VACCINE SAFETY

Introduction to Vaccine Safety Science & Policy in the United States

ICAN
Informed Consent Action Network
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Address for correspondence: whitepaper@icandecide.org

This white paper provides an introduction to vaccine safety science and policy in the United States.

Section "I" discusses how Congress granted pharmaceutical companies immunity from liability for vaccine injuries and transferred all responsibility for vaccine safety to the United States Department of Health & Human Services (**HHS**) and its agencies, including the Food & Drug Administration (**FDA**), the Centers for Disease Control (**CDC**) and the National Institutes of Health (**NIH**).

Section "II" discusses how most pediatric vaccines were licensed based on inadequate clinical trials, including follow-up periods too brief to capture adverse outcomes, and illegitimate placebos (e.g., other vaccines).

Section "III" discusses the CDC's deficient post-licensure vaccine safety surveillance.

Section "IV" discusses the conflicts of interest at HHS regarding vaccine safety, including the issues resulting from placing HHS in charge of vaccine safety and the conflicting duty of promoting and defending vaccines against any claim of injury.

Until a frank conversation is possible regarding vaccine safety, children susceptible to vaccine injury will not be protected from such injury. Nor will children injured by vaccines be able to access the services they need. We can do better in protecting and serving children who are susceptible or succumb to serious injuries from vaccination.

The first step in avoiding vaccine injuries and helping those already harmed is understanding the state of vaccine safety science and policy in America. This paper provides this understanding and highlights areas in need of improvement.

I. Who is responsible for vaccine safety?

Unlike nearly every other company in America, pharmaceutical companies have almost no liability for injuries caused by their vaccine products. How did this happen? As explained by the Institute of Medicine (**IOM**)[1], by 1986, the "litigation costs associated with claims of damage from vaccines had forced several companies to end their vaccine

[1] In 2016, the IOM formally changed its name to the National Academies of Sciences, Engineering, and Medicine.

research and development programs as well as to stop producing already licensed vaccines."[2] Instead of letting market forces compel vaccine makers to create safer vaccines, Congress granted pharmaceutical companies financial immunity from injuries caused by vaccines recommended by the CDC.[3] Congress did so by passing the National Childhood Vaccine Injury Act (the **1986 Act**).[4]

By granting immunity from actual or potential liability from injuries caused by vaccines, Congress eliminated the market forces that are generally relied upon to assure the safety of all other products. As the 1986 Act expressly provides: "No person may bring a civil action … against a vaccine administrator or manufacturer in a State or Federal court for damages arising from a vaccine-related injury or death."[5]

The 1986 Act even shields vaccine makers from liability where it is clear and unmistakable that the vaccine in question could have been designed safer.[6] As recently explained in a U.S. Supreme Court opinion:

> *[N]o one—neither the FDA nor any other federal agency, nor state and federal juries—ensures that vaccine manufacturers adequately take account of scientific and technological advancements. This concern is especially acute with respect to vaccines that have already been released and marketed to the public. Manufacturers ... will often have little or no incentive to improve the designs of vaccines that are already generating significant profit margins.*[7]

Recognizing that the 1986 Act eliminated the incentive for vaccine makers to assure the safety of their vaccine products, the 1986 Act explicitly places this responsibility in the hands of the United States Department of Health & Human Services (**HHS**).[8]

As provided in the 1986 Act, HHS is responsible for "research ... to prevent adverse reactions to vaccines," "develop[ing] the techniques needed to produce safe ... vaccines," "safety ... testing of vaccines," "monitoring ... adverse effects of vaccines," and "shall make or assure improvements in ... the licensing, manufacturing, processing, testing, labeling, warning, use instructions, distribution, storage, administration, field surveillance, adverse reaction reporting, ... and research on vaccines in order to reduce the risks of adverse reactions to vaccines."[9]

Since passage of the 1986 Act, the number of required pediatric vaccines has grown rapidly. In 1983, the CDC's childhood vaccine schedule included 11 injections of 4 vaccines.[10] As of 2017, the CDC's childhood vaccine schedule includes 56 injections of 30 different vaccines.[11]

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[2] https://www.nap.edu/read/2138/chapter/2#2
[3] 42 U.S.C. § 300aa-1 et seq.
[4] Ibid.
[5] 42 U.S.C. § 300aa-11
[6] Bruesewitz v. Wyeth LLC, 562 U.S. 223 (2011)
[7] Ibid.
[8] 42 U.S.C. § 300aa-2; 42 U.S.C. § 300aa-27
[9] Ibid.
[10] https://www.cdc.gov/vaccines/schedules/images/schedule1983s.jpg
[11] https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html (note that the influenza vaccine is different every year)

CDC Childhood Immunization Schedule[12]		
1986	2017	
DTP (2 months)	Influenza (pregnancy)	Influenza (18 months)
Polio (2 months)	TDaP (pregnancy)	Influenza (2 years)
DTP (4 months)	Hepatitis B (one day)	Influenza (3 years)
Polio (4 months)	Hepatitis B (one month)	Influenza (4 years)
DTP (6 months)	DTaP (2 months)	DTaP (4 years)
MMR (15 months)	Polio (2 months)	Polio (4 years)
DTP (18 months)	Hib (2 months)	MMR (4 years)
Polio (18 months)	PCV (2 months)	Varicella (4 years)
DTP (4 years)	Rotavirus (2 months)	Influenza (5 years)
Polio (4 years)	DTaP (4 months)	Influenza (6 years)
Tetanus (14 years)	Polio (4 months)	Influenza (7 years)
	Hib (4 months)	Influenza (8 years)
	PCV (4 months)	Influenza (9 years)
	Rotavirus (4 months)	Influenza (10 years)
	DTaP (6 months)	HPV (11 years)
	Polio (6 months)	Men (11 years)
	Hepatitis B (6 months)	TDaP (11 years)
	Hib (6 months)	Influenza (11 years)
	PCV (6 months)	HPV (11 ½ years)
	Rotavirus (6 months)	Influenza (12 years)
	Influenza (6 months)	HPV (12 years)
	MMR (12 months)	Influenza (13 years)
	Varicella (12 months)	Influenza (14 years)
	Hib (12 months)	Influenza (15 years)
	Hepatitis A (12 months)	Men (16 years)
	PCV (12 months)	Influenza (16 years)
	DTaP (15 months)	Influenza (17 years)
	Hepatitis A (18 months)	Influenza (18 years)

It is only when the CDC adds a vaccine to its recommended vaccine schedule that the manufacturer is granted immunity from liability for vaccine injuries. And due to a federal funding scheme, CDC recommended vaccines are then made compulsory to American children under state laws and subsidized by the Federal government for children unable to afford the vaccine.[13]

The end result is that under the 1986 Act, every pediatric vaccine recommended by the CDC creates for its manufacturer a liability-free captive market of 78 million children with guaranteed payment. This incentive structure is unequal in the marketplace and eliminates the normal market forces driving product safety. Hence the 1986 Act transferred essentially all responsibility for vaccine safety from the pharmaceutical companies to HHS.

II. Pre-Licensure Vaccine Safety Review

HHS, through the FDA, licenses all vaccines used by the American public.

All non-vaccine drugs licensed by the FDA undergo long-term multi-year double-blind safety studies during which the rate of adverse reactions in the group receiving the drug under review is compared to the rate of adverse reactions in a group receiving an inert placebo, such as a sugar pill or saline injection.

For example: Enbrel's pre-licensure trials followed subjects up to 80 months and controls received a saline injection.[14] Lipitor's pre-licensure trials lasted a median of 4.8 years and controls received a sugar pill.[15] Botox's pre-licensure trials lasted a median of 51 weeks and controls received a saline injection.[16] And even with these long-term studies, drugs are still often recalled.

While most drugs, like the ones above, are given to sick adults, pediatric vaccines are typically given universally to babies and toddlers. And while pharmaceutical companies remain liable for injuries caused by their

[12] The rapid growth of CDC's vaccine schedule is excepted to accelerate since there were 271 new vaccines under development in 2013 and far more currently under development. http://www.phrma.org/press-release/medicines-in-development-vaccines (listing 2,300 trials in search for "vaccines" between 2013 and 2017)

[13] See Section IV below.

[14] https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/103795s5503lbl.pdf

[15] https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020702s056lbl.pdf

[16] https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/103000s5302lbl.pdf

non-vaccine drugs, as discussed above, they have no liability for injuries caused by their vaccines. One would therefore expect that pre-licensure safety testing for vaccines would be more rigorous than that conducted for drugs.

Unfortunately, unlike all non-vaccine drugs licensed by the FDA, vaccines are *not* required to undergo long-term double-blind inert-placebo controlled trials to assess safety. In fact, not a single one of the clinical trials for vaccines given to babies and toddlers had a control group receiving an inert placebo. Further, most pediatric vaccines currently on the market have been approved based on studies with inadequate follow-up periods of only a few days or weeks.

For example, there are two Hepatitis B vaccines licensed for one day old babies in the United States – one manufactured by Merck and the other by GlaxoSmithKline. Merck's Hepatitis B vaccine was licensed by the FDA after trials which solicited adverse reactions for *only five days* after vaccination.[17] Similarly, GlaxoSmithKline's Hepatitis B vaccine was licensed by the FDA after trials which solicited adverse reactions for *only four days* after vaccination.[18]

Follow-up periods of 4 or 5 days are not nearly long enough to detect possible adverse effects such as autoimmune or neurological disorders, seizures, or death. Worse is that since neither of these clinical trials used a control group, it was impossible to scientifically determine if any adverse reaction in the limited four or five day safety review period was even caused by the Hepatitis B vaccine being evaluated.

