” Jorge says others working in the industry have done the same.

<https://thehighwire.com/the-dam-breaks-merck-insider-spills-bad-science-secrets/>

A FATHER SPEAKS

Michael Belkin testimony to Congress on Hepatitis B vaccine, May 18, 1999

My daughter Lyla Rose Belkin died on September 16, 1998 at the age of five weeks, about 15 hours after receiving her second Hepatitis B vaccine booster shot. Lyla was a lively, alert five-week-old baby when I last held her in my arms....She was never ill before receiving the Hepatitis B shot that afternoon. At her final feeding that night, she was extremely agitated, noisy and feisty — and then she fell asleep suddenly and stopped breathing. The autopsy ruled out choking. The NY Medical Examiner ruled her death Sudden Infant Death Syndrome.

But the NY Medical Examiner (Dr. Persechino) neglected to mention Lyla’s swollen brain or the hepatitis B vaccine in the autopsy report. The coroner spoke to my wife and I and our pediatrician (Dr. Zullo) the day of the autopsy and clearly stated that her brain was swollen. The pediatrician Dr. Zullo’s notes of that conversation are “brain swollen ... not sure cause yet ... could not see how recombinant vaccine could cause problem.”

SIDS is a diagnosis of exclusion...“it wasn’t this, it wasn’t that, everything has been ruled out and we don’t know what it was.” **A swollen brain is not SIDS. Through conversations with other experi-**

enced pathologists, I subsequently discovered that brain inflammation is a classic adverse reaction to vaccination (with any vaccine) in the medical literature.

I set out to do an investigation of the hepatitis B vaccine and attended a workshop at the National Academy of Sciences, Institute of Medicine on “Neo-Natal Death and the Hepatitis B Vaccine,” the ACIP meeting and a debate in New Hampshire between the Chairman of the ACIP Dr. Modlin and Dr. Waisbren about the safety of the hepatitis B vaccine. I also obtained the entire Vaccine Adverse Events Reporting System (VAERS) database on hepatitis B vaccine adverse reactions and have investigated it thoroughly.

These are my conclusions....

- Newborn babies are not at risk of contracting the hepatitis B disease unless their mother is infected. Hepatitis B is primarily a disease of junkies, gays, and promiscuous heterosexuals.
- The vaccine is given to babies because health authorities couldn't get those risk groups to take the vaccine.
- Adverse reactions out-number cases of the disease in government statistics.
- Nothing is being done to investigate those adverse reactions.
- Those adverse reactions include numerous deaths, convulsions and arthritic conditions that occur within days after hepatitis B vaccination.
- The CDC is misrepresenting hypothetical, estimated disease statistics as real cases of the disease.
- The ACIP is recommending new vaccines

for premature infants without having scientific studies proving it is safe.

- The US vaccine recommendation process is hopelessly compromised by conflicts of interest with vaccine manufacturers, the American Academy of Pediatrics and the CDC.

If hepatitis B vaccine was recommended in 1991 without scientific proof that it was safe in a broad sample of racially and genetically diverse babies less than 48 hours old before they established that recommendation, then the CDC has been experimenting on babies like guinea pigs....

I studied statistics at the University of California at Berkeley and went on to develop sophisticated proprietary risk/reward statistical models at Salomon Brothers from 1986-91 — and in my subsequent, ongoing business provide statistical economic and financial forecasts to mutual funds, investment banks, pension funds and hedge funds.

I studied VAERS hepatitis B vaccine data obtained by the National Vaccine Information Center (NVIC) under the Freedom of Information Act. The data has some flaws (incomplete fields, some multiple reports) but any qualified, impartial quantitative analyst or statistician not affiliated with Merck, Smithkline, the CDC, the FDA or the AAP who examines these reports will find a clear and undeniable pattern of central nervous system (CNS) and liver disease striking thousands of people within 0-4 days after vaccination with hepatitis B vaccine. These reports have been ignored, explained away, or considered “acceptable” by the FDA, CDC and drug companies.

<http://www.whale.to/vaccines/belkin.html>

VAERS (VACCINE ADVERSE EVENTS REPORTING SYSTEM) SPEAKS

The U.S. Department of Health and Human Services (HHS)-sponsored Harvard Medical School project reported, “Adverse effects from drugs and vaccines are common, but under-reported....**Like-wise, fewer than 1% of vaccine adverse events are reported.**”

When Harvard reached out to HHS to follow up on these results, the HHS did not return their phone calls or emails.

healthit.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf

<https://truthsnitch.com/2017/10/24/cdc-silence-million-dollar-harvard-project-charged-upgrading-vaccine-safety-surveillance-system/#sthash.NXboY1nK.goxOG60Z.dpbs>

As of May 31, 2019, there have been more than 91,474 adverse events reported to VAERS in connection with Hepatitis B and Hepatitis B containing vaccines. Approximately 50% of those serious Hepatitis B vaccine-related adverse events occurred in children under 3 years old, with approximately 1,663 deaths occurring in children under three years of age. Of the vaccine-related adverse

events reported to VAERS there were 2,142 related deaths, 13,990 hospitalizations, and 3,387 related disabilities. 21,112 of the adverse events were associated with Hepatitis B vaccine alone (not combined with other vaccines). **Keep in mind that these statistics, according to the Harvard study, represent fewer than 1% of actual vaccine adverse events.**

As of July 1, 2019, there had been 926 claims filed in the federal Vaccine Injury Compensation Program (VICP) for injuries and deaths following hepatitis B containing vaccinations, including 97 deaths and 829 serious injuries. **(The 1986 National Childhood Vaccine Injury Act eliminated financial liability from vaccine manufacturers, and instead established the government VICP.)**

<https://www.nvic.org/vaccines-and-diseases/hepatitis-b/quick-facts.aspx>

The number of cases brought to the court would be higher if vaccine injury was acknowledged by doctors and brought to the attention of parents.

Why many doctors do not acknowledge vaccine injury

“...If every single medication on the planet can cause a severe or fatal reaction, why not vaccines? If all medical treatments can harm some people, why do doctors deny that vaccines can do the same? ...We [medical students] are indoctrinated with the lie that vaccine injury doesn't exist. It's all just coincidence...I don't blame the [medical] students. I blame their teachers and the industry that funds the teachers, and the media that are paid by the same industry, and the government that is owned by that industry that is now mandating these products...Is there any hope that our medical community will ever admit that vaccine injury is real? Perhaps...I have hope in the younger generation of doctors. If they would just think for themselves and look at the science themselves instead of agreeing to accept what they have been told to think, then there is hope.”

<https://www.youtube.com/watch?v=PYB62JzuiQY> (Pediatrician Dr. Bob Sears)



MEDICAL STUDIES SPEAK

Brief excerpts:

HEPATITIS B VACCINATION OF MALE NEONATES AND AUTISM DIAGNOSIS, NHIS 1997-2002

J Toxicol Environ Health A. 2010

<https://www.ncbi.nlm.nih.gov/pubmed/21058170>

Boys vaccinated as neonates had threefold greater odds for autism diagnosis compared to boys never vaccinated or vaccinated after the first month of life. Non-Hispanic white boys were 64% less likely to have autism diagnosis relative to nonwhite boys. Findings suggest that U.S. male neonates vaccinated with the hepatitis B vaccine prior to 1999 (from vaccination record) had a threefold higher risk for parental report of autism diagnosis compared to boys not vaccinated as neonates during that same time period. Nonwhite boys bore a greater risk.

