

AN INTRODUCTION TO VACCINE SAFETY

Deciding to inject a product into your or your child's body is an important decision. This brief introduction to vaccine safety, cited to official government sources, will help you make an informed decision.



PHARMA HAS NO INCENTIVE TO ASSURE VACCINE SAFETY

Immunity from Liability for Vaccine Harms. By the early 1980s, pharmaceutical companies faced crippling liability for injuries to children caused by their vaccines.¹ Instead of letting these market forces drive them to develop safer vaccines, Congress passed the National Childhood Vaccine Injury Act (the **1986 Act**) which eliminated their liability for injuries caused by their vaccine products.²

Pharmaceutical Company Misconduct. Since 1986, Merck, GSK, Sanofi, and Pfizer have paid billions of dollars for misconduct and injuries related to their drug products.³ These same companies sell almost all childhood vaccines but, because of the 1986 Act, cannot similarly be held accountable for misconduct and injuries from their vaccine products.

HHS CONFLICTED FROM ASSURING VACCINE SAFETY

HHS Defends Against Vaccine Injury Claims. After eliminating pharma liability, the 1986 Act established the Vaccine Injury Compensation Program (**Vaccine Court**) to compensate people injured by vaccines.⁴ The U.S. Dep't of Health & Human Services (**HHS**) is the defendant in Vaccine Court, is represented by the Dep't of Justice, and vigorously defends against any vaccine injury claim.⁵ The injured must almost always prove the vaccine caused the injury.⁶ Despite these hurdles, since 1986, HHS has paid over \$5 billion for vaccine injuries.⁷

HHS Self-Incriminate if it Admits Harm. CDC and FDA are agencies within HHS. If they publish any study suggesting that a vaccine causes a harm, that study will be used against them in Vaccine Court.⁸ This greatly limits their incentive to publish adequate safety studies.

CDC Vaccine Schedule Created by Pharma Insiders. Congress has repeatedly found that the members of FDA and CDC committees responsible for approving most of the currently licensed and recommended vaccines had serious conflicts of interest with pharma companies.⁹

PRE-LICENSURE VACCINE SAFETY

Pediatric Vaccine Trials (i) Lack Placebos and (ii) Are Too Short. The clinical trials FDA relies on to license childhood vaccines do not include a placebo-control group, and safety review after injection is typically only days or weeks.¹⁰ The safety profile for a pediatric vaccine is simply not known before it is licensed and routinely used in children.¹¹ For example, safety was only monitored for five days after injection in the clinical trial for the Hep B vaccine given to newborns.

POST-LICENSURE VACCINE SAFETY

Package Inserts. After licensure and use by the public, federal law requires that the package insert for each vaccine include "only those adverse events for which there is some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event."¹² Inserts for childhood vaccines include over one hundred serious immune, neurological, and other chronic conditions that their manufacturers had a basis to believe are caused by their vaccines.¹³

Prevalence of Harm. CDC's Vaccine Adverse Events Reporting System (**VAERS**), to which doctors and patients may voluntarily report adverse vaccine events, received 61,232 reports in 2019, including 559 deaths, 1,436 permanent disabilities, and 4,660 hospitalizations.¹⁴ A gov't funded 3-year review by Harvard Medical School of 715,000 patients stated that "fewer than 1% of vaccine adverse events are reported" to VAERS.¹⁵ This could mean there are a hundredfold more adverse vaccine events than are reported to VAERS. CDC has nonetheless refused to mandate or automate VAERS reporting.¹⁶

CONTINUED ON NEXT PAGE...

POST-LICENSURE VACCINE SAFETY (CONTINUED)

Refusal to Publish Vac vs. Unvac Studies. A true epidemic in the U.S. is that 1 in 2 children now have an autoimmune, developmental, neurological, or chronic disorder.¹⁷ These conditions have sharply risen in lock-step with the growth of CDC's vaccine schedule.¹⁸ That schedule has risen from 7 injections of just 2 vaccines in 1986 to the current total of 50 injections of 12 different vaccines.¹⁹ The need to compare health outcomes of vaccinated and unvaccinated children is urgent. In 2017, a seminal study found that babies receiving the DTP vaccine died at 10 times the rate of unvaccinated babies.²⁰ A recent pilot study from the School of Public Health at Jackson State University found that vaccinated children had an increased risk of 290% for eczema, 390% for allergies, 420% for ADHD, 420% for autism, and 520% for learning disabilities.²¹ Yet, CDC refuses to publish any studies comparing health outcomes between vaccinated and unvaccinated children.²²