Similarly, the HiB vaccines manufactured by Merck and GlaxoSmithKline were licensed by the FDA based on trials in which adverse reactions were monitored for only three days and four days, respectively, after vaccination.[19] The only stand-alone polio vaccine in the United States was licensed after a mere 48-hour follow-up period.[20]

Even more amazing is that unlike every drug licensed by the FDA, the control groups in these vaccine trials did not receive an inert placebo.[21] Rather, the control group was given one or more previously licensed vaccines as the "placebo."[22] This means each new vaccine need only be roughly as safe as one (or in some cases numerous) previously licensed vaccines. Such flawed and unscientific study designs cannot establish the actual safety profile of any vaccine. The real adverse event rate for a vaccine can only be determined by comparing subjects receiving the vaccine with those receiving an inert placebo. Yet, this study design, required for every drug, is never required before or after licensing a vaccine.

It is unacceptable that the FDA licensing process for vaccines fails to assess the safety profile of each vaccine. It is also unacceptable that the FDA does not require the use of inert placebo controls to assure the integrity of even the minimal safety review conducted. As HHS's own paid experts, the

[17] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM110114.pdf
[18] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM224503.pdf
[19] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM253652.pdf; https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM179530.pdf
[20] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM133479.pdf
[21] Ibid. (prior two footnotes)
[22] Ibid.

IOM, explains: "Because [vaccine] trials are primarily … for determination of efficacy, conclusions about vaccine safety derived from these trials are limited."[23]

III. Post-Licensure Surveillance of Vaccine Safety & the Known and Unknown Risks of Vaccination

HHS also fails to conduct proper post-licensure monitoring and studies of vaccine safety.

1. CDC Blocks Automation of Vaccine Adverse Events Reporting

The paucity of pre-licensure safety reviews for vaccines (see discussion above) leaves the assessment of adverse reactions to the post-licensing period when they are being administered to children in the "real world."

In order to capture adverse events that may arise from vaccination in the "real world," the 1986 Act established the Vaccine Adverse Events Reporting System (**VAERS**) operated by HHS and co-sponsored by the CDC and FDA.[24] VAERS is a passive, not mandatory, reporting system.[25] Anyone, including health care providers, on a voluntary basis, may report adverse vaccine reactions to VAERS.[26] HHS compiles these adverse reaction reports in VAERS and the CDC uses VAERS as a "safety signal detection and hypothesis generating system" to identify potential injuries caused by vaccines.[27]

In 2016, VAERS received 59,117 reports of adverse reactions following vaccination including 432 deaths, 1,091 permanent disabilities, 4,132 hospitalizations, and 10,284 emergency room visits.[28]

A problem with VAERS is that it is a passive reporting system, relying on voluntary, rather than mandatory, reporting.[29] As such, numerous reviews of VAERS have found that only a tiny fraction of vaccine adverse events are reported. For example, an HHS-funded review of vaccine adverse events over a three-year period by Harvard Medical School involving 715,000 patients found that "fewer than 1% of vaccine adverse events are reported."[30] A U.S. House Report similarly stated: "Former FDA Commissioner David A. Kessler has estimated that VAERS reports currently represent only a fraction of the serious adverse events."[31]

Assuming VAERS captures 1 percent of adverse events (which is more than is estimated), then the number of adverse events reported to VAERS in 2016 would reflect for that year 5,911,700 adverse events, 43,200 deaths, 109,100 permanent disabilities, 413,200 hospitalizations, and 1,028,400 emergency

[23] https://www.nap.edu/read/13563/chapter/4
[24] https://wonder.cdc.gov/vaers.html
[25] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4632204/
[26] Ibid.
[27] Ibid.
[28] https://wonder.cdc.gov/vaers.html
[29] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4632204/
[30] https://healthit.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf
[31] https://www.congress.gov/106/crpt/hrpt977/CRPT-106hrpt977.pdf

room visits. If accurate, these figures are very troubling.

Of course, these figures are merely estimates. It would be far better if adverse events reports were automatically created and submitted to VAERS to avoid the issue of underreporting. Automated reporting would provide invaluable information that could clarify which vaccines might cause which harms and to whom, potentially allowing us to avoid these injuries and deaths.

The idea of automating adverse event reporting to VAERS is not new or even difficult to achieve.[32] The Agency for Healthcare Research and Quality, an agency within HHS, sought to do exactly that in 2007 when it provided an approximately $1 million grant to automate VAERS reporting at Harvard Pilgrim Health Care.[33] The result was the successful automation of adverse event reports at Harvard Pilgrim:

> *Preliminary data were collected from June 2006 through October 2009 on 715,000 patients, and 1.4 million doses (of 45 different vaccines) were given to 376,452 individuals. Of these doses, 35,570 possible reactions ... were identified.*[34]

These results should have been startling to HHS since they show that over only a three-year period, there were 35,570 reportable reactions in just 376,452 vaccine recipients. Given HHS's statutory mandate to assure safer vaccines, it should have rushed forward with automating VAERS reporting. However, this is not what happened.

After automating adverse event reports at Harvard Pilgrim, the developers of this system asked the CDC to take the final step of linking VAERS with the Harvard Pilgrim system so that these reports could be automatically transmitted into VAERS. Instead, the CDC refused to cooperate. As the Harvard grant recipients explained:

> *Unfortunately, there was never an opportunity to perform system performance assessments because the necessary CDC contacts were no longer available and the CDC consultants responsible for receiving data were no longer responsive to our multiple requests to proceed with testing and evaluation.*[35]

After three years and spending $1 million of taxpayers' money, the CDC refused to even communicate with the HHS' Harvard Medical School grant recipients.

While HHS generally strongly supports automating public health surveillance systems, when it comes to vaccine safety, the CDC has only supported projects that would limit VAERS to passive surveillance.[36] Automation would improve safety and address many of the long-standing issues and limitations raised by CDC regarding VAERS.[37]

Capturing "fewer than 1% of vaccine adverse events" thirty years after the passage of the 1986 Act is unacceptable – and potentially deadly.

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[32] https://healthit.ahrq.gov/ahrq-funded-projects/electronic-support-public-health-vaccine-adverse-event-reporting-system
[33] https://healthit.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf
[34] Ibid.
[35] Ibid.
[36] http://www.ajpmonline.org/article/S0749-3797(12)00249-8/pdf; https://www.ncbi.nlm.nih.gov/pubmed/26209838; https://www. ncbi.nlm.nih.gov/pmc/articles/PMC4632204/
[37] Ibid.

2. CDC Ignores IOM's Calls to Identify Injuries Caused by Vaccines

The IOM was formed in 1863 by congressional charter, to "provide expert advice on some of the most pressing challenges facing the nation and the world."[38] The IOM further claims its "members are among the world's most distinguished scientists, engineers, physicians, and researchers; more than 300 members are Nobel laureates."[39]

Under the 1986 Act, the IOM was charged with issuing reports on injuries from vaccination. In 1991, the IOM examined 22 commonly reported serious injuries following the DTP vaccine.[40] The IOM concluded the scientific literature supported a causal relationship between the DTP vaccine and 6 of these injuries: acute encephalopathy, chronic arthritis, acute arthritis, shock and unusual shock-like state, anaphylaxis, and protracted inconsolable crying.[41]

While this picture was troubling enough, equally concerning was that the IOM found that the scientific literature was insufficient to conclude whether or not the DTP vaccine can cause 12 other serious injuries commonly reported from this vaccine:

> *Aseptic meningitis (serious inflammation of the brain); Chronic neurologic damage; Learning disabilities and attention-deficit disorder; Hemolytic anemia; Juvenile diabetes; Guillain-Barre syndrome; Erythema multiforme; Autism; Peripheral mononeuropathy (nerve damage); Radiculoneuritis and other neuropathies; Thrombocytopenia; Thrombocytopenic purpura*[42]

These commonly reported serious injuries *could* be caused by this vaccine – the IOM just couldn't determine one way or another due to a lack of science.