IL-4 MEDIATES THE DELAYED NEURO-BEHAVIORAL IMPAIRMENTS INDUCED BY NEONATAL HEPATITIS B VACCINATION THAT INVOLVES THE DOWN-REGULATION OF THE IL-4 RECEPTOR IN THE HIPPOCAMPUS

Cytokine October 2018

<https://www.ncbi.nlm.nih.gov/pubmed/29751176>

This finding suggests that clinical events concerning neonatal IL-4 over-exposure, including neonatal hepatitis B vaccination and allergic asthma in human infants, may have **adverse implications for brain development and cognition.**

NEONATAL HEPATITIS B VACCINATION (HBV) IMPAIRED THE BEHAVIOR AND NEUROGENESIS OF MICE TRANSIENTLY IN EARLY ADULTHOOD

Psychoneuroendocrinology 2016

<https://www.ncbi.nlm.nih.gov/pubmed/27501128>

This work provides innovative data supporting the long suspected potential association of HBV with certain neuropsychiatric disorders such as **autism and multiple sclerosis.**

BOYS RECEIVING THE HEPATITIS B VACCINE SERIES WERE NINE TIMES MORE LIKELY TO NEED SPECIAL EDUCATION AND BE DEVELOPMENTALLY DISABLED

Toxicological and Environmental Chemistry 2008

<https://childrenshealthdefense.org/wp-content/uploads/35-2008-Hep-B-EIS.pdf>

This study found statistically significant evidence to suggest that boys in the United States who were vaccinated with the triple series Hepatitis vaccine, during the time period in which vaccines were manufactured with thimerosal, were more susceptible to **developmental disability** than were unvaccinated boys.

EVOLUTION OF MULTIPLE SCLEROSIS IN FRANCE SINCE THE BEGINNING OF HEPATITIS B VACCINATION (IN ADULTS)

Immunol Res. 2014

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4266455/>

Statistical data from these latter sources seem to show a significant correlation between the number of hepatitis B vaccinations performed and the declaration to the pharmacovigilance of **multiple sclerosis** occurring between 1 and 2 years later.

CENTRAL DEMYELINATING DISEASES AFTER VACCINATION AGAINST HEPATITIS B VIRUS: A DISPROPORTIONALITY ANALYSIS WITHIN THE VAERS DATABASE. (19-49 YEARS AGE)

Drug Saf. 2018

<https://www.ncbi.nlm.nih.gov/pubmed/29560597>

In VAERS, **MS (multiple sclerosis)** cases were up to five times more likely to be reported after an

HB vaccination than after any other vaccination.

This possible link was already a concern 14 years earlier:

RECOMBINANT HEPATITIS B VACCINE AND THE RISK OF MULTIPLE SCLEROSIS: A PROSPECTIVE STUDY

Neurology September 2004

<https://www.ncbi.nlm.nih.gov/pubmed/15365133>

These findings are consistent with the hypothesis that immunization with the recombinant hepatitis B vaccine is associated with an increased risk of **MS**.

WHAT IS IN THE HEPATITIS B VACCINE?

▶ Hep B (Engerix-B)	aluminum hydroxide, yeast protein, sodium chloride, disodium phosphate dihydrate, sodium dihydrogen phosphate dihydrate
▶ Hep B (Recombivax)	formaldehyde , potassium aluminum sulfate, amorphous aluminum hydroxyphosphate sulfate, yeast protein
▶ Hep B (Heplisav-B)	yeast protein, yeast DNA, deoxycholate, phosphorothioate linked oligodeoxynucleotide, sodium phosphate, dibasic dodecahydrate, sodium chloride, monobasic dehydrate, polysorbate 80
▶ Hep A/Hep B (Twinrix)	MRC-5 human diploid cells , formalin, aluminum phosphate, aluminum hydroxide, amino acids, sodium chloride, phosphate buffer , polysorbate 20, neomycin sulfate, yeast protein, water

Aluminum is an **adjuvant**, which is an ingredient in a vaccine that helps boost the immune response to the antigen and thus increase antibodies.

Has aluminum been tested for safety when injected into children?

CDC and FDA cite the 2011 study by Dr. Robert J. Mitkus for any concerns raised about injecting aluminum in children.

However, "... the only biological science Dr. Mitkus considered in making his safety assessment was a single study that infused (rather than injected) aluminum citrate (rather than aluminum hydroxide) into adults (rather than babies). At least Mitkus acknowledges this difference in the paper, noting 'The determinations of the kinetics of aluminum retention by Priest were based on experiments where human volunteers were given an intravenous injection of aluminum citrate. For vaccines, the injection is intramuscular, the aluminum is in an insoluble form (e.g., as the phosphate or hydroxide of aluminum), and muscle at the site of injection is considered to be a storage depot for aluminum.'

"In no other drug on the planet (except for vaccines) would safety standards ever be determined without using the actual product (aluminum hydroxide) administered in the proper way (intramuscular injection), into the proper patient population (infants)."

<https://childrenshealthdefense.org/news/a-lone-fda-scientist-could-end-the-autism-epidemic/>

Ingested aluminum - almost 100% eliminated from the body

Injected aluminum - almost 100% remaining in the body

Aluminum concerns of leading scientists around the world

<https://childrenshealthdefense.org/news/a-lone-fda-scientist-could-end-the-autism-epidemic/>

"Experimental research has showed that alum adjuvants have a potential to induce serious immunological disorders in humans." – Dr. Yehuda Shoenfeld, Tel-Aviv University (Israel), 2013

"I would now say that we have to think very carefully about who receives a vaccine that includes an aluminum adjuvant...is this vaccine a life-saving vaccine or not?" – Dr. Chris Exley, Keele University (England), 2017

"In the context of massive development of vaccine-based strategies worldwide, the present study may suggest that aluminium adjuvant toxicokinetics and safety require reevaluation." – Dr. Guillemette Crépeaux, Ecole Nationale Vétérinaire d'Alfort (France), 2016

"...it is somewhat surprising to find that in spite of over 80 years of use, the safety of Al adjuvants continues to rest on assumptions rather than scientific evidence." – Dr. Chris Shaw, University of British Columbia (Canada), 2012

"...continuously escalating doses of this poorly biodegradable adjuvant in the population may

become insidiously unsafe, especially in the case of overimmunization or immature/altered blood brain barrier.” – Dr. Romain Gherardi, Université Paris-Est Créteil (France), 2013

“It is not really a matter of much debate that aluminum in various forms can be neurotoxic.”
– Dr. Lucija Tomljenovic, University of British Columbia (Canada), 2013

Brief excerpts:

TESTING NEW HYPOTHESES OF NEUROLOGICAL AND IMMUNOLOGICAL OUTCOMES WITH ALUMINUM-CONTAINING VACCINES IS WARRANTED.

Journal of Trace Elements in Medicine and Biology 2019

https://www.sciencedirect.com/science/article/pii/S0946672X1830498X?dgcid=raven_sd_recommender_email

In between the works claiming a link between ASD (Autism Spectrum Disorders) and Al(aluminum)-adjuvants, there are three lines of scientific evidence suggesting correlation: ecological comparisons correlating immunization with Al-adjuvants and ASD, experiments in mice linking Al-adjuvants and behavioral disorders, and finally measurements of high concentration of Al in brain cells of subjects with ASD....**Al is a neurotoxin and immune stimulator.** Hence, it has in principle the potential to induce neuroimmune disorders. Dysfunctional immunity and impaired brain function are fundamental shortfalls in ASD.

THE PUTATIVE ROLE OF ENVIRONMENTAL ALUMINIUM IN THE DEVELOPMENT

OF CHRONIC NEUROPATHOLOGY IN ADULTS AND CHILDREN. HOW STRONG IS THE EVIDENCE AND WHAT COULD BE THE MECHANISMS INVOLVED?

Metab Brain Dis. 2017

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5596046/>

...aluminium exposure is associated with the production of pro-inflammatory cytokines and chemokines and with the development of chronic oxidative stress, mitochondrial dysfunction and glial activation or dysfunction; these changes in turn are associated with **ASD (Autism spectrum disorder)**.

