

THE DANGER OF ELIMINATING VACCINE EXEMPTIONS & CURTAILING VACCINE CRITICISM

Prior to any medical procedure, the U.S. Department of Health & Human Service (“HHS”) explains that the “voluntary consent of the human subject is absolutely essential.”¹ **Coercion invalidates informed consent.**² Infringing this right by eliminating vaccine exemptions and curtailing criticism is unethical and un-American given the following facts:

PHARMA HAS NO INCENTIVE TO ASSURE VACCINE SAFETY

1. Immunity from Liability for Vaccine Harms. By the early 1980s, pharmaceutical companies were facing crippling liability for injuries to children caused by their vaccines.³ 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 pharmaceutical company liability for injuries caused by their vaccine products.⁴

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.⁵ These same companies manufacture almost all childhood vaccines, but because of the 1986 Act, cannot similarly be held accountable for misconduct and injuries related to their vaccine products.

HHS CONFLICTED FROM ASSURING VACCINE SAFETY

3. HHS Must Defend Against Any Claim of Vaccine Injury. After eliminating liability for pharmaceutical companies, the 1986 Act established the Vaccine Injury Compensation Program (“**Vaccine Court**”), part of the U.S. Court of Federal Claims, to compensate

people injured by vaccines.⁶ Under the 1986 Act, HHS is the defendant in Vaccine Court and is legally obligated to defend against any claim that a vaccine causes injury.⁷ There is no right to discovery in Vaccine Court and HHS is represented by the formidable resources of the U.S. Department of Justice (“**DOJ**”).⁸ In nearly every case the injured person bears the burden to prove causation.⁹ Despite these hurdles, since 1986, HHS has paid over \$4 billion for vaccine injuries.¹⁰

4. HHS Incriminates Itself if it Publishes or Admits a Vaccine Can Cause a Harm. If HHS publishes any study supporting that a vaccine causes a harm, that study will then be used against HHS in Vaccine Court.¹¹ This greatly limits HHS’s incentive to publish safety studies.

5. CDC’s Childhood Vaccine Schedule Was Created by Pharma Insiders. Congress has repeatedly found that the members of the FDA and CDC committees responsible for approving most of the currently licensed and recommended childhood vaccines had serious conflicts of interests with pharmaceutical companies.¹²

VACCINE SAFETY: CONCERNS & LIMITATIONS

6. HHS Fails to Perform Basic Vaccine 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.”¹³ As HHS recently

¹ <https://ori.hhs.gov/chapter-3-The-Protection-of-Human-Subjects-nuremberg-code-directives-human-experimentation>

² <https://www.utcomchatt.org/docs/biomedethics.pdf>

³ <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.”)

⁴ 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.”); *Brusewitz 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”)

⁵ <https://www.citizen.org/sites/default/files/2408.pdf>

⁶ 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.”)

⁷ *Ibid.*

⁸ *Ibid.*

⁹ 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>

¹⁰ <https://www.hrsa.gov/sites/default/files/hrsa/vaccine-compensation/data/monthly-stats-february-2019.pdf>

¹¹ *See fn. 6 and 9.*

¹² <http://vaccinesafetycommission.org/pdfs/Conflicts-Govt-Reform.pdf>

¹³ 42 U.S.C. § 300aa-27

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.¹⁴

7. Pediatric Vaccine Clinical Trials (i) Lack Placebos and (ii) Are Too Short. The pivotal clinical trials relied upon to license childhood vaccines do not include a placebo-control group and safety review periods in these clinical trials are typically only days or months.¹⁵ The safety profile for a pediatric vaccine is therefore not known before it is licensed and routinely used in children.¹⁶

8. Post-Licensure Safety. 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.”¹⁷ 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.¹⁸

9. Prevalence of Vaccine Harm. The CDC’s Vaccine Adverse Events Reporting System (“**VAERS**”), to which doctors and patients may *voluntarily* report adverse vaccine events, received 58,381 reports in 2018, including 412 deaths, 1,237 permanent disabilities, and 4,217 hospitalizations.¹⁹ An HHS-funded three-year review by Harvard Medical School of 715,000 patients stated that “fewer than 1% of vaccine adverse events are reported” to VAERS.²⁰ This could mean there are a hundredfold more adverse vaccine events than are reported to VAERS. The CDC has nonetheless refused to mandate or automate VAERS reporting.²¹