The IOM lamented that it "encountered many gaps and limitations in knowledge bearing directly and indirectly on the safety of vaccines."[43] The IOM also remarked on the poor design of the few vaccine studies that had been conducted, stating these "studies are too small or have inadequate length of follow-up to have a reasonable chance of detecting true adverse reactions."[44] Moreover, the IOM reported that "existing surveillance systems of vaccine injury have limited capacity to provide persuasive evidence of causation."[45]

The IOM thus cautioned in its 1991 report that: "If research capacity and accomplishment in this field are not improved, future reviews of vaccine safety will be similarly handicapped."[46]

As charged under the 1986 Act, the IOM issued another report in 1994 entitled *Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causation.*[47] This second IOM Report examined the scientific literature for evidence that could either prove or disprove a causal link between 54

[38] http://www.national-academies.org/about/whoweare/index.html
[39] Ibid.
[40] https://www.nap.edu/read/1815/chapter/2#7
[41] Ibid.
[42] Ibid.
[43] https://www.nap.edu/read/1815/chapter/2#8
[44] https://www.nap.edu/read/1815/chapter/9
[45] Ibid.
[46] Ibid.
[47] https://www.nap.edu/read/2138/chapter/1

commonly reported serious injuries and vaccination for diphtheria, tetanus, measles, mumps, polio, hepatitis B, and Hib.[48]

For this Report, the IOM located sufficient science to support a causal connection between these vaccines and 12 injuries, including death, anaphylaxis, thrombocytopenia, and Guillain-Barre syndrome.[49]

Again, as with the IOM Report from 1991, for "the majority of vaccine-adverse event pairs the evidence was considered inadequate to accept or reject causality."[50] The problem that basic scientific studies had not been done continued to persist. The IOM could not determine whether there was a causal connection between vaccination and 38 of the most common serious injuries parents reported their children experienced following these vaccines, including:

> *Demyelinating diseases of the central nervous system, Sterility, Arthritis, Neuropathy, Residual seizure disorder, Transverse myelitis, Sensorineural deafness, Optic neuritis, Aseptic meningitis, Insulin-dependent diabetes mellitus, SIDS*[51]

This means that of the 54 vaccine-injury pairs studied, there was sufficient science to find a causal relationship of harm for 12, and to reject a relationship for 4.[52] But for the remaining 38, there was insufficient science to reach any conclusion.[53]

As in 1991, this IOM Report from 1994 again stated: "The lack of adequate data regarding many of the adverse events under study was of major concern to the committee. Presentations at public meeting indicated that many parents and physicians share this concern."[54]

Another acute concern raised by the IOM in 1994 was the potential risks posed by combining vaccines. The IOM noted that this subject simply had not been studied: "The committee was able to identify little information pertaining to the risk of serious adverse events following administration of multiple vaccines simultaneously. This is an issue of increasing concern as more vaccines and vaccine combinations are developed for routine use."[55]

In 2011, HHS paid the IOM to conduct another assessment regarding vaccine safety.[56] This Report, entitled *Adverse Effects of Vaccines: Evidence and Causality*, was the culmination of the largest review by the IOM regarding vaccine safety since the IOM's reports from 1991 and 1994.[57]

This third IOM Report reviewed the 158 most common vaccine injuries claimed to have occurred from vaccination for varicella, hepatitis B, tetanus, measles, mumps, and/or rubella.[58] The IOM located science which "convincingly supports a causal relationship" for 14 of these serious injuries, including pneumonia, meningitis, hepatitis, MIBE (deadly brain inflammation a year after vaccination), febrile seizures, and

[48] https://www.nap.edu/read/2138/chapter/2#12
[49] https://www.nap.edu/read/2138/chapter/2#12
[50] https://www.nap.edu/read/2138/chapter/1#vi
[51] https://www.nap.edu/read/2138/chapter/2#12
[52] Ibid.
[53] Ibid.
[54] https://www.nap.edu/read/2138/chapter/12
[55] https://www.nap.edu/read/2138/chapter/12#307
[56] https://www.nap.edu/read/13164/chapter/2#2
[57] Ibid.
[58] Ibid.

anaphylaxis.[59] The review found sufficient evidence to support "acceptance of a causal relationship" for 4 additional serious injuries.[60]

The IOM, however, found the scientific literature was insufficient to conclude whether or not those vaccines caused 135 other serious injuries commonly reported after their administration, including:

> *Encephalitis (brain inflammation), Encephalopathy (gradual degeneration of brain function, including memory, cognitive ability, concentration, lethargy, and eventually consciousness), Infantile Spasms, Afebrile Seizures, Seizures, Cerebellar Ataxia (inflammation of and/or damage to the cerebellum), Ataxia (the loss of full control of bodily movements), Acute Disseminated Encephalomyelitis (brief but widespread attack of inflammation in the brain and spinal cord that damages myelin – the protective covering of nerve fibers), Transverse Myelitis (neurological disorder caused by inflammation across both sides of one level, or segment, of the spinal cord that typically results in permanent impairments), Optic Neuritis (inflammation of the optic nerve and symptoms are usually unilateral, with eye pain and partial or complete vision loss), Neuromyelitis Optica (body's immune system over time repeatedly mistakenly attacks healthy cells and proteins in the body, most often those in the spinal cord and eyes resulting in permanent disability), Multiple Sclerosis, Guillain-Barre Syndrome (body's immune system attacks part of the peripheral nervous system), Chronic Inflammatory Demyelinating Polyneuropathy (auto-immune inflammatory disorder of the peripheral nervous system resulting in loss of nerve axons), Brachial Neuritis (auto-immune reaction against nerve fibers of the brachial plexus), Amyotrophic Lateral Sclerosis (rapidly progressive, invariably fatal neurological disease that attacks the nerve cells responsible for controlling voluntary muscles), Small Fiber Neuropathy (damage to the small unmyelinated peripheral nerve fibers), Chronic Urticaria (chronic hives), Erythema Nodosum (skin inflammation in the fatty layer of skin), Systemic Lupus Erythematosus (autoimmune disease in which the body's immune system mistakenly attacks healthy tissue), Polyarteritis Nodosa (inflammation resulting in injury to organ systems), Psoriatic Arthritis, Reactive Arthritis, Rheumatoid Arthritis, Juvenile Idiopathic Arthritis, Arthralgia (joint pain), Autoimmune Hepatitis, Stroke, Chronic Headache, Fibromyalgia, Sudden Infant Death Syndrome, Hearing Loss, Thrombocytopenia, Immune Thrombocytopenic Purpura*[61]

Thus, out of the 158 most common serious injuries reported to have been caused by the vaccines under review, the evidence "convincingly supports a causal relationship" for 14, "favors acceptance of a causal relationship" for 4, and "favors rejection of a causal relationship" for only 5 of them.[62] For the remaining 135 vaccine-injury pairs, over 86 percent of those reviewed, the IOM found

[59] https://www.nap.edu/read/13164/chapter/2#3
[60] Ibid.
[61] Ibid.
[62] Ibid.

that the science simply had not been performed.[63]

3. CDC Ignores IOM's Calls to Identify Children Susceptible to Vaccine Injury

Compounding the lack of adequate science to simply ascertain whether the most commonly reported serious adverse reactions following vaccination are caused by vaccines, the IOM Reports discussed above have consistently acknowledged there is individual susceptibility to serious vaccine injuries.

The IOM has also acknowledged that research on such susceptibility must be done on an individual basis, considering a child's personal genome, behaviors, microbiome, intercurrent illness, and present and past environmental exposure.[64] Unfortunately, HHS has not conducted this research.

In 1994, the IOM, building on concerns raised in its 1991 Report, stated: "The committee was able to identify little information pertaining to why some individuals react adversely to vaccines when most do not."[65] The IOM urged that "research should be encouraged to elucidate the factors that put certain people at risk."[66]

Yet, seventeen years later, in 2011, the IOM acknowledged this research had still not been done:

> *Both epidemiologic and mechanistic research suggest that most individuals who experience an adverse reaction to vaccines have a preexisting susceptibility. These predispositions can exist for a number of reasons—genetic variants (in human or microbiome DNA), environmental exposures, behaviors, intervening illness, or developmental stage, to name just a few—all of which can interact as suggested graphically in Figure 3-1.*
>
> *Some of these adverse reactions are specific to the particular vaccine, while others may not be. Some of these predispositions may be detectable prior to the administration of vaccine. … [M]uch work remains to be done to elucidate and to develop strategies to document the immunologic mechanisms that lead to adverse effects in individual patients.*

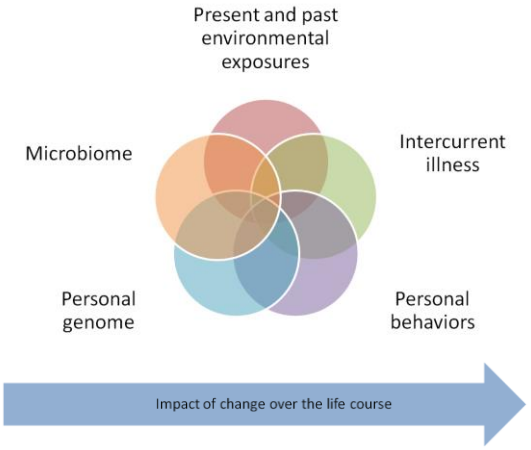

FIGURE 3-1 Present and past environmental exposures.[67]

In 2013, HHS commissioned the IOM to review the safety of the entire vaccine schedule.[68] The IOM again explained that while "most children who experience an adverse reaction to immunization have preexisting susceptibility," the IOM:

[63] Ibid.
[64] https://www.nap.edu/read/13164/chapter/5#82
[65] https://www.nap.edu/read/2138/chapter/12#307. *See also* https://www.nap.edu/read/1815/chapter/9
[66] Ibid.
[67] https://www.nap.edu/read/13164/chapter/5#82
[68] https://www.nap.edu/read/13563/chapter/1

> *found that evidence assessing outcomes in sub populations 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.*[69]

HHS had failed to even define the terminology for the study of susceptible subpopulations; hence IOM admonished HHS to "develop a framework that clarifies and standardizes definitions of ... populations that are potentially susceptible to adverse events."[70] While every vaccine brand is the same, it is plain that every child is different.

