ICAN
Informed Consent Action Network

THE EVIDENCE & SCIENCE SUPPORT VACCINE EXEMPTIONS

INTRODUCTION: The basic facts and government data regarding vaccine efficacy, safety and trends do not support eliminating vaccine exemptions.

MEASLES: Children in third-world countries with poor nutrition (particularly vitamin A deficiency), sanitation and living conditions frequently die of various infections, including measles. This is not true in first world countries. Between 1900 and 1962, as living conditions improved in most parts of this country, the mortality rate from measles declined by over 98%.[1] In 1962, a year before the first measles vaccine, the Centers for Disease Control ("CDC") reports a total of 408 deaths from measles.[2] That amounts to 1 in 500,000 Americans at a time when measles infected nearly every American. Even without a measles vaccine, the decline in measles mortality leading up to 1962 would have likely continued along with continued improvements in living conditions and medical care.

Measles dates to the beginning of recorded human history and its elimination is a modern experiment. Studies reveal that those who have not had measles will have far higher rates of various cancers.[3] 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 333% increased rate of Hodgkin Lymphoma.[4] Combined, these cancers killed 20,960 Americans in 2018.[5] As another example, individuals who never had measles had a 100% increased rate of ovarian cancer.[6] In 2018, ovarian cancer killed 14,070 Americans.[7] Eliminating measles in this country has almost certainly caused far more deaths from cancer than would have occurred from measles.

Additionally, 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]."[8] Heart disease killed 610,000 Americans in 2018.[9]

Eliminating our ecological relationship with measles has had serious unintended consequences that upend the assumed risk/reward of eliminating measles.[10] Compounding this issue, the MMR vaccine (which introduces into the body manmade viruses, and the animal and human substrates upon which they are grown, by a route humans have never been infected by viruses – injection) has serious risks, many known and others suspected but not properly researched.[11]

For example, the MMR vaccine causes seizures in about 1 in 640 children[12], five times the rate from measles[13], as well as "thrombocytopenic purpura," "chronic arthritis," and "brain damage."[14] As discussed below, since virtually no vaccine has been licensed for children based on a placebo-controlled clinical trial and post-licensure studies are limited (and the few that compare vaccinated with unvaccinated children are alarming), there are many suspected harms from the MMR and other vaccines the CDC has yet to confirm.

NATIONAL CHILDHOOD VACCINE INJURY ACT OF 1986: Product liability attorneys provide a critical check in ensuring unsafe products are improved or eliminated from the market through civil lawsuits. By the early 1980s, pharmaceutical companies were facing crippling liability for injuries to children caused by their vaccines.[15] Instead of letting these market forces drive them to develop safer vaccines, Congress passed the National Childhood Vaccine Injury Act (the "1986 Act") that effectively eliminated pharmaceutical company liability for injuries caused by their vaccine products.[16] With a liability-free captive

[1] https://www.cdc.gov/nchs/data/vsus/vsrates1940_60.pdf (measles death rate per 100,000 people declined from 13.3 in 1900 to 0.2 in 1960)
[2] https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/e/reported-cases.pdf
[3] https://www.ncbi.nlm.nih.gov/pubmed/16490323
[4] https://www.ncbi.nlm.nih.gov/pubmed/16406019
[5] https://seer.cancer.gov/statfacts/html/nhl.html; https://seer.cancer.gov/statfacts/html/hodg.html
[6] https://www.ncbi.nlm.nih.gov/pubmed/16490323
[7] https://seer.cancer.gov/statfacts/html/ovary.html
[8] https://www.ncbi.nlm.nih.gov/pubmed/26122188
[9] https://www.cdc.gov/heartdisease/facts.htm
[10] https://www.ncbi.nlm.nih.gov/pubmed/4960501
[11] https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf
[12] https://www.ncbi.nlm.nih.gov/pubmed/15265850
[13] Since the measles death from 1959 to 1962 was appx. 400 per 4 million cases (see fn. 2) 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.
[14] https://www.hrsa.gov/sites/default/files/vaccinecompensation/vaccineinjurytable.pdf; https://www.cdc.gov/vaccines/hcp/vis/vis-statements/mmr.pdf
[15] 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.")
[16] 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

market of over 70 million children, since 1986 the childhood vaccine schedule has gone from 7 injections (DTP & MMR) to 50 injections (Hep B, DTaP, Hib, PCV13, IPV, IIV, MMR, VAR, Hep A, Men, Tdap & HPV), and the vaccine market from a few hundred million to over $35 billion.[17]