10. Children Susceptible to Vaccine Injury. 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.²²

11. Carcinogenicity, Mutagenicity & Infertility. Most vaccines have never been evaluated for their potential to cause cancer, mutate genes or cause infertility.²³

12. Autism. Autism is the most controversial of the claimed vaccine injuries and the one HHS and CDC declare they 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.²⁴ The CDC tells these parents that “Vaccines Do Not Cause Autism.”²⁵ However, there is no science to support this claim for almost all vaccines. For example, reports from the IOM in 1991 and 2012, and HHS in 2014, tried but failed to identify any study to support that DTaP does not cause autism.²⁶ The same is true for Hep B, Hib, PCV 13, and IPV.²⁷ The only vaccine actually studied with regard to autism is MMR, and a Senior CDC Scientist claims the CDC did find an increased rate of autism after MMR in the only MMR/autism study ever conducted by the CDC with American children.²⁸ Moreover, HHS’s primary autism expert in Vaccine Court recently provided an affidavit explaining that vaccines can cause autism in some children.²⁹ Given the lack of studies regarding vaccines and autism, it should come as no surprise that there is a dearth of scientific studies that support the CDC’s other claims regarding vaccine safety.

13. HHS Refuses to Conduct Vaccinated Vs. Unvaccinated Studies of Vaccine Schedule. A true epidemic in the U.S. is the fact that 1 in 2 children have an autoimmune, developmental, neurological, or chronic disorder.³⁰ These conditions have sharply

¹⁴ <http://icandecide.org/government/ICAN-HHS-Stipulated-Order-July-2018.pdf>

¹⁵ <https://icandecide.org/hhs/ICAN-Reply.pdf> (see Section I)

¹⁶ *Ibid.*

¹⁷ <https://icandecide.org/hhs/ICAN-Reply.pdf> (see Appendix B)

¹⁸ *Ibid.*

¹⁹ <https://wonder.cdc.gov/vaers.html>

²⁰ <https://healthit.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf>

²¹ <https://icandecide.org/hhs/ICAN-Reply.pdf> (see Section III)

²² <https://icandecide.org/hhs/ICAN-Reply.pdf> (see Section V)

²³ <https://www.fda.gov/biologicsbloodvaccines/vaccines/approvedproducts/ucm093833.htm>

²⁴ <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/>

²⁵ <https://www.cdc.gov/vaccinesafety/concerns/autism.html>

²⁶ <https://www.nap.edu/read/1815/chapter/2#7>; <https://www.nap.edu/read/13164/chapter/12?term=autism#545>; https://www.ncbi.nlm.nih.gov/books/NBK230053/pdf/Bookshelf_NBK230053.pdf

²⁷ <https://icandecide.org/hhs/ICAN-Reply.pdf> (see Section VI)

²⁸ <http://www.rescuepost.com/files/william-thompson-statement-27-august-2014-3.pdf>; <https://soundcloud.com/fomotion/cdc-whistle-blower-full-audio>; <https://www.c-span.org/video/?c4546421/rep-bill-posey-calling-investigation-cdcs-mmr-reasearch-fraud>

²⁹ <http://icandecide.org/documents/zimmerman.pdf>

³⁰ <https://www.ncbi.nlm.nih.gov/pubmed/21570014>

risen in lock-step with the increases in the CDC's recommended vaccine schedule.³¹ That schedule has risen from 7 injections of just 2 vaccines in 1986 to the current total of 50 injections of 12 different vaccines.³² 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.³³ In another study, children received influenza vaccine or a saline placebo; while both groups had a similar rate of influenza, the vaccinated group had a 440% increased rate of non-influenza infections.³⁴ A recent pilot study from the School of Public Health at Jackson State University found that 33% of vaccinated preterm babies had a neurodevelopmental disorder compared to 0% of the unvaccinated preterm babies; and vaccinated children in this study had an increased risk of 290% for eczema, 390% for allergies, 420% for ADHD, 420% for autism, and 520% for learning disabilities.³⁵ Nonetheless, HHS and CDC refuse to publish any studies comparing the health outcomes between vaccinated and unvaccinated children.³⁶