The IOM correctly points out in 2011 that given the "widespread use of vaccines" and "state mandates requiring vaccination of children … it is essential that safety concerns receive assiduous attention."[71] This is the same call for diligent attention that the IOM made in 1991 and 1994. Unfortunately, all of these calls for action have gone unheeded. The critical scientific inquiry to identify individuals susceptible to serious vaccine injury has simply never commenced.

Since the IOM's first call for this science in 1991, HHS has spent tens of billions promoting and purchasing vaccines, and vaccine makers have accumulated hundreds of billions in vaccine revenue.[72] Yet, during this time, no material funds have been allocated to identify susceptible subpopulations, let alone what injuries are caused by vaccines.[73]

4. CDC Views Vaccine Safety as a Public Relations Issue

The CDC, unfortunately, has treated vaccine safety as a public relations issue rather than a public health imperative. For example, the CDC claims on its website that "Vaccines Do Not Cause Autism" even though this broad claim is plainly not supported by the scientific literature.[74]

Indeed, as part of the IOM's 2011 review of vaccine safety, it was asked by HHS whether there is a causal relationship between autism and the DTaP vaccine administered to children at two, four, six, and fifteen months of age.[75] The IOM could not locate a single study supporting that DTaP does not cause autism.[76] The IOM therefore concluded: "The evidence is inadequate to accept or reject a causal relationship between diphtheria toxoid–, tetanus toxoid–, or acellular pertussis–containing vaccine and autism."[77] The IOM's full explanation for this finding is as follows:

[69] https://www.nap.edu/read/13563/chapter/9#130
[70] Ibid.
[71] https://www.nap.edu/read/13164/chapter/3#28
[72] https://www.hhs.gov/about/budget/index.html#previous; https://www.statista.com/statistics/265102/revenues-in-the-global-vaccine-market/; https://www.ft.com/content/93374f4a-e538-11e5-a09b-1f8b0d268c39
[73] For example, while in 2016 vaccine makers reported over $33 billion from vaccine sales and the CDC reported spending over $5 billion promoting and purchasing vaccines (Ibid.), the CDC Immunization Safety Office's budget is apparently only around $20 million. http://www.ajpmonline.org/article/S0749-3797(15)00314-1/pdf
[74] https://www.cdc.gov/vaccinesafety/concerns/autism.html
[75] https://www.nap.edu/read/13164/chapter/2#2
[76] https://www.nap.edu/read/13164/chapter/12#545
[77] Ibid.

AUTISM

Epidemiologic Evidence

The committee reviewed one study to evaluate the risk of autism after the administration of DTaP vaccine. This one study (Geier and Geier, 2004) was not considered in the weight of epidemiologic evidence because it provided data from a passive surveillance system and lacked an unvaccinated comparison population.

Weight of Epidemiologic Evidence

The epidemiologic evidence is insufficient or absent to assess an association between diphtheria toxoid–, tetanus toxoid–, or acellular pertussis–containing vaccine and autism.

Mechanistic Evidence

The committee did not identify literature reporting clinical, diagnostic, or experimental evidence of autism after the administration of vaccines containing diphtheria toxoid, tetanus toxoid, and acellular pertussis antigens alone or in combination.

Weight of Mechanistic Evidence

The committee assesses the mechanistic evidence regarding an association between diphtheria toxoid–, tetanus toxoid–, or acellular pertussis–containing vaccine and autism as lacking.

Causality Conclusion

Conclusion 10.6: The evidence is inadequate to accept or reject a causal relationship between diphtheria toxoid–, tetanus toxoid–, or acellular pertussis–containing vaccine and autism.[78]

It is troubling that the only study the IOM could locate regarding whether DTaP causes autism, (Geier and Geier, 2004), concluded there *was* an association between DTaP and autism.[79] No research has been published since 2011 that could change the IOM's conclusion. Based on the foregoing, the CDC cannot validly make the blanket assertion that "Vaccines Do Not Cause Autism."

As with DTaP, there are also no published studies showing that autism is not caused by Hepatitis B, Rotavirus, Hib, Pneumococcal, Inactivated Poliovirus, Influenza, Varicella, or Hepatitis A vaccines – all of which HHS recommends babies receive by one year of age.[80]

Instead, HHS's claim that "Vaccines Do Not Cause Autism" relies almost entirely upon studies exclusively studying only one vaccine, MMR (which is administered no earlier than one year of age), or only one vaccine ingredient, thimerosal, with regard to autism.[81] Putting aside the controversy surrounding these studies, studies which focus on only one vaccine and one ingredient while ignoring the entire balance of the CDC's pediatric vaccine schedule cannot support the

[78] Ibid.

[79] Ibid. Ironically, this study was disregarded "because it provided data from a passive surveillance system [VAERS] and lacked an unvaccinated comparison population," which would be true of any study using VAERS data.

[80] https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent. html

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

CDC's overarching declaration that "Vaccines Do Not Cause Autism."

As for the MMR vaccine, the CDC's senior scientist for its seminal MMR-autism study has recently revealed that the CDC concealed an association between MMR and autism. Dr. William Thompson has been a scientist at CDC for nearly two decades and is the CDC's Senior Scientist on dozens of the CDC's peer-reviewed publications, including the core group of the CDC's vaccine-autism safety studies.[82]

Dr. Thompson recently provided a statement through his attorney that the CDC "omitted statistically significant information" showing an association between the MMR vaccine and autism in the first and only MMR-autism study ever conducted by the CDC with American children.[83]

Dr. Thompson, in a recorded phone call in 2014, described how the CDC concealed a finding indicating that healthy children who received the MMR vaccine may be eight times more likely to develop autism than those without the vaccine.[84] He stated: "Oh my God, I can't believe we did what we did. But we did. It's all there. It's all there. I have handwritten notes."[85] Dr. Thompson stated that "If I were forced to testify or something like that, I'm not gonna lie ... I basically have stopped lying."[86] Expressing contrition for concealing the MMR-autism association, Dr. Thompson stated:

> *I have great shame now when I meet families with kids with autism because I have been part of the problem … the CDC is so paralyzed right now by anything related to autism. They're not doing what they should be doing because they're afraid to look for things that might be associated. So anyway there's still a lot of shame with that. … I am completely ashamed of what I did.*[87]

Dr. Thompson also provided the following statement explaining the CDC's concealment of the autism-MMR association with regard to African-American males:

> *My primary job duties while working in the immunization safety branch from 2000 to 2006, were to later co-lead three major vaccine safety studies. … We hypothesized that if we found statistically significant effects at either 18 or 36 month thresholds, we would conclude that vaccinating children early with MMR vaccine could lead to autism-like characteristics or features. We all met and finalized the study protocol and analysis plan ... [and after implementing this plan we found] the adjusted race effect statistical significance was huge.*
>
> *All the authors and I [therefore] met and decided ... to exclude reporting any race effects. The co-authors scheduled a meeting to destroy documents related to the study. The remaining four co-authors all met and brought a big garbage can into the meeting room, and reviewed and went through all the hardcopy documents that we had thought we should discard, and put them into a huge garbage can. However,*

[82] https://www.ncbi.nlm.nih.gov/pubmed/?term=Thompson+WW%5BAuthor%5D
[83] http://www.rescuepost.com/files/william-thompson-statement-27-august-2014-3.pdf
[84] https://soundcloud.com/fomotion/cdc-whistle-blower-full-audio
[85] Ibid.
[86] Ibid.
[87] Ibid.

> *because I assumed it was illegal and would violate both FOIA and DOJ requests, I kept hardcopies of all documents in my office, and I retain all associated computer files. I believe we intentionally withheld controversial findings from the final draft of the Pediatrics paper.*[88]

Hence, for the only vaccine (MMR) actually studied by the CDC with regard to autism, it appears the CDC concealed an association between that vaccine and autism.

When the former Director of the National Institutes of Health, Dr. Bernadine Healy, was asked about whether public health authorities are correct to claim that vaccines do not cause autism, she answered: "You *can't* say that."[89] When asked again, Dr. Healy explained: "The more you delve into it – if you look at the basic science – if you look at the research that's been done, in animals – if you also look at some of these individual cases – *and*, if you look at the evidence that there *is* no link - what I come away with is: *The question has not been answered*."[90]

Former NIH Director Dr. Healy goes on to explain:

> *This is the time when we do have the opportunity to understand whether or not there are susceptible children, perhaps genetically, perhaps they have a metabolic issue, mitochondrial disorder, immunological issue, that makes them more susceptible to vaccines plural, or to one particular vaccine, or to a component of vaccine. … A susceptible group does not mean that vaccines are not good. What a susceptible group will tell us is that maybe there is a group of individuals, or a group of children, that shouldn't have a particular vaccine or shouldn't have vaccine on the same schedule. …*
>
> *I think the government, or certain health officials in the government, are - have been too quick to dismiss the concerns of these families without studying the population that got sick. I haven't seen major studies that focus on - three hundred kids, who got autistic symptoms within a period of a few weeks of a vaccine.*
>
> *I think that the public health officials have been too quick to dismiss the hypothesis as irrational, without sufficient studies of causation. I think that they often have been too quick to dismiss studies in the animal laboratory, either in mice, in primates, that do show some concerns with regard to certain vaccines. …*
>
> *The reason why they didn't want to look for those susceptibility groups was because they're afraid if they found them—however big or small they were—that that would scare the public away. First of all, I think the public's smarter than that; the public values vaccines. But, more importantly, I don't think you should ever turn your back on any scientific hypothesis because you're afraid of what it might show!* [91]