Autism. Autism is the most controversial of the claimed vaccine injuries and the one CDC declares to have thoroughly studied. Most parents with autistic children claim vaccines – including DTaP, Hep B, Hib, PCV13, and IPV, each injected 3 times by 6 months – are a cause of their child's autism.²³ CDC responds with "Vaccines Do Not Cause Autism."²⁴ ICAN had to sue CDC for the studies it claims supports that these vaccines do not cause autism.²⁵ CDC then identified 20 studies, 18 of which studied a different vaccine (MMR²⁶) or an ingredient not in these vaccines (thimerosal), and one irrelevant study regarding antigens.²⁷ Incredibly, the final study CDC identified was a review of DTaP/autism that found no studies supporting that DTaP doesn't cause autism (and one study that supported it does!).²⁸ Worse, HHS's own autism expert recently testified vaccines can cause autism in some children.²⁹ **Given the lack of studies regarding vaccines and autism, it is unsurprising that few or no studies support CDC's other vaccine safety claims.**

Susceptible Children. While the Institute of Medicine (IOM) has explained that "most individuals who experience an adverse reaction to vaccines have a preexisting susceptibility," HHS and CDC have failed to conduct studies to identify children susceptible to vaccine harms while at the same time recommending vaccines for all children.³⁰

Carcinogenicity, Mutagenicity, & Infertility. Most vaccines have never been evaluated for their potential to cause cancer, mutate genes, or cause infertility.³¹

Failure to Perform Basic Safety Requirements. After eliminating the market forces that assured vaccine safety, Congress made HHS directly responsible for vaccine safety pursuant to a section of the 1986 Act entitled the "Mandate for safer childhood vaccines."³² As seen above and as HHS recently conceded in federal court, it has not performed even the basic requirements of this section, such as submitting reports to Congress on how HHS has improved vaccine safety.³³

UNINTENDED CONSEQUENCES

Eliminating Measles & Mumps Has Increased Heart Disease. The mortality rate from measles declined by over 98% between 1900 and 1962 as living conditions improved in this country.³⁴ In 1962, a year before the first measles vaccine, CDC reported a total of 408 measles deaths.³⁵ That amounts to 1 in 500,000 Americans at a time measles infected nearly every American.³⁶ However, having measles and mumps reduces the risk of dying from heart disease. A 22-year prospective study of over 100,000 individuals in Japan revealed that "measles and mumps, especially in case of both infections, were associated with lower risks of mortality from atherosclerotic CVD [heart disease]."³⁷ Heart disease kills around 700,000 Americans a year.³⁸ Eliminating our ecological relationship with measles, mumps, and rubella has had serious unintended consequences.³⁹

Failure to Prevent Transmission. Many vaccines, like COVID-19 vaccines, fail to prevent transmission. For example, it is now accepted that those vaccinated with DTaP remain susceptible to become infected with pertussis, potentially every month, but will not display symptoms and hence can silently transmit pertussis to others.⁴⁰ In contrast, those unvaccinated to pertussis may have pertussis once, have symptoms and hence know to stay home, and then cannot be infected again for many years.⁴¹ Other vaccines, including the current polio vaccine similarly do not prevent transmission.⁴²

Other issues. There are many other vaccine safety issues not addressed due to space constraints. For example, aluminum adjuvant particles in vaccines (which animal studies reveal deposit in brain and bones), or the millions of snippets of human DNA cultured from the cell lines of aborted fetuses found in certain vaccines and the potential adverse implications of these things.⁴³

ADDITIONAL INFORMATION

The right to be informed about the risks before consenting to a vaccine is essential. Prior to any medical procedure, HHS explains the "voluntary consent of the human subject is absolutely essential."⁴⁴ Coercion invalidates consent. Mandating any medical product, let alone a liability-free product, violates our basic individual and civil rights and is unethical and immoral.

For more information, visit www.icandecide.org. To read ICAN's exchange with HHS/CDC/FDA regarding vaccine safety, visit <https://icandecide.org/article/vaccine-safety-debate/> and to watch our weekly news show, visit www.thehighwire.com.