ALUMINUM IN THE CENTRAL NERVOUS SYSTEM (CNS): TOXICITY IN HUMANS AND ANIMALS, VACCINE ADJUVANTS, AND AUTOIMMUNITY

Immunol Res. July 2013

<https://www.ncbi.nlm.nih.gov/pubmed/?term=23609067>

The literature demonstrates clearly negative impacts of aluminum on the nervous system across the age span....In young children, a highly significant correlation exists between the number of pediatric aluminum-adjuvanted vaccines administered and the rate of **autism spectrum disorders**.

ALUMINUM ADJUVANTS OF VACCINES INJECTED INTO THE MUSCLE: NORMAL FATE, PATHOLOGY AND ASSOCIATED DISEASE

Morphologie June 2016

<https://www.ncbi.nlm.nih.gov/pubmed/26948677>

Although generally well tolerated on the short term, it has been suspected to occasionally cause **delayed neurologic problems** in susceptible individuals.

For more information on aluminum in vaccines, please see *My Child, My Choice, HPV Vaccine, Issue 1*

Polysorbate 80, another ingredient, is used as a stabilizer, surfactant, and emulsifier to keep the components of the vaccine evenly distributed in the liquid.

It is used in many drug formulations to open up the blood brain barrier (for example, in chemotherapy drugs). Thus, when a vaccine contains polysorbate 80, toxic ingredients (like aluminum) may pass from the blood into the brain.

SUPERPARAMAGNETIC IRON OXIDE NANOPARTICLES MODIFIED WITH TWEEN 80 PASS THROUGH THE INTACT BLOOD-BRAIN BARRIER IN RATS UNDER MAGNETIC FIELD

ACS Appl Mater Interfaces May 11, 2016
<https://www.ncbi.nlm.nih.gov/pubmed/27092793>

This study showed that a metal, iron oxide, was carried into the brain with the use of Polysorbate 80.

Formaldehyde is used in certain vaccines to inactivate viruses and to detoxify bacterial toxins.

A new report (August 2014) from the National Research Council has upheld the listing of formaldehyde as “**known to be a human carcinogen**” in the National Toxicology Program 12th Report on Carcinogens(RoC).

<http://www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=18948>

MRC-5 human diploid cells (residual components including human DNA and protein) are used to grow the vaccine antigens.

Two different strains of human diploid cell cultures made from fetuses have been used extensively for vaccine production for decades. WI-38, developed in the United States in 1961, came from lung cells from a female fetus of 3-months’ gestation. MRC-5, developed in the United Kingdom in 1966, was developed from lung cells from a 14-week-old male fetus, aborted by the mother for “psychiatric reasons.”

UNITED STATES HOUSE OF REPRESENTATIVES SELECT PANEL OF THE COMMITTEE ON ENERGY AND COMMERCE “BIOETHICS AND FETAL TISSUE” WEDNESDAY, MARCH 2, 2016 RESPONSE TO ADDITIONAL QUESTIONS FOR THE RECORD SUBMITTED BY: KATHLEEN M. SCHMAINDA, PHD APRIL 8, 2016

docs.house.gov/meetings/IF/IF04/20160302/104605/HHRG-114-IF04-Wstate-SchmaindaK-20160302-SD002.pdf

To summarize, early fetal tissue and cell lines used for vaccine development were developed using suboptimal methods. Consequently, these cell lines should not be considered a “gold standard” mode of vaccine development. Rather their continued use would be considered to be “bad science.” Currently, there are plenty of ethical alternatives available for cell line development, all using better methodology... there remain significant, unresolved questions on the public health dangers of products resulting from use of aborted fetal cell lines; these potential health concerns should also be investigated....

Vaccines made from MRC-5 cell line:

Pentacel, Hep A, Twinrix, MMRV, Varicella, Shingles

Vaccines made from WI-38 cell line:

MMR, MMRV

Phosphate buffer helps to maintain a constant pH.

“For research use only, **not for human or veterinary use.**”

“The toxicological effects of this product have not been thoroughly tested.”

<https://www.caymanchem.com/msdss/400032m.pdf>

HEPLISAV-B FOR ADULTS – SAFETY ISSUES

In February 2018, ACIP voted unanimously to approve a new Hepatitis B vaccine HEPLISAV-B (2 doses) for those 18 years or older (including pregnant women) who were not previously vaccinated or are under vaccinated for Hepatitis B.

Before the vote took place, one voting member, Dr. Hunter, asked, **“Is there any comment on using this vaccine at the same time with other adjuvanted vaccines?”** The response: **“We have no data to make a recommendation one way or the other. So, just so you, just to sort of put this into context of other vaccines, while preclinical studies were not done using these vaccines simultaneously, our general approach to immunization is that they can be given at the same time in different limbs.”** Dr Hunter asked, **“Are adjuvanted, multiple adjuvanted vaccines used in Europe or other markets?”** The response (Dr. Ward): **“Not to my knowledge.”**

After the vote, members were asked for comments.

Dr. Stephens (who had voted yes) commented: **“Just a slight reservation....I am concerned about that signal, that myocardial infarction [heart attack] signal. I am concerned about the use of this new adjuvant and certainly urge us to continue to look at the post-marketing data carefully.”** Dr Hunter (who had voted yes) then asked when that post-marketing data would be available to them. The response (Dr. Sun): **“For the myocardial infarction study we’re seeing that the data likely for completion is May 31, 2020, and there will also be studies looking at autoimmune diseases, as well as herpes zoster, and there will be a pregnant registry as well.”**

ACIP meeting here:

<https://www.youtube.com/watch?v=7UzQqan3uF8>

(NOTE: THESE ARE THE SAME INDIVIDUALS WHO DECIDE WHAT VACCINES GET INJECTED INTO YOUR CHILDREN.)

HAS THIS VACCINE BEEN TESTED FOR SAFETY IN PREGNANT WOMEN?

HEPLISAV-B manufacturer's insert: "There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to HEPLISAV-B during pregnancy. Women who receive HEPLISAV-B during pregnancy are encouraged to contact 1-844-443-7734. **There are no clinical studies of HEPLISAV-B in pregnant women. Available human data on HEPLISAV-B administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy.**"

www.heplisavb.com/images/pdf/HEPLISAV-B-Prescribing-Information.pdf

THE STORY BEHIND HEPLISAV-B'S APPROVAL

FDA LICENSES NEW HEPATITIS B VACCINE DESPITE BIG SAFETY CONCERNS

August 2018

thevaccinereaction.org/2018/08/fda-licenses-new-hepatitis-b-vaccine-despite-big-safety-concerns

According to an article published in Medscape, the first application by Dynavax Technologies for licensure was rejected by the FDA for the following reason: Although safety analyses showed no statistically significant differences between Heplisav and the currently licensed hepatitis B vaccine Engerix-B (GlaxoSmithKline) in local and systemic solicited adverse events or deaths, **there were numerically greater numbers of patients receiving Heplisav who had evidence of autoimmune disorders, including thyroid disorders.** The increases were not statistically significant, but advisory panel members said the safety database was too small to detect rare adverse events....

In 2016, the FDA rejected a second application for licensure. **That time the agency was concerned about an increased rate of cardiovascular events and deaths in people who had been given Heplisav-B vaccine versus Engerix-B.**

In a randomized clinical trial involving approximately 8,400 subjects, 5,600 study participants received Heplisav-B and 2,800 participants received Engerix-B. During the trial, approximately 14 subjects in the Heplisav-B group had heart attacks in comparison to one subject in the Engerix-B group. Taking into account that the Heplisav-B group was twice as large as the Engerix-B group, **the risk for heart attacks was seven times higher for people who had been given the experimental vaccine.**

In an attempt to minimize the significance of the increased rate of serious heart complications, Dynavax argued that the higher number heart attacks recorded in the Heplisav-B group was due to the "fewer than expected" instances that occurred with the Engerix-B group....