The CDC's claim that "Vaccines Do Not Cause Autism" also fails to address the

[88] https://www.c-span.org/video/?c4546453/senator-posey-calls-investigation-cdc-fraud
[89] http://www.cbsnews.com/news/the-open-question-on-vaccines-and-autism/
[90] Ibid.
[91] Ibid.

science supporting a link between vaccines and autism.[92] For example, the CDC has not addressed a study which found a 300% increased rate of autism among newborns receiving the hepatitis B vaccine at birth compared to those that did not.[93] Nor a recent and first ever vaccinated vs. unvaccinated pilot study which found vaccinated children had a 420% increased rate of autism and that vaccinated preterm babies had an even higher rate of autism.[94] There is also a persuasive body of science supporting a connection between aluminum adjuvants in vaccines and autism which the CDC has, despite request, failed to directly or persuasively address.[95]

The CDC also failed to address the fact that a review of vaccine injuries compensated by HHS, through the vaccine injury compensation program established by the 1986 Act, "found eighty-three cases of autism among those compensated for vaccine-induced brain damage."[96]

The CDC ignores all the foregoing and continues to rely on its prior MMR-autism studies which, even putting aside Dr. Thompson's claims of concealment, are not applicable to any of the 25 doses of seven vaccines the CDC advised doctors to inject into babies during the first year of life.[97]

The critical need for the CDC to properly engage in vaccine safety science regarding autism is made even more vital by the fact that vaccine makers are immune from liability for vaccine injury and vaccines are not safety-tested prior to licensure to assess whether they cause autism. Without proper *long-term* safety studies comparing those receiving the vaccine to a true placebo group, it is impossible to know prior to licensure whether these products cause autism. There are also no follow-up studies which compare vaccinated to unvaccinated individuals and hence no supportable basis to claim that vaccines do not cause any cases of autism. For the CDC to make this claim, it must demonstrate that a child receiving the entire vaccine schedule is at no greater risk of becoming autistic than a child that is unvaccinated. No such study has ever been done.

The IOM Report referenced above has confirmed that the CDC cannot make this claim even for children receiving only the DTaP, let alone the entire vaccine schedule. It is thus plain that the CDC cannot validly claim that "Vaccines Do Not Cause Autism." The truth is, the CDC, at best, does not know.

5. CDC & IOM Ignore Massive Body of Science Supporting Vaccine Injuries

While the 2011 IOM Report has 75 pages of citations to peer-reviewed sources, there are far more peer-reviewed articles documenting vaccine injuries apparently not even considered by the 2011 IOM Report. Resources for references to these citations can be provided upon request.

[92] https://www.cdc.gov/vaccinesafety/concerns/autism.html
[93] http://hisunim.org.il/images/documents/scientific_literature/Gallagher_Goodman_HepB_2010.pdf
[94] http://www.cmsri.org/wp-content/uploads/2017/05/MawsonStudyHealthOutcomes5.8.2017.pdf
[95] http://vaccine-safety.s3.amazonaws.com/WhitePaper-AlumAdjuvantAutism.pdf
[96] http://digitalcommons.pace.edu/cgi/viewcontent.cgi?article=1681&context=pelr
[97] Further, studies of MMR and autism are simply erroneous because of healthy user bias, which has been emphasized as a serious source of error in epidemiological vaccine safety studies by the CDC's own scientists. https://www.ncbi.nlm.nih.gov/pubmed/1415136

A major theme among these peer-reviewed vaccine papers is the connection between vaccination and chronic disease, mainly autoimmunity and immune mediated neurological disorders and injuries. As detailed above, in the last 30 years, the CDC's childhood vaccine schedule has rapidly increased from 11 injections of 4 vaccines in 1986 to 56 injections of 30 vaccines in 2017. This upsurge has occurred in lock step with the precipitous increase in childhood chronic illness and developmental disabilities which have, during this same period, risen among American children from 12.8% to 54%.[98]

Many of the same disorders that have sharply risen during this period, including neurological and autoimmune disorders, are associated with vaccination as reflected in VAERS[99], manufacturer inserts for vaccines[100], and claims in the Vaccine Injury Compensation Program[101].

The causal mechanisms of these disorders are increasingly understood, and increasingly implicate vaccine exposure during early development.[102] For example, it is now known that early life immune activation can cause autism, mental illnesses, and immune disorders.[103] Vaccines and vaccine adjuvants (particularly in cases of adverse reactions) can cause the types of immune activation known to cause these disorders later in life.[104] Accordingly, there is an urgent and long-overdue need for higher quality vaccine safety research looking at long term neurological and immune outcomes.

Nonetheless, the 2011 IOM Report makes it clear that little has been ruled out with regard to what injures are caused by vaccines. In 2013, the IOM was again engaged by HHS to review the safety of the entire vaccine schedule on a population level.[105] The "committee's literature searches and review were intended to identify health outcomes associated with some aspect of the childhood immunization schedule."[106] "Allergy and asthma, autoimmunity, autism, other neurodevelopmental disorders (e.g., learning disabilities, tics, behavioral disorders, and intellectual disability), seizures, and epilepsy were included as search terms."[107]

Instead of answers, the IOM found that no studies had been conducted to validly assess the safety of the entire vaccine schedule or even portions of the vaccine schedule:

> *[F]ew studies have comprehensively assessed the association between the entire immunization schedule or variations in the overall schedule and categories of health outcomes, and no study … compared the differences in health outcomes … between entirely unimmunized populations of children and fully immunized children. Experts who addressed the committee pointed not to a body of evidence that had been overlooked but rather to the fact that existing research has not been designed to test the entire immunization schedule. …*

[98] https://www.ncbi.nlm.nih.gov/pubmed/20159870
[99] https://wonder.cdc.gov/vaers.html
[100] https://www.fda.gov/biologicsbloodvaccines/vaccines/approvedproducts/ucm093833.htm; See also Section III(7) below.
[101] http://www.uscfc.uscourts.gov/aggregator/sources/7; See also Section IV(4) below.
[102] https://www.ncbi.nlm.nih.gov/pubmed/27540164
[103] https://www.ncbi.nlm.nih.gov/pubmed/25311587
[104] https://www.ncbi.nlm.nih.gov/pubmed/26531688; https://www.ncbi.nlm.nih.gov/pubmed/27908630
[105] https://www.nap.edu/read/13563/chapter/1
[106] https://www.nap.edu/read/13563/chapter/2#5
[107] Ibid.

> *[Also,] studies designed to examine the long-term effects of the cumulative number of vaccines or other aspects of the immunization schedule have not been conducted.*[108]

While most of the 78 million children in America follow the CDC's childhood vaccine schedule, currently at 56 injections, no science has been done to confirm the safety of this schedule.[109] Even more alarming is that the IOM acknowledges that science does not yet even know "if there is a relationship between short-term adverse events following vaccination and long-term health issues."[110]

Due to the lack of science regarding the safety of the CDC vaccine schedule, the best the IOM could do was conclude: "There is no evidence that the schedule is not safe."[111] Left unsaid, but equally true: There is no evidence that the schedule is safe.

6. CDC Refuses to Conduct Vaccinated vs. Unvaccinated Study

The best and most efficient way to answer a large portion of the questions raised regarding vaccine safety would be a long-term, properly powered (*i.e.*, sized) study comparing the overall health outcomes of vaccinated and completely unvaccinated children. Parents and safety advocacy groups have been demanding for decades that HHS perform such a study. Even the CDC's internal vaccine committee recognizes that assessing "adverse events require more detailed epidemiologic studies to compare the incidence of the event among vaccinees to the incidence among unvaccinated persons."[112]

HHS has nonetheless consistently refused to study health outcomes of the completely unvaccinated. There have been, however, small-scale studies performed outside of HHS comparing vaccinated with completely unvaccinated children. And these smaller studies have consistently reported that the unvaccinated have much better health outcomes.

Dr. Peter Aaby is renowned for studying and promoting vaccines in Africa with over 300 published studies.[113] In 2017, he published a study finding children vaccinated with DTP were 10 times more likely to die in the first 6 months of life than the unvaccinated.[114] Dr. Aaby's study therefore concluded that: "All currently available evidence suggests that DTP vaccine may kill more children from other causes than it saves from diphtheria, tetanus or pertussis."[115] More disturbing is that children vaccinated with DTP were dying from causes never associated with this vaccine, such as respiratory infections, diarrhea, and malaria.[116] This indicated that while DTP

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[108] Ibid.
[109] Ibid.
[110] https://www.nap.edu/read/13563/chapter/5#45
[111] https://www.nap.edu/read/13563/chapter/2#12
[112] https://www.cdc.gov/mmwr/preview/mmwrhtml/rr6002a1.htm
[113] https://www.ncbi.nlm.nih.gov/pubmed/?term=PETER+AABY%5BAuthor+-+Full%5D
[114] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5360569/ Dr. Aaby's study was more reliable than other vaccine safety studies because the subjects were accurately matched. An increasingly recognized problem in vaccine safety studies is that subjects are typically not well-matched. People with pre-existing health problems are reluctant to receive a vaccine, and are therefore unwittingly used as controls. When this happens, the control group is sicker than the vaccine-exposed group at the outset of the study. Studies with this problem give wrong results, and make the vaccine look much safer than it really is. Dr. Aaby's study was one of the few specifically designed to avoid this error.
[115] Ibid.
[116] Ibid.

reduced the incidence of diphtheria, tetanus, and pertussis, it increased susceptibility to other infections.[117]

It is equally troubling that Dr. Aaby's study was based on data that had been collecting dust for over 30 years.[118] This begs the question: what other serious vaccine injuries are we missing because of neglect to conduct proper vaccine safety science?