MMR VACCINE

14. Measles is a Mild Childhood Illness. The mortality rate from measles declined by over 98% between 1900 and 1962 as living conditions improved in this country.³⁷ In 1962, a year before the first measles vaccine, the CDC reported a total of 408 deaths.³⁸ That amounts to 1 in 500,000 Americans at a time when measles infected nearly every American.³⁹

15. Eliminating Measles Has Increased Cancer Rates. Eliminating measles has increased cancer rates. For example, the International Agency for Research on Cancer found that individuals who never had measles had a 66% increased rate of Non-Hodgkin Lymphoma

and a 233% increased rate of Hodgkin Lymphoma.⁴⁰ Combined, these cancers killed 20,960 Americans in 2018.⁴¹ As another example, individuals who never had measles, mumps or rubella had a 50% increased rate of ovarian cancer.⁴² In 2018, ovarian cancer killed 14,070 Americans.⁴³ Eliminating measles in this country has caused more deaths from cancer.

16. Eliminating Measles Has Increased 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].”⁴⁴ Heart disease killed 610,000 Americans in 2018.⁴⁵ Eliminating our ecological relationship with measles, mumps and rubella has had serious unintended consequences.

17. Side effects from MMR vaccine. The MMR vaccine has serious risks. For example, the MMR vaccine causes seizures in about 1 in 640 children, five times the rate from measles, as well as “thrombocytopenic purpura,” “chronic arthritis,” and “brain damage.”⁴⁶ However, because the MMR was not licensed based on a placebo-controlled clinical trial and post-licensure studies are limited, there are many suspected harms the CDC has yet to confirm or rule out, such as those listed on Merck's package insert for the MMR.⁴⁷

18. Waning Immunity. While the vaccination rate for measles in the United States has been stable over the last 20 years, what has changed is that Americans who have had measles (which confers lifetime immunity) are being replaced by those vaccinated with MMR (which does not typically confer lifetime immunity).⁴⁸ MMR produces no immunity in 2% to 10% of vaccinees; and 22 years after two doses of MMR approximately 33% of vaccinees are again

³¹ <https://www.ncbi.nlm.nih.gov/pubmed/20159870>

³² <https://www.cdc.gov/vaccines/schedules/images/schedule1983s.jpg>; <https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf>

³³ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5360569/>

³⁴ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3404712/>

³⁵ <http://www.oatext.com/pdf/JTS-3-186.pdf>; <http://www.oatext.com/pdf/JTS-3-187.pdf>

³⁶ <https://icandecide.org/hhs/ICAN-Reply.pdf> (see Section VII)

³⁷ https://www.cdc.gov/nchs/data/vsus/vsrates1940_60.pdf;

https://www.cdc.gov/nchs/data/vsus/VUSUS_1962_2A.pdf

³⁸ https://www.cdc.gov/nchs/data/vsus/VUSUS_1962_2A.pdf

³⁹ *Ibid.*; <https://www.census.gov/library/publications/1962/compendia/statab/83ed.html>

⁴⁰ <https://www.ncbi.nlm.nih.gov/pubmed/16406019>

⁴¹ <https://seer.cancer.gov/statfacts/html/nhl.html>;

<https://seer.cancer.gov/statfacts/html/hodg.html>

⁴² <https://www.ncbi.nlm.nih.gov/pubmed/16490323>

⁴³ <https://seer.cancer.gov/statfacts/html/ovary.html>

⁴⁴ <https://www.ncbi.nlm.nih.gov/pubmed/26122188>

⁴⁵ <https://www.cdc.gov/heartdisease/facts.htm>

⁴⁶ <https://www.hrsa.gov/sites/default/files/vaccinecompensation/vaccineinjurytable.pdf>; <https://www.cdc.gov/vaccines/hcp/vis/vis-statements/mmr.pdf>; <https://physiciansforinformedconsent.org/measles/vrs/> (since the measles death from 1959 to 1962 was appx. 400 per 4 million cases <https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/e/reported-cases.pdf> and death to seizure ratio is appx. 3.25 <https://www.cdc.gov/vaccines/pubs/pinkbook/meas.html> this amounts to 1 seizure in 3,095 measles cases).