In July 2017, the FDA's Vaccine and Related Biological Products Advisory Committee convened to re-evaluate the scientific evidence and make a decision on whether Heplisav-B should or should not be approved for use in the U.S. A majority of the committee consisted of immunology and infectious disease professionals with only one cardiologist on the team, Milton Packer, MD, who is a Distinguished Scholar in Cardiovascular Science at the Baylor University Medical Center in Dallas, Texas.

According to Dr. Packer, it was possible the strong inflammatory response induced by the

Heplisav-B vaccine's novel adjuvant was causally related to the higher number of heart attacks in study participants who received the experimental vaccine....

The FDA asked the committee to vote on whether there was reasonable evidence that Heplisav-B vaccine is safe. Twelve committee members voted in favor of the safety of the new vaccine, one voted against it and three abstained. Dr. Packer was one of those who abstained.

Dr. Packer explains why he abstained:

Why did I abstain? Based on the available data, it was impossible for anyone to know if the increase in heart attack risk in the Dynavax group was real or spurious....There is a simple rule in life: if you don't know, you should say you don't know.

Following the meeting, the FDA requested more information from Dynavax on its post-marketing study. Four months later, in November 2017, the FDA licensed Heplisav-B for use in the U.S. by adults over age 18. However, continued approval hinges on a post-marketing study that will compare health outcome results from people who have received Heplisav-B with those who have received Engerix-B.

On the FDA website, the agency claims that, "FDA regulations for the development of vaccines ensure their safety, purity, potency, and effectiveness."

However, the fact that Heplisav-B vaccine was approved for public use despite clear evidence in pre-licensure clinical trials that the

new vaccine is associated with development of autoimmunity, heart attacks and death calls into question the FDA's commitment to adhering to its own regulations.

FDA LETTER TO DYNAVAX, MANUFACTURER OF HEPLISAV-B

Based on "appropriate scientific data," the FDA ordered Dynavax to conduct two post-marketing studies and to establish a pregnancy registry.

- 1. "Post-Marketing Observational Study to Evaluate the Occurrence of Acute Myocardial Infarction in Adults 18 Years of Age and Older Who Receive HEPLISAV-B Compared with Another Hepatitis B Vaccine."** ...the study conducted in Kaiser Permanente Southern California will evaluate approximately 25,000 patients who receive HEPLISAV-B and approximately 25,000 patients who receive another hepatitis B vaccine. *Study Completion Date: May 31, 2020; Final Report Submission: June 30, 2021*
- 2. "Post-Marketing Observational Surveillance of the Safety of HEPLISAV-B in Adults 18 Years of Age and Older to Evaluate the Incidence of New Onset Immune-mediated Diseases, Herpes Zoster, and Anaphylaxis."** *Study Completion: August 31, 2020 Final Report Submission: February 28, 2022*
- 3. Data in this [pregnancy] registry will be used to assess risks relevant to pregnancy,** including pregnancy outcomes of pre-term births, major congenital malformations, spontaneous abortions, and still births. The registry will collect information on 250-300 pregnant women. *Study Completion: August 9, 2023 Final Report Submission: December 31, 2023*

<https://www.fda.gov/media/108828/download>

VAXELIS VACCINE



FACTS ON VAXELIS

WHAT IS VAXELIS?

Vaxelis is a hexavalent (six-in-one) vaccine to prevent diphtheria, tetanus, pertussis, poliomyelitis, hepatitis B, and Hib. It was FDA-approved in December 2018 and is expected to be available in 2020.

It is given as a 3-dose series in children from 6 weeks through 4 years of age (prior to the 5th birthday).

This new six-in-one vaccine (that was given together with the rotavirus and Prevnar vaccines in clinical trials) was tested against a control group that got other combinations of vaccines, not against a true placebo.

WILL THE USE OF VAXELIS LEAD TO UNNECESSARY EXTRA DOSES OF OTHER VACCINES? YES.

CLINICAL REVIEW OF VAXELIS

<https://www.fda.gov/media/119740/download>

...a child who receives the proposed schedule of VAXELIS and then receives Pentacel will receive 4 doses of IPV during the first two years of life....Some State immunization requirements for school entry include receipt of the last dose of IPV after the fourth birthday. **Thus, some children who receive three doses of VAXELIS according to the proposed schedule may receive an extra (fifth) dose of IPV at 4-6 years of age.**

Additionally, **an infant who has received a birth dose of a mono-valent hepatitis vaccine will**

receive three more doses of hepatitis B vaccine upon completing the infant series with VAXELIS, to give a total of four doses.

WHAT KIND OF SAFETY DATA IS AVAILABLE ON THIS NEW VACCINE?

<https://www.fda.gov/media/119465/download>

From the manufacturer's insert:

"VAXELIS may be used to complete the hepatitis B vaccination series following 1 or 2 doses of other hepatitis B vaccine" but **"data are not available"** on the safety and effectiveness of VAXELIS in such infants and children."

NOTE: Considering there were only 3,409 new cases (mostly in adults) of acute Hepatitis B in the U.S. in 2017 (<https://www.cdc.gov/nchs/data/hus/2018/010.pdf>), is it medically irresponsible for children to get an unnecessary extra dose of the aluminum-containing Hepatitis B vaccine?

"VAXELIS may be used to complete the first 3 doses of the 5-dose DTaP series in infants and children who have received 1 or 2 doses of Pentacel or DAPTACEL" but **"data are not available"** on the safety and immunogenicity of such mixed sequences."

"Data are not available" on the safety and effectiveness of using VAXELIS following 1 or 2 doses of a DTaP vaccine from a different manufacturer."

"VAXELIS may be administered to infants and children who have received 1 or 2 doses of IPV vaccine" but **"data are not available"** on the safety and ef-

fectiveness of VAXELIS in such infants and children.”

NOTE: Considering polio does not exist in the U.S. today, is it medically irresponsible for children to get an unnecessary extra dose of the polio vaccine?

“VAXELIS may be administered to infants and children who have received 1 or 2 doses of H. influenzae type b Conjugate Vaccine” but **“data are not available** on the safety and effectiveness of VAXELIS in such infants and children.”

“Apnea following intramuscular vaccination has been observed in some infants born prematurely.”

“The solicited adverse reactions following any dose were irritability (≥55%), crying (≥45%), injection site pain (≥44%), somnolence (≥40%), injection site erythema (≥25%), decreased appetite (≥23%), fever ≥38.0°C (≥19%), injection site swelling (≥18%), and vomiting (≥9%).”

“In the 2 U.S. studies, death was reported in 6 participants (0.2%) who received VAXELIS and in 1 participant (0.1%) who received Pentacel + RECOMBIVAX HB vaccines (the control group); none were assessed as vaccine-related. Causes of death among infants who received VAXELIS were asphyxia, hydrocephalus, unknown cause, sepsis and 2 cases of Sudden Infant Death Syndrome (occurring 1, 2, 10, 42, 44 and 49 days post-vaccination, respectively).

“VAXELIS has not been evaluated for carcinogenic or mutagenic potential or impairment of fertility.”

DO EUROPEAN COUNTRIES USE A HEXAVALENT VACCINE? YES.