A pilot study comparing 650 vaccinated and unvaccinated homeschooled children in the United States provides a glimpse of the potential scope of vaccine harm.[119] The study found that, compared to completely-unvaccinated children, fully-vaccinated children had an increased risk of 390% for allergies, 420% for ADHD, 420% for autism, 290% for eczema, 520% for learning disabilities, and 370% for any neuro-developmental delay.[120] Fully-vaccinated pre-term infants had an increased risk of 1,450% for a neurodevelopmental disorder, which includes a learning disability, ADHD or autism, compared to completely unvaccinated preterm infants.[121]

Another recent study compared children receiving the flu shot with those receiving a saline injection in a prospective randomized double-blind study.[122] Both groups had the same rate of influenza but the group receiving the flu shot had a 440% increased rate of non-influenza infection.[123] Like the DTP study, the flu vaccine increased susceptibility to other infections.

As a final example, the CDC in 2001 unwittingly conducted a narrow vaccinated versus unvaccinated study comparing children receiving the Hepatitis B vaccine during the first month of life versus those who did not.[124] The results of this study were never released by the CDC, and an abstract of the study was only recently obtained under a FOIA request.[125] Children vaccinated with Hepatitis B vaccine in the first month of life, compared to children receiving no vaccines in the first month of life, had an increased risk of 829% for ADHD, 762% for autism, 638% for ADD, 565% for tics, 498% for sleep disorders, and 206% for speech delays.[126]

The foregoing limited studies should have raised alarm bells at the CDC regarding the urgency of a proper vaccinated versus unvaccinated study that stakeholders have been demanding the CDC perform for over 20 years. The IOM has even confirmed such a study can be conducted using the CDC's VSD, a database of health records for almost ten million individuals maintained by the CDC.[127] As explained by the IOM: "It is possible to make this comparison [between vaccinated and unvaccinated children] through analyses of patient information contained in large databases such as VSD."[128] Such a retrospective epidemiological study would be quick, cheap and efficient; CDC could literally

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[117] Ibid.
[118] Ibid.
[119] http://www.oatext.com/pdf/JTS-3-186.pdf
[120] Ibid.
[121] http://www.oatext.com/pdf/JTS-3-187.pdf
[122] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3404712/
[123] Ibid.
[124] http://vaccine-safety.s3.amazonaws.com/CDC_FOIA_Response_UnpublishedStudy.pdf The CDC's study abstract discusses comparing thimerosal exposure by one month of age. Since the only vaccine recommended by one month of age was Hepatitis B, and since only thimerosal containing Hepatitis B vaccine was available at the time of this study, this study primarily compared children receiving Hepatitis B with children that did not receive this vaccine.
[125] Ibid.
[126] Ibid.
[127] https://www.nap.edu/read/13563/chapter/2#13
[128] Ibid.

conduct this study using the VSD in a matter of minutes. Yet it has never, as far as the public knows, been done. [129]

Every year tens of millions of American children are compelled to receive pediatric vaccines. Yet a large-scale study with completely-unvaccinated controls has never been performed to assess the long-term safety of the CDC's recommended vaccine schedule.[130] When vaccine makers are generating over $33 billion in vaccine revenue annually and the CDC is spending over $5 billion annually to promote and purchase vaccines, there is no justification for not performing this study.[131]

7. CDC Ignores Vaccine Manufacturer Disclosures of Potential Adverse Reactions

Vaccine makers are required by law to report to the FDA complaints they receive from consumers of serious adverse reactions from their vaccines.[132] A partial list of these serious adverse reactions is detailed below. While studies have been conducted for a few of these to confirm whether they are in fact caused by vaccines, the CDC has failed to conduct such studies for most of them.

Meningitis *(acute inflammation of protective membranes covering the brain and spinal cord)*; Thrombocytopenia *(low blood platelet count which can result from autoimmune action)*; Stevens-Johnson's Syndrome *(severe autoimmune reaction in which the top layer of skin is burned off and dies)*; Alopecia Areata *(autoimmune skin disease resulting in the loss of hair on the scalp and elsewhere on the body)*; Arthritis *(painful and disabling autoimmune disease that includes joint pain, swelling and progressive stiffness in the fingers, arms, legs and wrists)*; Rhinitis *(irritation and inflammation of nasal mucous membranes impacting ability to breathe properly)*; Insomnia; Lupus Erythematosus *(autoimmune disease in which immune system attacks healthy tissue, including skin, joint, kidney, brain, and other organs)*; Hypotension *(abnormally low blood pressure)*; Guillian-Barre Syndrome *(autoimmune disease that attacks the nerves in the legs, upper body, arms and/or face)*; Polyarteritis Nodosa *(systemic vasculitis that affect medium-sized and small muscular arteries resulting in ruptures and other damage)*; Encephalitis *(inflammation of the brain, which can result in permanent injury)*; Bell's Palsy *(disfiguring paralysis or weakness on one side of the face)*; Radiculopathy *(compressed or pinched nerve)*; Myelitis *(inflammation of spinal cord that can involve nerve pain, paralysis and incontinence)*; Multiple Sclerosis *(immune system attacks nerve fibers, causing them to deteriorate)*; Optic Neuritis *(inflammation*

[129] The CDC's inaction does not appear to be mere neglect since CDC Senior Scientist, Dr. Thompson, recently stated that a proper large scale vaccine safety study "needs to be done" but that the CDC is "not doing what they should be doing because they're afraid to look for things that might be associated." https://soundcloud.com/fomotion/cdc-whistle-blower-full-audio Dr. Thompson even explained that they have the data to conduct such a study and that "we're insane to be sitting on this data and not have an independent group" conduct this study but that it will not happen because "they don't really want people to know that this data exists." Ibid.

[130] In fact, due to the CDC's refusal to act, bills have been proposed in Congress to require such a study, but, the political clout for passage could not be mustered. *See, e.g.,* H.R. 1757 (2013) and H.R. 1636 (2015) ("to conduct or support a comprehensive study comparing total health outcomes ... in vaccinated populations in the United States with such outcomes in unvaccinated populations in the United States").

[131] https://www.hhs.gov/sites/default/files/fy2017-budget-in-brief.pdf; https://www.bccresearch.com/market-research/pharmaceuticals/vaccine-technologies-markets-report-phm014f.html

[132] 21 C.F.R. § 600.80(c)

causing eye pain and partial or complete vision loss); Aplastic anemia *(damage to the bone marrow which slows or shuts down the production of new blood cells)*; Aseptic Meningitis *(acute inflammation of the brain and spinal cord which can lead to death)*; Henoch-Schonlein purpura *(abnormal immune response resulting in inflammation of microscopic blood vessels which can result in multiple organ damage)*; Myalgia *(muscle pain that can become chronic)*; Radial nerve and recurrent nerve paralysis *(nerve injury to the radial nerve that can cause weakness or difficulty moving the wrist, hand or fingers)*; Encephalopathy with EEG disturbances *(damage or malfunction of the brain with severity ranging from altered mental status to dementia, seizures and coma)*; Grand Mal Convulsion *(loss of consciousness and violent muscle contractions)*; Sudden Infant Death Syndrome *(sudden death of infant in good health)*; Diabetes mellitus *(chronic, lifelong condition effecting ability to use energy found in food)*; Pancreatitis *(pancreas attacks its own digestive enzymes)*; Encephalomyelitis *(inflammation of the brain and spinal cord)*; Transverse myelitis *(autoimmunity causing inflamed spinal cord which may result in paralsis)*; *Pneumonitis (inflammation of lung tissue)*; Ocular Palsies *(damage to the nerve of the eye that controls eye movement)*; Ataxia *(brain damage resulting loss of full control of bodily movement, impaired speech, eye movement, and swallowing)*; Retrobulbar Neuritis *(inflammation and damage to the optic nerve between the back of the eye and the brain)*; Epididymitis *(inflammation testicle tube which can lead to abscess formation, testicular pain, painful urination, tissue death, and decreased functionality of gonads)*; Orchitis *(inflammation of one or more testicles that can cause infertility, testicular atrophy, pain, and severe pain)*; Nerve Deafness *(hearing loss from damage to the nerve that runs from the ear to the brain)*.[133]

IV. CONFLICTS OF INTEREST IN VACCINE SAFETY

The 1986 Act created a system in which vaccines are licensed, recommended, encouraged, subsidized, and defended by HHS (the **Vaccine Program**).

The lack of evidence supporting vaccine safety is partially the result of the 1986 Act's unfortunate scheme which places the same agency, HHS, in charge of two conflicting duties. On the one hand, HHS is responsible for vaccine safety. On the other hand, HHS is simultaneously required to promote vaccine uptake and defend against any claim that vaccines cause any harm.