Recognizing it eliminated the market forces assuring safety, Congress made the Secretary of the U.S. Department of Health & Human Services ("**HHS**") directly responsible for vaccine safety pursuant to a section of the 1986 Act entitled "Mandate for safer childhood vaccines."[18] But HHS recently conceded in Federal court that it has failed to perform even the ministerial acts required by this section.[19]

HHS's dereliction of its vaccine safety duty results in part from the fact that HHS, under the 1986 Act, is the defendant in the Vaccine Injury Compensation Program ("**Vaccine Court**"), part of the U.S. Court of Federal Claims, where HHS must and does vigorously defend against any claim that a vaccine causes injury.[20] The result is that if HHS publishes any study supporting that a vaccine causes a certain harm, it can and will be used against HHS in Vaccine Court.

Despite the fact that parents must battle HHS and the Department of Justice ("**DOJ**") to prove causation in nearly every case without any discovery as-of-right, HHS has paid over $4 billion for vaccine injuries.[21] These are typically for clear and immediate vaccine injuries; those that manifest later – such as a chronic, immune or neurological disorders – are almost never compensated.[22]

Compounding this structural conflict, the U.S. House Committee on Gov't Reform issued a report which found that the "overwhelming majority of members" of the CDC and FDA's vaccine committees had conflicts of interest because of "substantial ties to the pharmaceutical industry," and that these committees reflect "a system where government officials make crucial decisions affecting American children without the advice and consent of the governed."[23]

PRE-LICENSURE SAFETY: For virtually every pediatric vaccine that CDC promotes for routine injection, the pivotal clinical trials relied upon for its licensure did not include a placebo-control group.[24] These clinical trials either lacked any control, used an unlicensed vaccine/substance as a control, or used a licensed vaccine as a control which itself had never been licensed based on a placebo-controlled trial.[25] These trials therefore do not assess actual safety because a vaccine with a high serious adverse event rate will still be licensed if the rate is similar to the control group.

For example, Prevnar 13 (injected at 2, 4, 6, and 12 months) was licensed in 2010 based on a clinical trial that used Prevnar as a control.[26] But Prevnar was licensed based on a clinical trial that used another experimental vaccine as a control.[27] Prevnar 13 was nonetheless licensed despite the fact that serious adverse events "occurred in 8.2% among Prevnar 13 recipients and 7.2% among Prevnar recipients" since both groups had a similar rate of adverse events.[28]

Moreover, the safety review period in clinical trials relied upon to license pediatric vaccines are typically only days or months.[29] For example, the two Hep B vaccines licensed for newborns were licensed based on clinical trials which monitored for adverse events for no longer than *five days* after vaccination.[30] Tracking safety for mere days or months after

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")

[17] https://www.cdc.gov/vaccines/schedules/images/schedule1983s.jpg; https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf; https://files.eric.ed.gov/fulltext/ED255480.pdf; https://www.bccresearch.com/market-research/pharmaceuticals/global-markets-for-vaccine-technologies-phm014g.html

[18] 42 U.S.C. § 300aa-27

[19] http://icandecide.org/government/ICAN-HHS-Stipulated-Order-July-2018.pdf

[20] 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.")

[21] Requiring proof of causation was not what Congress intended in passing the 1986 Act. Instead, 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 This adds insult to injury because had HHS conducted the safety science it demands as proof in Vaccine Court, the child's injury may have been avoided. https://www.hrsa.gov/sites/default/files/hrsa/vaccine-compensation/data/monthly-stats-february-2019.pdf

[22] https://www.uscfc.uscourts.gov/aggregator/sources/7

[23] http://vaccinesafetycommission.org/pdfs/Conflicts-Govt-Reform.pdf

[24] https://icandecide.org/hhs/ICAN-Reply.pdf (see Section I(A))

[25] https://icandecide.org/hhs/ICAN-Reply.pdf (see Section I(A))

[26] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM201669.pdf; http://labeling.pfizer.com/showlabeling.aspx?id=134

[27] http://labeling.pfizer.com/showlabeling.aspx?id=134

[28] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM201669.pdf

[29] https://icandecide.org/hhs/ICAN-Reply.pdf (see Section I(B))

[30] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM110114.pdf; https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM224503.pdf

injecting a baby will not reveal if the vaccine caused autoimmune, neurological or developmental disorders that are likely to only be apparent or diagnosed after the child is a few years of age.[31]

POST-LICENSURE SAFETY: Given the foregoing, any assessment of vaccine safety will only occur after the vaccine is being routinely administered to children.