ALL SOURCES ON NEXT PAGE

FOOTNOTES

- 1 <https://www.nap.edu/read/2138/chapter/2#2> (“The litigation costs associated with claims of damage from vaccines had forced several companies [by 1986] to end their vaccine ... programs as well as to stop producing already licensed vaccines.”).
- 2 [42 U.S.C. § 300aa-11](#) (“No person may bring a civil action for damages in the amount greater than \$1,000 or in an unspecified amount against a vaccine administrator or manufacturer in a State or Federal court for damages arising from a vaccine-related injury or death.”); [Bruesewitz v. Wyeth LLC, 562 U.S. 223, 243 \(2011\)](#) (“the National Childhood Vaccine Injury Act preempts all design-defect claims against vaccine manufacturers brought by plaintiffs who seek compensation for injury or death caused by vaccine side effects”).
- 3 <https://www.citizen.org/sites/default/files/2408.pdf>.
- 4 [42 U.S.C. § 300aa-12](#) (“In all proceedings brought by the filing of a petition [in Vaccine Court] the Secretary [of HHS] shall be named as the respondent.”); <https://www.congress.gov/106/crpt/hrpt977/CRPT-106hrpt977.pdf> (HHS amended the Vaccine Court rules to make it extremely difficult to obtain compensation and “DOJ attorneys make full use of the apparently limitless resources available to them,” “pursued aggressive defenses in compensation cases,” “establish[ed] a cadre of attorneys specializing in vaccine injury” and “an expert witness program to challenge claims.”).
- 5 *Ibid.*
- 6 The 1986 Act created a Vaccine Injury Table (the Table) which was intended to permit the Vaccine Court to quickly compensate certain common vaccine injuries. [42 U.S.C. § 300aa-12](#). For Table injuries, the burden shifts to HHS to prove the vaccine is not the cause. [42 U.S.C. § 300aa-13](#). After passage of the 1986 Act, almost 90% of claims were Table claims and quickly settled. [Stevens v. Secretary of HHS, No. 99-594V \(Office of Special Masters 2001\)](#). However, in the 1990s, HHS amended the Table such that now 98% of new claims are off-Table. <http://www.gao.gov/assets/670/667136.pdf>. As a result, injured children “must prove that the vaccine was the cause” in almost all cases. <https://www.ncbi.nlm.nih.gov/nlmcatalog/101633437>.
- 7 <https://www.justice.gov/jmd/page/file/1489621/download>.
- 8 See footnotes 4 and 7; <https://uscfc.uscourts.gov/vaccine-programoffice-special-masters>.
- 9 <https://icandecide.org/congress-report>.
- 10 <https://icandecide.org/hhs/ICAN-Reply.pdf> (see Section I)
- 11 *Ibid.*
- 12 <https://icandecide.org/hhs/ICAN-Reply.pdf> (see Appendix B)
- 13 *Ibid.*
- 14 <https://wonder.cdc.gov/vaers.html>.
- 15 <https://digital.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf>.
- 16 <https://icandecide.org/hhs/ICAN-Reply.pdf> (see Section III)
- 17 <https://www.ncbi.nlm.nih.gov/pubmed/21570014>.
- 18 <https://www.ncbi.nlm.nih.gov/pubmed/20159870>.
- 19 <https://www.cdc.gov/vaccines/schedules/images/schedule1983s.jpg>; <https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html>.
- 20 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5360569/>.
- 21 <https://www.oatext.com/pdf/JTS-3-186.pdf>.
- 22 <https://icandecide.org/hhs/ICAN-Reply.pdf> (see Section VII)
- 23 <https://www.ncbi.nlm.nih.gov/pubmed/16685182>; <https://www.ncbi.nlm.nih.gov/pubmed/25398603>; <https://www.ncbi.nlm.nih.gov/pubmed/16547798>; <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1448378/>.
- 24 <https://www.cdc.gov/vaccinesafety/concerns/autism.html>.
- 25 <https://icandecide.org/autism-complaint>.
- 26 A Senior CDC Scientist claims CDC did find an increased rate of autism in the only MMR/autism study ever conducted by CDC with American children. <https://www.c-span.org/video/?c4546421/user-clip-rep-bill-posey-calling-investigation-cdcs-mmr-reasearch-fraud>.