Regrettably, it appears that HHS has chosen to focus almost entirely on its vaccine promotion and defense responsibilities to such a degree that it has essentially abandoned its vaccine safety responsibility.

The Vaccine Program has transformed what should be a government watchdog over the pharmaceutical industry with regard to vaccines into an industry partner, with the same interests of promoting and literally defending, with the Department of Justice (**DOJ**) as its defense firm, against any claim of

[133] See vaccine products inserts at https://www.fda.gov/biologicsbloodvaccines/vaccines/approvedproducts/ucm093833.htm

vaccine injury. The result – as reflected in scathing reports by Congress and the HHS Inspector General – is that the Vaccine Program is fraught with pervasive conflicts of interests both structurally and literally with pharmaceutical company insiders.

Usually, when a government watchdog becomes ineffective or conflicted, consumers turn to the last line of recourse against harm caused by a product: class action and product liability attorneys. But in the case of vaccines, even they have been neutered because of the immunity from financial lability given to pharmaceutical companies for harms caused by their vaccines.

The Vaccine Program created by the 1986 Act has unfortunately resulted in a complete lack of accountability for vaccine safety.

1. HHS Licenses Vaccines

The introduction of a new vaccine begins with its licensure by the FDA. A committee at the FDA, the Vaccines and Related Biological Products Advisory Committee (**VRBPAC**), "advises the FDA on whether or not to license new vaccines for commercial use."[134] In reality this committee effectively decides whether a new vaccine gets licensed since its recommendations for licensure are almost always accepted by the FDA. Unfortunately, the members of this board are often pharmaceutical insiders and, as discussed in Section II above, they license vaccines with virtually no safety data.

By the year 2000, most pediatric vaccines on the CDC's vaccine schedule were already licensed by the FDA. That same year, the U.S. House of Representatives' Committee on Government Reform (the **Committee**) issued a report revealing serious conflicts of interest in the VRBPAC.[135] The Committee "determined that conflict of interest rules employed by the FDA and the CDC have been weak, enforcement has been lax, and committee members with substantial ties to pharmaceutical companies have been given waivers to participate in committee proceedings."[136] The Committee further explained that:

> *Perhaps one of the major problems contributing to the overall influence of the pharmaceutical industry over the vaccine approval and recommendation process may be the loose standards that are used by the agency in determining whether a conflict actually exists. In many cases, significant conflicts of interest are not deemed to be conflicts at all.*[137]

For instance, the Committee found that "3 out of 5 FDA advisory committee [VRBPAC] members who voted to approve the rotavirus vaccine in December 1997 [then the most recently approved vaccine by the VRBPAC] had financial ties to pharmaceutical companies that were developing different versions of the vaccine."[138]

Among these five VRBPAC members present and voting to license the rotavirus vaccine: one member's employer had a $9,586,000 contract for a rotavirus vaccine;

[134] http://vaccinesafetycommission.org/pdfs/Conflicts-Govt-Reform.pdf
[135] http://vaccinesafetycommission.org/pdfs/Conflicts-Govt-Reform.pdf
[136] Ibid.
[137] Ibid.
[138] Ibid.

another member was the principal investigator for a grant from Merck for the development of a rotavirus vaccine; two other members received almost $1,000,000 from vaccine manufacturers toward vaccine development; and even the "consumer advocate" member (an ardent vaccine supporter) had received honoraria, in addition to travel expenses, from Merck.[139]

These members voted to approve this pediatric vaccine even though a temporary voting member raised the following concern: "I would ask the FDA to work with the sponsor to further quantitate what these serious side effects are – specifically the adverse effects, driven in particular by febrile illness – is inducing hospitalizations and what is that level of access. I still don't feel like I have a good grasp of that at this point."[140]

Regarding the VRBPAC, the Committee concluded: "The overwhelming majority of members, both voting members and consultants, have substantial ties to the pharmaceutical industry."[141] Hence, even putting aside the astonishing lack of safety review prior to licensure, extensive conflicts were found to pervade the HHS committee that largely determined whether to license the pediatric vaccines currently on the market.

2. HHS Recommends Vaccines

After a pediatric vaccine is licensed with virtually no safety data by an HHS committee rife with conflicts of interest, another HHS committee, the CDC's Advisory Committee on Immunization Practices (**ACIP**), decides whether to recommend the vaccine for all children in America.

ACIP is the only federal entity to make vaccination recommendations and these recommendations are consistently approved by the CDC.[142] A recommendation by ACIP "for routine use of a vaccine is tantamount to a Federal mandate for vaccine use."[143] This is because "HHS regulations require that all grants for childhood immunizations are subject to the States' implementation of procedures to ensure routine vaccination ... [and] vigorous enforcement of school immunization laws."[144]

ACIP-recommended vaccines are also subsidized by the federal government.[145] In fact, 41% of the entire childhood vaccine market is purchased through ACIP resolutions.[146] This currently amounts to over $4 billion paid to vaccine makers by the CDC, accounting for a third of the CDC's current budget.[147]

Putting all this together: as a result of the 1986 Act, **when the ACIP votes to recommend a pediatric vaccine for general use, the pharmaceutical industry is handed a liability-free, captive market of 78 million children with guaranteed payment**. It is not surprising that with this economic incentive,

[139] Ibid.
[140] Ibid.
[141] Ibid.
[142] Ibid.
[143] Ibid.
[144] Ibid.
[145] https://doi.org/10.1086/420748
[146] Ibid. (Once ACIP votes to add a vaccine to the Vaccine for Children program, payment is provided to vaccine makers without needing additional Congressional appropriations. As pointed out by the CDC: "It is unusual that a federal advisory committee has the power and authority to add benefits to an entitlement program." It is also noteworthy that another 11% of the pediatric vaccine market is purchased through other Congressional appropriations and another 5% from state and local government funding.)
[147] https://www.hhs.gov/sites/default/files/fy2017-budget-in-brief.pdf

the vaccine market has catapulted from $170 million in 1982 to over $33 billion in 2016.[148]

Given these economic incentives, it is obvious that the ACIP should be scrupulously shielded from even an apparent – let alone actual – conflict of interest with vaccine makers. Unfortunately, government reports have found the exact opposite.

The ACIP is comprised of 15 voting members that are *not* federal government employees. Fourteen of these voting members must be medical professionals in the area of immunization.[149] There are also eight non-voting members who represent federal agencies with responsibility for immunization programs and an additional 26 non-voting members of liaison organizations, many of which receive financial support from vaccine makers.[150] As the U.S. House Committee on Government Reform concluded:

> *The absence of any consumer advocates on the ACIP has resulted in an advisory committee that is inherently not 'fairly balanced.'*[151]

Far worse than the structural conflicts in ACIP's composition are the actual conflicts of interests of its members. These conflicts have been highlighted by multiple government reports but due to gridlock and disparate influence on Congress by pharmaceutical companies, Congress has never moved to fix the issues and conflicts it has identified.

One investigation by the U.S. House Committee on Government Reform resulted in a June 15, 2000 report entitled *Conflicts of Interest in Vaccine Policy Making*.[152] The Committee found that ACIP members routinely fail to disclose conflicts with vaccine manufacturers.[153] Moreover, as a matter of routine, "[t]he CDC grants blanket waivers to the ACIP members each year that allow them to deliberate on any subject, regardless of their conflicts, for the entire year."[154] In the congressional inquiry, legal counsel for the ACIP *conceded* that even when serious conflicts are identified, "we generally give them [waivers] to everyone ... we give them out freely."[155] The Committee on Government Reform was troubled:

> *The CDC's policy of issuing annual waivers creates an environment where people do not take the conflict of interest issue as seriously as they should. This policy, in concert with sloppy monitoring of the completeness of members' financial disclosure statements, allows for a clubby environment where ethical concerns are downplayed.*[156]

As an example of this "clubby environment," the Committee found: "Members of the ACIP are allowed to vote on a recommendation for one company's vaccine even if they have

[148] https://www.bccresearch.com/market-research/pharmaceuticals/vaccine-technologies-markets-report-phm014f.html; https://www.ncbi.nlm.nih.gov/books/NBK216815/
[149] https://www.cdc.gov/vaccines/acip/committee/downloads/nominations.pdf
[150] https://www.cdc.gov/vaccines/acip/committee/acip-charter-2016.pdf
[151] http://vaccinesafetycommission.org/pdfs/Conflicts-Govt-Reform.pdf
[152] Ibid.
[153] Ibid.
[154] Ibid.
[155] Ibid.
[156] Ibid.

financial ties to a competing firm developing a similar vaccine."[157]

Highlighting these conflict issues, the Committee drew focus on the vaccine most recently approved by the ACIP, a rotavirus vaccine, and whatever conflicts they could identify for the eight members of the ACIP that voted to approve that vaccine for routine pediatric use.[158] The Committee's findings were damning: (1) The chairman served on Merck's Immunization Advisory Board; (2) another member, who shared the patent on a rotavirus vaccine, had a $350,000 grant from Merck to develop the vaccine, and was a consultant for Merck; (3) another member was under contract with the Merck Vaccine Division and received funds from various vaccine makers including Pasteur, and was a principal investigator for SmithKline; (4) another member received a salary and other payments from Merck; (5) another member participated in vaccine studies with Merck, Wyeth, and SmithKline; and (6) another member received grants from Merck and SmithKline.[159]