Brief excerpts:

INFANRIX HEXA AND SUDDEN DEATH: A REVIEW OF THE PERIODIC SAFETY UPDATE REPORTS SUBMITTED TO THE EUROPEAN MEDICINES AGENCY

Indian Journal of Medical Ethics September 2017
<https://www.ncbi.nlm.nih.gov/pubmed/28918379>

There have been a number of spontaneous reports of sudden unexpected death soon after the administration of Infanrix hexa (combined diphtheria, tetanus, acellular pertussis, hepatitis B, inactivated poliomyelitis and Haemophilus influenza type B vaccine). The manufacturer, GlaxoSmith-Kline (GSK), submits confidential periodic safety update reports (PSURs) on Infanrix hexa to the European Medicines Agency (EMA). The latest is the PSUR 19. Each PSUR contains an analysis of observed/expected sudden deaths, which shows that the number of observed deaths soon after immunization is lower than that expected by chance...**It is apparent that the deaths acknowledged in the PSUR 16 were deleted from the PSUR 19. The number of observed deaths soon after vaccination among children older than one year was significantly higher than that expected by chance once the deleted deaths were restored and included in the analysis.** The manufacturer must explain the figures that have been submitted to the regulatory authorities. The procedures undertaken by the EMA to evaluate the manufacturer’s claims in the PSUR need to be reviewed.

SAFETY OF THE INFANRIX HEXA VACCINE: CONFIDENTIAL DOCUMENT FROM GSK TO THE AUTHORITIES

Initiative Citoyenne December 2012

<http://ddata.over-blog.com/3/27/09/71/2012-2013/confid.pdf>

The document in question details the adverse effects of this vaccine, reported back to the manufacturer from various European countries between the 23rd of October 2009 and the 22nd of October 2011. **We can understand why it is confidential: no less than 825 different types of complication and adverse effect are mentioned.**

...During this specific period of time, GSK received 1,742 reports of adverse effects, of which 503 were serious effects not listed and 56 were serious adverse effects listed. **The events registered included 36 deaths (over the two-years period), most of which occurred within three days after the child received the Infanrix Hexa vaccine.** According to GSK, the adverse effect notification rate was 14.6 per 100,000 doses distributed but don't forget that the number of doses actually used/administered is always lower than the number of doses distributed. It is also important to point out that, according to an article in the November 2011 issue of *Revue française du Practicien* (a French magazine for the medical profession), **only 1 to 10% of serious vaccine adverse effects are actually reported and logged. The extent of the problem is therefore grossly under-estimated.**

SUDDEN INFANT DEATH FOLLOWING HEXAVALENT VACCINATION: A NEUROPATHOLOGIC STUDY

Current Medicinal Chemistry, Volume 21, Number 7, 2014

<https://www.ncbi.nlm.nih.gov/pubmed/24083600>

This study does not prove a causal relationship between the hexavalent vaccination and SIDS. **However, we hypothesize that vaccine components could have a direct role in sparking off a lethal outcome in vulnerable babies.** In conclusion, we sustain the need that deaths occurring in a short space of time after hexavalent vaccination are appropriately investigated and submitted to a post-mortem examination particularly of the autonomic nervous system by an expert pathologist to objectively evaluate the possible causative role of the vaccine in SIDS.

BETA-TRYPTASE AND QUANTITATIVE MAST-CELL INCREASE IN A SUDDEN INFANT DEATH FOLLOWING HEXAVALENT IMMUNIZATION.

Forensic Sci Int. August 2008

<https://www.ncbi.nlm.nih.gov/pubmed/18538957>

A fatal case of a 3-month-old female infant, who died within 24 hours of vaccination with hexavalent vaccine, is presented. Clinical data, post-mortem findings (acute pulmonary oedema, acute pulmonary emphysema), quali-quantitative data collected from immunohistochemical staining (degranulating mast cells) and laboratory analysis with a high level of beta-tryptase in serum, 43.3 microg/l, allows us to conclude that **acute respiratory failure likely due to post hexavalent immunization-related shock was the cause of death.**

PRETERM AND LOW BIRTHWEIGHT BABIES



SAME SCHEDULE

AMERICAN ACADEMY OF PEDIATRICS' GUIDELINES (AAP)

IMMUNIZATIONS FOR PRETERM BABIES

www.healthychildren.org/English/safety-prevention/immunizations/Pages/Immunizations-For-Preterm-Babies.aspx

“Some parents of preterm and low birth weight babies are concerned about immunizing their newborns according to the standard schedule created by the AAP and other medical organizations. Their main worry is whether the recommendations were made with full-term, normal weight babies in mind and whether the same guidelines apply to their own newborns. Your pediatrician will tell you that all of these babies should be given the routinely recommended childhood vaccinations when they reach the ages at which these shots are normally given to all children.

*“The hepatitis B vaccine deserves special mention. Newborns should receive their first dose of hepatitis B vaccine within the first 24 hours of birth. Newborns who for a medical or other reason did not get the vaccine at birth should get their first dose as soon as possible, and complete all 3 doses at the recommended intervals. **All of the available vaccines are safe** when given to preterm and low birth weight babies.*

*“Any side effects associated with the vaccines **are similar** in both full-term and preterm babies.”*

REALLY?

RECOMBIVAX HB MANUFACTURER'S INSERT:

“Apnea [cessation of breathing during sleep] following intramuscular vaccination has been observed in some infants born prematurely.

Decisions about when to administer an intramuscular vaccine, including RECOMBIVAX HB, to infants born prematurely should be based on consideration of the individual infant's medical status and the potential benefits and possible risks of vaccination.”

<https://www.fda.gov/media/74274/download>

ENGERIX-B MANUFACTURER'S INSERT:

“Apnea [cessation of breathing during sleep] following intramuscular vaccination has been observed in some infants born prematurely.

Decisions about when to administer an intramuscular vaccine, including ENGERIX-B, to infants born prematurely should be based on consideration of the individual infant's medical status and the potential benefits and possible risks of vaccination.”

<https://www.fda.gov/media/119403/download>



MORE CONCERNS

Brief excerpts:

ADVERSE EVENTS AFTER ROUTINE IMMUNIZATION OF EXTREMELY LOW-BIRTH-WEIGHT INFANTS.

AMA Pediatr. August 2015

<https://www.ncbi.nlm.nih.gov/pubmed/26030302>

Most of the 13,926 infants (91.2%) received 3 or more immunizations. The **incidence of sepsis evaluations increased** from 5.4 per 1000 patient-days in the preimmunization period to 19.3 per 1000 patient-days in the postimmunization period (adjusted rate ratio [ARR], 3.7; 95% CI, 3.2-4.4). The **need for increased respiratory support increased** from 6.6 per 1000 patient-days in the preimmunization period to 14.0 per 1000 patient-days in the postimmunization period (ARR, 2.1; 95% CI, 1.9-2.5), and **intubation increased** from 2.0 per 1000 patient-days to 3.6 per 1000 patient-days (ARR, 1.7; 95% CI, 1.3-2.2)....

All ELBW infants in the NICU had an increased incidence of sepsis evaluations and increased respiratory support and intubation after routine immunization.

PRIMARY IMMUNIZATION OF PREMATURE INFANTS WITH GESTATIONAL AGE <35 WEEKS: CARDIORESPIRATORY COMPLICATIONS AND C-REACTIVE PROTEIN RESPONSES ASSOCIATED WITH ADMINISTRATION OF SINGLE AND MULTIPLE SEPARATE VACCINES SIMULTANEOUSLY

J Pediatr. August 2007

<https://www.ncbi.nlm.nih.gov/pubmed/17643770>

Overall, 16% of infants had vaccine-associated cardiorespiratory events within 48 hours postimmunization.

RECURRENCE OF CARDIORESPIRATORY EVENTS FOLLOWING REPEAT DTAP-BASED COMBINED IMMUNIZATION IN VERY LOW BIRTH WEIGHT PREMATURE INFANTS.