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."[32] Inserts for childhood vaccines include over a hundred very concerning immune, neurological and other chronic conditions that their manufacturers had a basis to believe were caused by their vaccines.[33] Unfortunately, the studies to determine whether these health issues are caused by vaccines have not been conducted.[34]

Let's look at the most controversial of the claimed vaccine injuries and the one health authorities declare they have thoroughly studied – autism. Between 40% to 70% of parents with autistic children claim vaccines – including DTaP, Hep B, Hib, PCV13, and IPV, each injected three times by six months – is a cause of their child's autism.[35] The CDC tells these parents that "Vaccines Do Not Cause Autism."[36] However, reports from the Institute of Medicine ("IOM") in 1991 and 2012 and HHS in 2014 could not identify a single study supporting that DTaP does not cause autism.[37] There is similarly no study to support that Hep B, Hib, PCV 13, and IPV vaccines do not cause autism.[38] The only vaccine actually studied with regard to autism is MMR; and a Senior CDC Scientist claims the CDC concealed a finding of increased autism after MMR in the only MMR/autism study ever conducted by the CDC with American children.[39] (Moreover, HHS's primary autism expert in Vaccine Court recently provided an affidavit explaining he told HHS/DOJ that vaccines can cause autism in some children, but they buried this information.[40]) Since autism is the vaccine issue that health authorities assert they have most thoroughly studied, it should come as little surprise that there is a void of science to support vaccine safety, including with regard to over one hundred disorders vaccine makers have a basis to claim are caused by vaccines.

For example, virtually none of the childhood vaccines have ever even been evaluated for whether they cause cancer, mutate genes or cause infertility despite the evidence that certain vaccines may cause one or more of these serious medical issues.[41]

The prevalence of vaccine harm can be gleaned from the CDC's Vaccine Adverse Events Reporting System ("VAERS") to which doctors and patients may voluntarily report an adverse vaccine event.[42] In 2018, VAERS received 58,381 reports of adverse vaccine events, including 412 deaths, 1,237 permanent disabilities, and 4,217 hospitalizations.[43] 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."[44] This could mean there are a hundred-fold more adverse vaccine events than are reported to VAERS.

The critical need to compare total health outcomes between vaccinated and unvaccinated children, something the CDC refuses to do, is plain from the few such studies that have been conducted. In 2017, a seminal study found that babies receiving the DTP vaccine died at 10 times the rate of unvaccinated babies.[45] The vaccinated babies were dying of causes never associated with DTP vaccine, such as

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[31] https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf ("because the child-hood immunization schedule is essentially a long-term exposure, occurring over 18 to 24 months, long-term adverse events may be more biologically plausible than short-term events"); ADHD, a common neurological disorder, "5 years of age was the average age of diagnosis." https://www.cdc.gov/ncbddd/adhd/features/key-findings-adhd72013.html. Learning disabilities, a group of common developmental issues, are often "identified once a child is in school." https://www.nichd.nih.gov/health/topics/learning/conditioninfo/diagnosed. Asthma, a common autoimmune condition, "diagnosis can be difficult before 5 years of age." https://www.mayoclinic.org/diseases-conditions/childhood-asthma/diagnosis-treatment/drc-20351513

[32] 21 C.F.R. 201.57

[33] https://www.fda.gov/biologicsbloodvaccines/vaccines/approvedproducts/ucm093833.htm; https://icandecide.org/hhs/ICAN-Reply.pdf (see Appendix B)

[34] https://www.nap.edu/read/1815/chapter/2#7; https://www.nap.edu/read/2138/chapter/2#12; https://www.nap.edu/read/13164/chapter/2#3

[35] 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/

[36] https://www.cdc.gov/vaccinesafety/concerns/autism.html

[37] 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

[38] https://icandecide.org/hhs/ICAN-Reply.pdf (see Section VI)

[39] 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

[40] http://icandecide.org/documents/zimmerman.pdf

[41] https://www.fda.gov/biologicsbloodvaccines/vaccines/approvedproducts/ucm093833.htm (for example, Merck explains that MMRV "has not been evaluated for its carcinogenic, mutagenic, or teratogenic potential, or its potential to impair fertility.")

[42] https://wonder.cdc.gov/vaers.html

[43] https://wonder.cdc.gov/vaers.html

[44] https://healthit.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf

[45] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5360569/

respiratory infections, diarrhea, and malaria.[46] In another study children received influenza vaccine or a saline placebo, and while both groups had a similar rate of influenza, the vaccinated group had a 440% increased rate of non-influenza infections.[47] Thus, the influenza vaccine, like the DTP vaccine, increased susceptibility to other infections.