- 27 <https://icandecide.org/autism-court-order>.
- 28 <https://nap.nationalacademies.org/read/13164/chapter/12?term=autism#545>.
- 29 <http://icandecide.org/documents/zimmerman.pdf>.
- 30 <https://icandecide.org/hhs/ICAN-Reply.pdf> (see Section V)
- 31 <https://www.fda.gov/biologicsbloodvaccines/vaccines/approvedproducts/ucm093833.htm>.
- 32 [42 U.S.C. § 300aa-27](#).
- 33 https://icandecide.org/wp-content/uploads/2023/05/2023-01-04-IR0012_Final-Response-No-Records_HHS.pdf; <https://icandecide.org/wp-content/uploads/2023/05/Meetings-held-by-the-Task-Force-for-Safer-Childhood-Vaccines.pdf>.
- 34 https://www.cdc.gov/nchs/data/vsus/vsrates1940_60.pdf; https://www.cdc.gov/nchs/data/vsus/Vsus_1962_2A.pdf.
- 35 https://www.cdc.gov/nchs/data/vsus/Vsus_1962_2A.pdf.
- 36 *Ibid.*; <https://www.census.gov/library/publications/1962/compendia/statab/83ed.html>.
- 37 <https://www.ncbi.nlm.nih.gov/pubmed/26122188>.
- 38 <https://www.cdc.gov/heartdisease/facts.htm>.
- 39 Moreover, eliminating measles appears to have increased certain cancers. For example, a 66% increase in Non-Hodgkin Lymphoma and 233% increase in Hodgkin Lymphoma, which killed 21,170 Americans in 2022. <https://pubmed.ncbi.nlm.nih.gov/16406019/> (See Table 2. In the NHL column divide 1 (never had measles) with .6 (had measles) resulting in 66% increased risk, and in HL column divide 1 (never had measles) with .3 (had measles) resulting in 233% increased risk.); <https://seer.cancer.gov/statfacts/>. Studies even found remission of Hodgkins after measles. <https://pubmed.ncbi.nlm.nih.gov/4574047/>. Another study found 50% increase in ovarian cancer if never had measles, which killed 12,810 Americans in 2022. *Ibid.*; <https://pubmed.ncbi.nlm.nih.gov/16490323/>. Other studies similarly found “a lower cancer risk for patients with a history of FICD [febrile infectious childhood diseases]” <https://pubmed.ncbi.nlm.nih.gov/9824838/> as well as less allergies and atopic diseases, and a reduced risk of Parkinson’s Disease. <https://pubmed.ncbi.nlm.nih.gov/19255001/>; <https://pubmed.ncbi.nlm.nih.gov/16854347/> and <https://pubmed.ncbi.nlm.nih.gov/4061437/>.
- 40 <https://pubmed.ncbi.nlm.nih.gov/31333640/> (“aPV pertussis vaccines do not prevent colonization. Consequently, they do not reduce the circulation of B. pertussis and do not exert any herd immunity effect.”); <https://www.ncbi.nlm.nih.gov/pubmed/24277828>; <https://www.ncbi.nlm.nih.gov/pubmed/30793754>; <https://www.ncbi.nlm.nih.gov/pubmed/29180031>.
- 41 *Ibid.*
- 42 <https://www.cdc.gov/vaccines/pubs/pinkbook/tetanus.html> (“Tetanus is not contagious from person to person.”); <https://polioeradication.org/polio-today/polio-prevention/the-vaccines/ipv/> (“IPV [inactivated polio vaccine] induces very low levels of immunity in the intestine. As a result, when a person immunized with IPV is infected with wild poliovirus, the virus can still multiply inside the intestines and be shed in the feces ... IPV does not stop transmission of the virus.”); <https://www.cdc.gov/vaccines/vpd/mening/public/index.html> (“data suggest MenACWY vaccines have provided protection to those vaccinated, but probably not to the larger, unvaccinated community (population or herd immunity)”).
- 43 <http://vaccinepapers.org/wp-content/uploads/Autism-brochure-Color-8.5x11.pdf>; <https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/b/excipient-table-2.pdf>; <https://www.ncbi.nlm.nih.gov/pubmed/5949788>; <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC274969/>; <https://pubmed.ncbi.nlm.nih.gov/29108182/>; <https://thehighwire.com/videos/aborted-fetal-tissue-in-vaccines/>.
- 44 <https://ori.hhs.gov/chapter-3-The-Protection-of-Human-Subjects-nuremberg-code-directives-human-experimentation>.