J Pediatr. September 2008

<https://www.ncbi.nlm.nih.gov/pubmed/18718262>

We evaluated the tolerance to immunization of 64 very low birth weight preterm infants. **Thirty-three of the infants experienced a cardiorespiratory event** after the first vaccination, and 6 of these 33 (18%) had a recurrence after the second vaccination, including 2 infants previously discharged to home.

PRETERM BIRTH, VACCINATION AND NEURODEVELOPMENTAL DISORDERS: A CROSS-SECTIONAL STUDY OF 6- TO 12-YEAR-OLD VACCINATED AND UNVACCINATED CHILDREN

Journal of Translational Science 2017

<https://www.oatext.com/pdf/JTS-3-187.pdf>

Preterm infants receive the same doses of the recommended vaccines and on the same schedule as term infants. The possible role of vaccination in neurodevelopmental disorders (NDD) among premature infants is unknown, in part because pre-licensure clinical trials of pediatric vaccines have excluded ex-preterm infants....A convenience sample of 666 children was obtained, of which 261 (39%) were unvaccinated, 7.5% had an NDD (defined as a learning disability, Attention Deficit Hyperactivity Disorder and/

or Autism Spectrum Disorder), and 7.7% were born preterm. No association was found between preterm birth and NDD in the absence of vaccination, but vaccination was significantly associated with NDD in children born at term (OR 2.7, 95% CI: 1.2, 6.0). However, **vaccination coupled with preterm birth was associated with increasing odds of NDD**, ranging from 5.4 (95% CI: 2.5, 11.9) compared to vaccinated but non-preterm children, to 14.5 (95% CI: 5.4, 38.7) compared to children who were neither preterm nor vaccinated.

PILOT COMPARATIVE STUDY ON THE HEALTH OF VACCINATED AND UNVACCINATED 6- TO 12-YEAR-OLD U.S. CHILDREN (THE MAWSON STUDY)

Journal of Translational Science 2017

<https://www.oatext.com/pdf/JTS-3-186.pdf>

...preterm birth and vaccination combined was strongly associated with NDD (neurodevelopmental delay) in the final adjusted model with interaction, more than doubling the odds of NDD compared to vaccination alone. Preterm birth has long been known as a major factor for NDD, but since preterm infants are routinely vaccinated, the separate effects of preterm birth and vaccination have not been examined. The present study suggests that vaccination could be a contributing factor in the pathogenesis of NDD but also that preterm birth by itself may have a lesser or much reduced role in NDD (defined here as ASD, ADHD and/or a learning disability) than currently believed. The findings also suggest that **vaccination coupled with preterm birth could increase the odds of NDD beyond that of vaccination alone.**

“The science is not settled. There is always more to learn.”

A HOSPITAL NURSE SPEAKS

Michelle Rowton of Nurses Against Mandatory Vaccines commented on the current medical practice of vaccinating infants too early following the Center for Disease Control's schedule.

"I think what a lot of people don't realize in a closed space like NICU (Neonatal Intensive Care Unit) is that they've decided that we need to vaccinate these babies on-time. Two months after they're born... bam! — there it goes. This baby could be four months early and still supposed to be inside their mother, weighing three or four pounds and getting the same amount of vaccines as a 200-pound man."

Rowton then went further to break bombshell news by saying:

"I've sat in a room with our on-call staff of physicians and practitioners (when they say) 'Oh wow, this is so embarrassing this 25 weeker never actually required a breathing tube and going on the vent after he was born, he was so strong. But we gave him his two-month vaccinations and he got intubated last night ha ha, oops how embarrassing.' The step-down units are calling the NICU's and saying 'Hey we're going to go ahead and give these four babies their two-month shots today, make sure you have beds ready because we all know they're going to have increased breathing difficulties, feeding and digestion difficulties, apnea, and bradycardia.' This is what goes on."

<https://www.youtube.com/watch?v=i-J8yuYMBnA>

"IT'S YOUR CHOICE. CHOOSE WISELY."

Newborns of mothers who are not infected with Hepatitis B are not at risk for this illness. Babies who will not be in an environment with high-risk adults for Hepatitis B will likely not get this infection either. Hepatitis B is rarely a serious or deadly disease in children, whereas serious adverse effects from this vaccine (including death) have been reported to VAERS. Studies show that premature and low birthweight babies are even at more risk from this (and all other) vaccines.

Therefore, carefully consider whether your newborn baby needs the Hepatitis B vaccine in the hospital (see blue boxes on page 29) and whether you should postpone this vaccine series until it is needed for daycare or school entry. If you decide you don't want your newborn baby to get this vaccine in the hospital, inform your obstetrician and your child's pediatrician, write this in a simple birth plan, and hand a copy of your birth plan to everyone involved in your care at the hospital. You can also visit or call the hospital in ad-

vance and ask them how your decision can be ensured. Be vigilant where your newborn baby is at all times because babies HAVE been vaccinated without parental consent, and have someone with you who is aware of your decision in case you are preoccupied.

The new Heplisav-B vaccine for adults was FDA approved even with serious safety concerns. For most adults, Hepatitis B infection is not serious nor deadly. This vaccine has not been tested for safety in pregnant women.

Therefore, carefully consider if you should get the Heplisav-B vaccine, given its serious safety

concerns – including a heart-attack signal. If you are pregnant, carefully consider if you should get the Heplisav-B vaccine, which has not been tested for safety in this population.

Many safety issues have not been addressed with the new VAXELIS vaccine. A similar six-in-one vaccine in Europe raises cause for serious concern.

Therefore, carefully consider if you want to give your child the VAXELIS vaccine, given the “unavailable” safety data and high rate of adverse effects reported.

UNEXPLAINED FEVER IN NEONATES MAY BE ASSOCIATED WITH HEPATITIS B VACCINE

Arch Dis Child Fetal Neonatal Ed. 1999

<https://www.ncbi.nlm.nih.gov/pubmed/10525025>

The increase in the number of cases of unexplained neonatal fever seems to be associated with the introduction of routine hepatitis B vaccination on the first day of life.

From Hepatitis B vaccine manufacturer's insert:

“...the most frequently reported systemic adverse reactions (>1% injections), in decreasing order of frequency, were irritability, **fever**, diarrhea, fatigue/weakness, diminished appetite, and rhinitis.”

<https://www.fda.gov/files/vaccines%2C%20blood%20%26%20biologics/published/package-insert-recombivax-hb.pdf>

YOU DECIDE – because your body and your child's body belong to G-d, not to the government.

TROUBLING ISSUES



CLINICAL TRIALS – FACTS OR FICTION?

RESEARCH MISCONDUCT IDENTIFIED BY THE US FOOD AND DRUG ADMINISTRATION OUT OF SIGHT, OUT OF MIND, OUT OF THE PEER-REVIEWED LITERATURE

JAMA Intern Med. April 2015

<https://www.ncbi.nlm.nih.gov/pubmed/25664866>

RESULTS: Fifty-seven published clinical trials were identified for which an FDA inspection of a trial site had found significant evidence of 1 or more of the following problems: **falsification or submission of false information, 22 trials (39%); problems with adverse events reporting, 14 trials (25%); protocol violations, 42 trials (74%); inadequate or inaccurate recordkeeping, 35 trials (61%); failure to protect the safety of patients and/or issues with oversight or informed consent, 30 trials (53%); and violations not otherwise categorized, 20 trials (35%).** Only 3 of the 78 publications (4%) that resulted from trials in which the FDA found significant violations mentioned the objectionable conditions or practices found during the inspection. No corrections, retractions, expressions of concern, or other comments acknowledging the key issues identified by the inspection were subsequently published.