In a recent pilot study from the School of Public Health at Jackson State University which, for the first time, compared vaccinated with unvaccinated children in the United States, 33% of vaccinated preterm babies had a neuro-developmental disorder compared to 0% of the unvaccinated preterm babies; and the 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.[48]

VACCINATED ARE MORE LIKELY TO SPREAD INFECTIONS: The goal of preventing the spread of infections is also, at present, best accomplished by excluding vaccinated children from school.

According to the FDA, those vaccinated with DTaP will have less symptoms but will become infected and transmit pertussis for as long as the unvaccinated, and because DTaP generates defective immunity, "will be more susceptible to pertussis throughout their lifetimes."[49] Meaning, the children vaccinated for pertussis are more likely to remain in school and spread pertussis while the unvaccinated child with pertussis will have symptoms and know to stay home.

Pertussis is very common and more of a concern than measles; hence if children not vaccinated for measles should be excluded from school, children vaccinated for pertussis should certainly be excluded from school. Similarly, children vaccinated or not vaccinated with inactivated polio vaccine can equally become infected and transmit polio; but, it is the vaccinated that are considered less likely to have symptoms and hence more likely to spread polio.[50]

Also, consider that the chicken pox vaccine can shed chicken pox virus for six weeks after vaccination but vaccinated children are not excluded from school during the shedding period[51]; obese individuals shed influenza A virus for up to 104% longer, yet are not excluded[52]; and most adults do not follow the adult vaccine schedule, yet are not excluded.[53]

Even with regard to measles, the vaccination rate for measles in the United States has been stable or increasing over the last 20 years.[54] What has changed is that Americans that have had measles (which confers lifetime immunity) are being replaced by those vaccinated with MMR (which does not typically confer lifetime immunity). MMR produces no immunity in 2% to 10% of vaccinees[55] and, according to the CDC and FDA, 22 years after two doses of MMR approximately 33% of vaccinees are again potentially susceptible to measles.[56] The proportion after 30 years is even higher.[57] Yet, the only focus is on children whose parents have reason to believe the MMR may cause them harm, while ignoring the foregoing issues with the MMR vaccine in the vaccinated population.

CONCLUSION: Given the foregoing, it is untenable that anyone would seek to replace the right of informed consent (which arises from the Nuremberg code's obligation to inform and obtain voluntary consent) by eliminating compulsory vaccine exemptions and replace this right with an obligation to vaccinate under the coercion of exclusion from school or worse. Coercion invalidates informed consent, and the use of coercion in the practice of medicine compromises the fiduciary relationship physicians are to have with their patients.[58]

[46] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5360569/
[47] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3404712/
[48] http://www.oatext.com/pdf/JTS-3-186.pdf; http://www.oatext.com/pdf/JTS-3-187.pdf
[49] https://www.ncbi.nlm.nih.gov/pubmed/24277828; https://www.ncbi.nlm.nih.gov/pubmed/30793754; https://www.ncbi.nlm.nih.gov/pubmed/29180031 ("vaccination does not prevent B. pertussis infection in humans, nor the circulation of the organism in human populations [and] … asymptomatic transmission is the most parsimonious explanation for the resurgence of pertussis in countries with high-vaccination coverage")
[50] http://polioeradication.org/polio-today/polio-prevention/the-vaccines/ipv/; https://www.ncbi.nlm.nih.gov/pubmed/17429085 (91% of unvaccinated children and 94-97% of IPV vaccinated children upon being exposed to attenuated poliovirus were colonized)
[51] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM142813.pdf
[52] https://www.ncbi.nlm.nih.gov/pubmed/30085119; https://www.ncbi.nlm.nih.gov/pubmed/28584297; https://www.ncbi.nlm.nih.gov/pubmed/28584297
[53] https://www.cdc.gov/vaccines/schedules/downloads/adult/adult-combined-schedule.pdf; https://www.cdc.gov/vaccines/imz-managers/coverage/adultvaxview/pubs-resources/index.html
[54] https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/e/coverage-levels.pdf
[55] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3570049/
[56] https://www.ncbi.nlm.nih.gov/pubmed/17339511; https://www.ncbi.nlm.nih.gov/pubmed/2230231; https://www.ncbi.nlm.nih.gov/pubmed/24585562 (Documenting "measles transmission from a twice-vaccinated individual")
[57] https://www.ncbi.nlm.nih.gov/pubmed/17339511
[58] https://www.utcomchatt.org/docs/biomedethics.pdf