⁴⁷ <https://www.fda.gov/downloads/BiologicsBloodVaccines/UCM123789.pdf>

⁴⁸ <https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/G/coverage.pdf>

potentially susceptible to measles.⁴⁹ The proportion after 30 years is even higher.⁵⁰ Yet the only focus is on children whose parents have reason to believe the MMR may cause them harm, while ignoring the efficacy issues with this vaccine.

OTHER VACCINES

19. DTaP Vaccine. According to the FDA, those vaccinated with DTaP will have fewer symptoms of pertussis, but will become infected and transmit pertussis, and “will be more susceptible to pertussis throughout their lifetimes.”⁵¹ This means the children vaccinated for pertussis are more likely to catch and spread pertussis as asymptomatic carriers, while the unvaccinated are less likely to catch pertussis (and when they do will have symptoms and know to stay home).⁵² Since pertussis is very common and more of a concern than measles, as long as children vaccinated for pertussis are permitted to attend school, children not vaccinated for measles should also be permitted to attend school. In any event, the immunity provided by DTaP for pertussis, tetanus, and diphtheria wanes within a few years.⁵³

20. Inactivated Polio Vaccine. For the last 20 years, the only polio vaccine used in the U.S. is inactivated polio vaccine (“IPV”), which is injected intramuscularly, after it was determined that the oral polio vaccine can cause paralysis.⁵⁴ Polio is spread through fecal to oral contamination, and IPV does not prevent colonization and transmission of polio; it only potentially prevents polio from traveling to the spinal column.⁵⁵ Hence, those vaccinated or not vaccinated with IPV can equally become infected and transmit polio; but, it is the vaccinated who are considered less likely to have symptoms and thus more likely to spread polio.

21. Chicken Pox Vaccine. Children vaccinated for chicken pox can spread chicken pox virus for six weeks after vaccination.⁵⁶ Moreover, the immunity from this vaccine wanes and, absent natural boosting from exposure to chicken pox virus, can lead to shingles.⁵⁷ The increased risk of shingles from use of this vaccine is why countries, such as the United Kingdom, have not added it to their routine vaccine schedule.⁵⁸

22. Note. There are additional efficacy and safety issues with the above vaccines and other vaccines 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 in certain vaccines.⁵⁹

ADDITIONAL INFORMATION

The foregoing highlights a few of the vaccine safety and efficacy issues necessitating the need for informed consent for vaccination and the ability to openly criticize our vaccine policies.

At the least, the following should occur before censoring concerns regarding vaccine safety:

- Vaccine safety duties should be removed entirely from HHS and placed into an independent board;
- Pharmaceutical companies should be liable for injuries caused by their vaccine products; and
- The childhood vaccine schedule and each vaccine should be safety tested in a properly sized long-term placebo-controlled clinical trial.

For additional information or to arrange a presentation, please contact Cat Layton at cat@icandecide.org

⁴⁹ <https://www.ncbi.nlm.nih.gov/pubmed/17339511>

⁵⁰ Ibid.

⁵¹ <https://www.ncbi.nlm.nih.gov/pubmed/24277828>; <https://www.ncbi.nlm.nih.gov/pubmed/30793754>; <https://www.ncbi.nlm.nih.gov/pubmed/29180031> (“neither DTP, nor DTaP or Tdap prevent asymptomatic infection and silent transmission of the pathogen”)

⁵² Ibid.

⁵³ Ibid.

⁵⁴ <http://polioeradication.org/polio-today/polio-prevention/the-vaccines/ipv/>

⁵⁵ Ibid.

⁵⁶ <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM142813.pdf>

⁵⁷ <https://www.ncbi.nlm.nih.gov/pubmed/22659447>;

<https://www.ncbi.nlm.nih.gov/pubmed/24275643>

⁵⁸ <https://www.nhs.uk/common-health-questions/childrens-health/why-are-children-in-the-uk-not-vaccinated-against-chickenpox/>

⁵⁹ http://vaccinepapers.org/wp-content/uploads/vaccine_papers_brochure_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://www.ncbi.nlm.nih.gov/pubmed/29108182>