CONCLUSIONS AND RELEVANCE: **When the FDA finds significant departures from good clinical practice, those findings are seldom reflected in the peer-reviewed literature, even when there is evidence of data fabrication or other forms of research misconduct.**

MEDICAL JOURNALS ARE AN EXTENSION OF THE MARKETING ARM OF PHARMACEUTICAL COMPANIES

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1140949/>

“Journals have devolved into information laundering operations for the pharmaceutical industry,” wrote Richard Horton, editor of the *Lancet*, in March 2004. In the same year, Marcia Angell, former editor of the *New England Journal of Medicine*, lambasted the industry for becoming “primarily a marketing machine” and co-opting “every institution that might stand in its way.”

...between two-thirds and three-quarters of the trials published in the major journals—*Annals of Internal Medicine*, *JAMA*, *Lancet*, and *New England Journal of Medicine*—are funded by the industry. For the *BMJ*, it’s only one-third—partly, perhaps, because the journal has less influence than the others in North America, which is responsible for half of all the revenue of drug companies, and partly because the journal publishes more cluster-randomized trials (which are usually not drug trials).

Why are pharmaceutical companies getting the results they want? Why are the peer-review systems of journals not noticing what seem to be biased results? The systematic review of 2003 looked at the technical quality of the studies funded by the industry and found that it was as good—and often better—than that of studies funded by others. This is not surprising as the companies have huge resourc-

es and are very familiar with conducting trials to the highest standards.

The companies seem to get the results they want not by fiddling the results, which would be far too crude and possibly detectable by peer review, but rather by asking the “right” questions...and there are many hired guns who will think up new ways and stay one jump ahead of peer reviewers.

EXAMPLES OF METHODS FOR PHARMACEUTICAL COMPANIES TO GET THE RESULTS THEY WANT FROM CLINICAL TRIALS

- Conduct a trial of your drug against a treatment known to be inferior.
- Trial your drugs against too low a dose of a competitor drug.
- Conduct a trial of your drug against too high a dose of a competitor drug (making your drug seem less toxic).
- Conduct trials that are too small to show differences from competitor drugs.
- Use multiple endpoints in the trial and select for publication those that give favorable results.
- Do multicenter trials and select for pub-

lication results from centers that are favorable.

- Conduct subgroup analyses and select for publication those that are favorable.
- Present results that are most likely to impress—for example, reduction in relative rather than absolute risk.

INDUSTRY FUNDS SIX TIMES MORE CLINICAL TRIALS THAN FEDS, RESEARCH SHOWS

The Baltimore Sun December 15, 2015

<https://www.baltimoresun.com/health/bs-hs-trial-funding-20151214-story.html>

The drug and device industry now funds six times more clinical trials than the federal government, according to Johns Hopkins University researchers.

That means companies with financial interests in the studies now have more control over what doctors and patients learn about new treatments....

In the Johns Hopkins study, published Tuesday in the *Journal of the American Medical Association*, Ehrhardt found that the number of clinical trials funded by companies increased 43 percent from 2006 to 2014, while the number of NIH-funded trials decreased 24 percent over the same period.

By 2014, 6,550 clinical trials were funded by industry and 1,048 by the NIH.

BEHIND THE (VAX)\$CENES

CENTERS FOR DISEASE CONTROL AND PREVENTION: PROTECTING THE PRIVATE GOOD?

BMJ May 2015

www.semanticscholar.org/paper/Centers-for-Disease-Control-and-Prevention%3A-the-Lenzer/4cd3b113b4097e84a8536b7fd1a4ed4416297e41

The CDC includes the following disclaimer with its recommendations: “CDC, our planners, and our content experts wish to disclose they have no financial interests or other relationships with the manufacturers of commercial products... CDC does not accept commercial support.”

The CDC’s image as an independent watchdog over the public health has given it enormous prestige, and its recommendations are occasionally enforced by law.

Despite the agency’s disclaimer, **the CDC does receive millions of dollars in industry gifts and funding, both directly and indirectly**, and several recent CDC actions and recommendations have raised questions about the science it cites, the clinical guidelines it promotes, and the money it is taking....

Funding of CDC took a turn in 1983, when the CDC was authorized to accept external “gifts” from industry and other private parties. **In 1992, Congress passed legislation to encourage relationships between industry and the CDC** by creating the non-profit CDC Foundation, which began operations in 1995....

[Neil] Calman (president and chief executive of the Institute for Family Health in New York) told the *BMJ*, “Industry funding undermines trust and in-

troduces a bias in the presentation of results and treatment recommendations that is deplorable for a government agency. ***If the allegations of industry funding and influence are true, we will have to look very carefully at recommendations we are following now and those made in the future by the CDC.***” Calman said, “Industry claims their scientific methodology ensures their studies are unbiased—just as the CDC claims money doesn’t affect their recommendations. Yet multiple studies clearly—and repeatedly—show that who sponsors a study, or issues a guideline, makes a difference.”

CDC FOUNDATION, OUR PARTNERS

Partial list of corporate and organization partners that includes leading vaccine manufacturers (many hospitals have vaccine centers, as indicated):

AstraZeneca PLC, Aventis Pasteur, GlaxoSmithKline Biologicals S.A., Merck, Novartis, Pfizer Inc, Sanofi Pasteur, Inc, Wyeth Pharmaceuticals (all vaccine manufacturers), Pharmaceutical Research and Manufacturers of America (lobbying group for the pharma industry); NYU School of Medicine (Vaccine Center), Emory University School of Medicine (Vaccine Center), John Hopkins Bloomberg School of Public Health (Vaccine Initiative), Stanford University (LPCH Vaccine Program), Duke University School of Medicine (Vaccine Institute), Vanderbilt University Medical Center (Vaccine Center); Bill & Melinda Gates Foundation; Sabin Vaccine Initiative

<https://www.cdcfoundation.org/partner-list/corporations>

<https://www.cdcfoundation.org/partner-list/organizations>

VACCINES THEN AND NOW

CHILDHOOD VACCINE SCHEDULE

1962 (5 DOSES)	1983 (24 DOSES)	2019 (72 DOSES)		
Polio	DTP (2 months)	Flu (pregnancy)	Polio (6 months)	Flu (6 years)
Smallpox	Polio (2 months)	Tdap (pregnancy)	Flu (6 months)	Flu (7 years)
DTP	DTP (4 months)	Hep B (birth)	Flu (7 months)	Flu (8 years)
	Polio (4 months)	Hep B (2 months)	HIB (12 months)	Flu (9 years)
	DTP (6 months)	Rotavirus (2 months)	PCV (12 months)	HPV (9 years)
	MMR (15 months)	DTaP (2 months)	MMR (12 months)	Flu (10 years)
	DTP (18 months)	HIB (2 months)	Varicella (12 months)	HPV (10 years)
	Polio (18 months)	PCV (2 months)	Hep A (12 months)	Flu (11 years)
	DTP (4 years)	Polio (2 months)	DTaP (18 months)	HPV (11 years)
	Polio (4 years)	Rotavirus (4 months)	Flu (18 months)	Tdap (12 years)
	Td (15 years)	DTaP (4 months)	Hep A (18 months)	Meningococcal (12 years)
		HIB (4 months)	Flu (30 months)	Flu (13 years)
		PCV (4 months)	Flu (42 months)	Flu (14 years)
		Polio (4 months)	DTaP (4 years)	Flu (15 years)
		Hep B (6 months)	Polio (4 years)	Flu (16 years)
		Rotavirus (6 months)	MMR (4 years)	Meningococcal (16 years)
		DTaP (6 months)	Varicella (4 years)	Flu (17 years)
		HIB (6 months)	Flu (5 years)	Flu (18 years)
		PCV (6 months)		

More vaccines (including for STDs gonorrhea, chlamydia, and HIV) are being developed. (Note increase of vaccines after the 1986 National Childhood Vaccine Injury Act was enacted.)

DO MORE VACCINES = BETTER HEALTH?

AMERICAN BABIES ARE LESS LIKELY TO SURVIVE THEIR FIRST YEAR THAN BABIES IN OTHER RICH COUNTRIES

Time January 2018

<https://time.com/5090112/infant-mortality-rate-usa/>

Babies born in America are less likely to reach their first birthday than babies born

in other wealthy countries....While infant mortality rates have declined across the OECD since 1960, including in America, the U.S. has failed to keep pace with its high-income peers....

Compared to 19 similar OECD countries, **U.S. babies were three times more likely to die from extreme immaturity and 2.3 times more likely to experience sudden infant death syndrome between 2001 and 2010.**

AMERICAN KIDS ARE 70 PERCENT MORE LIKELY TO DIE BEFORE ADULTHOOD THAN KIDS IN OTHER RICH COUNTRIES

January 2018

<https://www.vox.com/health-care/2018/1/8/16863656/childhood-mortality-united-states>

A new study ranks 20 wealthy countries on childhood deaths. **The US comes in last. A child born in the United States has a 70 percent greater chance of dying before adulthood than kids born into other wealthy, democratic countries....**the United States lags far behind peer countries on child health outcomes.

THE INSTITUTE OF MEDICINE (IOM) SPEAKS

INSTITUTE OF MEDICINE 2013 COMMITTEE REPORT

(commissioned by the National Vaccine Program Office of the U.S. Department of Health and Human Services)

<https://www.ncbi.nlm.nih.gov/books/NBK206938/>

First, the concept of the immunization “schedule” is not well developed....key elements of the entire schedule—the number, frequency, timing, order, and age at administration of vaccines—have not been systematically examined in research studies.

The second major issue that the committee encountered was **uncertainty over whether the scientific literature has addressed all health outcomes and safety concerns.** The committee

could not tell whether its list was complete or whether a more comprehensive system of surveillance might have been able to identify other outcomes of potential significance to vaccine safety. In addition, the conditions of concern to some stakeholders, such as immunologic, neurologic, and developmental problems, are illnesses and conditions for which etiologies, in general, are not well understood.

Finally, the committee found that **evidence assessing outcomes in subpopulations of children who may be potentially susceptible to adverse reactions to vaccines (such as children with a family history of autoimmune disease or allergies or children born prematurely) was limited** and is characterized by uncertainty about the definition of populations of interest and definitions of exposures and outcomes.

AND THE LAST WORD GOES TO THE WORLD HEALTH ORGANIZATION...

W.H.O. GLOBAL VACCINE SAFETY SUMMIT, DEC. 2-3, 2019, GENEVA, SWITZERLAND

(Attended by leading world leaders on vaccine science and safety)

Excerpts:

DR. SOUMYA SWAMINATHAN, CHIEF SCIENTIST, W.H.O. PEDIATRICIAN

“I think we cannot overemphasize the fact that we really don’t have very good safety monitoring systems in many countries.”

PROFESSOR HEIDI LARSON, PHD, DIRECTOR, VACCINE CONFIDENCE PROJECT

“We have a very wobbly health professional frontline that is starting to question vaccine and the safety of vaccines....In medical school, you are lucky if you have a half day on vaccines.... We have a lot of ambiguity in the safety field.... There’s a lot of safety science that’s needed.... You can’t repurpose the same old science to make it sound better if you don’t have the science that’s relevant to the new problem. We need much more investment in safety science.”

DR. DAVID KASLOW, PHD, PATH

“One of the things we really need to invest in are better biomarkers, better mechanistic understanding of how these things work so we can better understand adverse events as they come up.”

DR. BASSEY OKPOSEN, A DOCTOR FROM NIGERIA

asked if there is a possibility of different vaccine antigens, preservatives, adjuvants, etc., from different vaccine companies cross-reacting with each other and causing problems for children getting multiple vaccines at one time, and whether safety studies have been done on these possible cross-reactions.

(PARTIAL) RESPONSE FROM DR. ROBERT CHEN, SCIENTIFIC DIRECTOR, BRIGHTON COLLABORATION

“...We’re really only in the beginning of the era of large data sets, where hopefully you can start to harmonize the data bases from multiple studies and there’s actually an initiative underway to try to get more national vaccine safety data bases linked together so we can start to answer these types of questions that you just raised....”

DR. MARTIN HOWELL FRIEDE, PHD, COORDINATOR, INITIATIVE FOR VACCINE RESEARCH, W.H.O.

“When we add an adjuvant, it’s because it is essential. We do not add adjuvants to vaccines because we want to do so. But when we add

them, it adds to the complexity. I give courses every year on how do you develop vaccines, how do you make vaccines, and the first lesson is, while you are making your vaccine, if you can avoid using an adjuvant, please do so. Lesson two is, if you are going to use an adjuvant, use one that has a history of safety, and lesson three is, if you're not going to do that, think very carefully."

DR. DAVID KASLOW, PHD, PATH

"Coming down the pike, maybe relatively quickly, is a new target population for us in vaccines...women who are pregnant.... Part of the problem is that we don't have a strong enough pharmacoepidemiologic baseline in the targeted populations that we are studying to be able to say, is this an expected adverse event due to pregnancy or is this related to the vaccines?"

STEPHEN EVANS, PROFESSOR OF PHARMACOEPIDEMIOLOGY, LONDON SCHOOL OF HYGIENE AND TROPICAL MEDICINE

"It seems to me they [adjuvants] multiply the reactogenicity in many instances and therefore

it seems to be that it is not unexpected if they multiply the incidence of adverse reactions that are associated with the antigen but may not have been detected through lack of statistical power in the original studies. Now I wonder if this thinking is correct, and if it is, if it has some implications for how we do pharmacovigilance."

(PARTIAL) RESPONSE FROM DR. MARTIN HOWELL FRIEDE

"As we add adjuvants, especially some of the more recent ones...we do see increased local reactogenicity. The primary concern though usually is systemic adverse events rather than local adverse events, and we tend to get in the phase two and the phase three studies quite good data on local reactogenicity...but this is not the major health concern. The major health concern which we are seeing are accusations of long-term effects."

<https://www.youtube.com/watch?v=msFgWPhQmdU>

**DO NOT CALL IT SCIENCE IF YOU AREN'T ALLOWED
TO QUESTION IT.
CALL IT A BELIEF SYSTEM.
CALL IT A RELIGION.
CALL IT A CULT.
BUT STOP CALLING IT SCIENCE.**

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MYCHILDMYCHOICEMEDFREE@GMAIL.COM***

PLEASE FEEL FREE TO PRINT AND DISTRIBUTE.

FOR MORE INFORMATION YOU MAY HAVE MISSED ON THE TOPICS DISCUSSED AND OTHER VACCINE ISSUES:

BOOKS

The Vaccine-Friendly Plan (Dr. Paul Thomas)

Vaccines – A Reappraisal (Dr. Richard Moskowitz)

Dissolving Illusions – Disease, Vaccines, and the Forgotten History
(Dr. Suzanne Humphries and Roman Bystriany)

WEBSITES

www.nvic.org

www.ahrp.org

www.vactruth.com

www.vaxxed.com

www.vaxxed2.com

www.learntherisk.org

www.icandecide.org

<https://thehighwire.com/> (WATCH)

www.childrenshealthdefense.org

<https://immunityeducationgroup.org/>

www.gardasil-and-unexplained-deaths.com

www.vaccineprospectus.com/short-introduction

DOCUMENTARIES (videos online)

Trace Amounts: Ethyl Mercury | Educational Documentary

Silent Epidemic: The Untold Story of Vaccines 2013 Documentary

Vaxxed



**If this car seat was
made by a company
who couldn't be sued
for defect
would you still
trust it?**

**Vaccine manufacturers
have been immune to
such lawsuits
since 1986.**