The Committee was deeply troubled that these members were nonetheless allowed to vote to recommend a pediatric vaccine for universal use.[160]

The Committee was further concerned by its finding that "ACIP liaison representatives have numerous ties to vaccine manufacturers."[161] The Committee found that these liaison members, through whom third-party organizations are permitted to provide opinions regarding a vaccine under review, "provide more than just the opinions."[162] The Committee found them "more like" a voting member of ACIP "than an advisory representative."[163] The advice of these liaison representatives "is solicited frequently by CDC personnel on issues where their organization has a financial interest."[164]

The ACIP also routinely forms subcommittees (called "working groups") which convene behind closed doors and whose recommendations are typically rubber stamped by the ACIP.[165] The Committee was troubled by extensive and routine use of working groups since the participants in these working groups often had conflicts which would have prohibited them from voting during an actual ACIP meeting.[166] The Committee explained: "The ACIPs prolific use of working groups to draft vaccine policy recommendations outside the specter of public scrutiny opens the door to undue special interest access."[167] Regarding the ACIP's most recent working group recommending approval of a vaccine, the Committee found:

> *The working group has ten members, seven of whom have identifiable conflicts of interest with vaccine manufacturers or vaccine interest groups. The group's meetings were held in private with no minutes or records of the proceedings taken. It appears that members who were not allowed to vote because of conflicts of interest ... were allowed to work*

[157] Ibid.
[158] Ibid.
[159] Ibid.
[160] Ibid.
[161] Ibid.
[162] Ibid.
[163] Ibid.
[164] Ibid.
[165] Ibid.
[166] Ibid.
[167] Ibid.

extensively on the recommendation for a long period of time in the working group.[168]

The Committee's damning overall conclusion was that ACIP's process for recommending a vaccine reflected "a system where government officials make crucial decisions affecting American children without the advice and consent of the governed."[169]

After the Committee's scathing report in 2000, one would expect nothing less than drastic reform of ACIP – something that would differentiate it from a biased and self-interested pharmaceutical company board so that the interests of American children are placed ahead of the companies with the resources to influence government. This expectation unfortunately has not been fulfilled.

Indeed, in December 2009, the HHS Office of Inspector General issued another report after an extensive review of the conflicts of CDC's advisory committee members, known as Special Government Employee (**SGEs**), with the first among these committees being the ACIP.[170] The Inspector General found that the "CDC had a systemic lack of oversight of the ethics program for SGEs."[171] For example, the Inspector General found that: "Most of the experts who served on advisory panels in 2007 to evaluate vaccines for flu and cervical cancer had potential conflicts that were never resolved."[172]

The Inspector General reached this conclusion after reviewing the conflict forms, Form 450's, filed by SGEs at the CDC. CDC "must obtain from SGEs" a completed Form 450, which includes "assets, sources of income, and non-income-earning activities."[173] Then, "[b]efore permitting SGEs to participate in committee meetings, CDC must review these forms and certify them to indicate that they are complete and that it has identified and resolved all conflicts of interest."[174] Reviewing CDC's compliance with these requirements, the Inspector General found that nothing had changed in the years since the scathing Congressional Committee on Government Reform report in 2000.[175]

Indeed, the Inspector General found that "CDC certified OGE Forms 450 with at least one omission in 2007 for 97 percent … of SGEs."[176] Almost all of these "had more than one type of omission."[177] Compounding this problem, the Inspector General found that "58 percent … of SGEs had at least one potential conflict of interest that CDC did not identify."[178] Splicing down this 58% of unidentified conflicts, 40% involved employment or grants, 13% involved equity ownership, and 5% involved consulting.[179]

These conflicts are serious, and the CDC "did not inform the SGEs that they would violate the criminal conflict-of-interest statute if they participated in committee work regarding particular matters affecting their specific employers' financial interests."[180]

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[168] Ibid.
[169] Ibid.
[170] https://oig.hhs.gov/oei/reports/oei-04-07-00260.pdf
[171] Ibid.
[172] http://www.nytimes.com/2009/12/18/health/policy/18cdc.html?mcubz=0
[173] https://oig.hhs.gov/oei/reports/oei-04-07-00260.pdf
[174] Ibid.
[175] Ibid.
[176] Ibid.
[177] Ibid.
[178] Ibid.
[179] Ibid.
[180] Ibid.

The Inspector General further concluded that even when the CDC actually identified a conflict, the CDC improperly granted broad waivers despite already being castigated for this improper practice in 2000.[181] Even worse, "32 percent … of SGEs with certified forms had at least one potential conflict of interest that CDC identified but did not resolve."[182] Amazingly, 13 percent of SGEs were allowed to participate in committee meetings without even having a Form 450 on file.[183]

In sum, even after the blistering 2000 Committee on Government Reform report, and numerous damning Congressional hearings before that committee regarding CDC's conflicts with vaccine makers, little changed.[184] Instead of resolving and avoiding these conflicts, the "incestuous relationship" between the CDC and vaccine makers has apparently become even more hardened and enmeshed.[185]

Since an ACIP vote to recommend a vaccine hands a vaccine maker a liability-free market of 78 million American children with guaranteed payment, an ACIP vote must be completely insulated from any influence by pharmaceutical companies. Instead, the ACIP and its working groups, are inundated with conflicts of interest and ties to these companies.

3. HHS Promotes Vaccines

Not only is the process for licensing and recommending vaccines riddled with conflicts, so is HHS's process for promoting vaccines.

While the CDC states on its website – not less than 130 times – that "CDC does not accept commercial support," this is simply not true.[186] For example, in reviewing this very issue, the British Medical Journal, which it asserts is "one of the world's most influential and widely read medical journals," reported in 2015:

> *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.*[187]

Explaining the concern with CDC receiving industry funding, the Journal described this as "classic stealth marketing, in which industry puts their message in the mouths of a trusted third party [here the CDC]."[188] The Journal quoted a methodologist and emeritus professor of medicine at UCLA stating, "Most of us were shocked to learn the CDC takes

[181] Ibid.
[182] Ibid.
[183] Ibid.
[184] *Compare* http://vaccinesafetycommission.org/pdfs/Conflicts-Govt-Reform.pdf *with* Ibid.
[185] https://cdn.voiceamerica.com/health/010278/arranga040814.mp3
[186] https://search.cdc.gov/search?query=%22cdc+does+not+accept+commercial+support%22&utf8=%E2%9C%93&affiliate=cdc-main
[187] http://vapers.org.uk/wp-content/uploads/2015/05/CDC-Industry-Funding.pdf
[188] Ibid.

funding from industry," adding that, "it is outrageous that industry apparently is allowed to punish the CDC if the agency conducts research that has the potential to cut into profits."[189]

As another example, Congress expressly created a private foundation, the "CDC Foundation," through which private entities, such as pharmaceutical companies, can support programs at the CDC, endow positions at the CDC, and even place individuals to work at the CDC, paid through "private funding."[190]

Since 1995 the CDC Foundation has raised $620 million to pay for 824 programs at the CDC.[191] In 2015 alone, the CDC Foundation raised $157 million for privately funded programs at the CDC, which then obtain the stamp of legitimacy of the CDC.[192] Merck, for example, funded an $832,916 program through the CDC Foundation to "expand CDC's ... viral hepatitis prevention and vaccination activities."[193] As a result, the CDC is reliant on the CDC Foundation for the continued funding of these projects, and even for the services of the staff placed at the CDC by the CDC Foundation, since the CDC is only permitted to use these funds as expressly directed by the CDC Foundation.[194] This foundation even funds and thus directs CDC "management training courses."[195]

Worse, the promotion track for CDC management extends into vaccine makers. The most prominent example is former CDC Director Dr. Julie Gerberding who headed the CDC from 2002 to 2009. Dr. Gerberding oversaw several controversial studies regarding vaccines produced by Merck, including notably the MMR vaccine, which sought to silence those calling for an increase in the safety profile of those vaccines. When she left the CDC she was rewarded with the position of President of Merck Vaccines in 2010 with a reported estimated $2.5 million annual salary and lucrative stock options.[196]

In contrast, the few CDC officials who have attempted to blow the whistle on how vaccine safety research is conducted and treated at the CDC have become targets of character assassination. For example, following revelations of Dr. Thompson's statements regarding the CDC's improper conduct[197] (some of which was discussed above), he soon found himself marginalized and publicly maligned, despite the CDC's prior reliance on him for over a decade to produce most of its core vaccine safety science.[198]

As Congressman Bill Posey explained in 2014 after investigating the CDC's approach to vaccine safety: the CDC and vaccine industry's "media network [will] twist the truth to disparage, to malign, to vilify, to denigrate anybody who wants any kind of accountability" and added that his review of CDC emails discussing vaccine safety "will make you absolutely sick to your stomach."[199]

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189 Ibid.
190 42 U.S.C.A. §§ 280e-11(h)(1), (2)
191 http://www.cdcfoundation.org/FY2015
192 Ibid.
193 Ibid.
194 42 U.S.C.A. § 280e-11(h)(2)(a)), (7)(b)
195 https://www.cdcfoundation.org/sites/default/files/upload/pdf/CDCF-Form990-2014.pdf
196 https://www.sec.gov/cgi-bin/own-disp?action=getowner&CIK=0001628884
197 https://soundcloud.com/fomotion/cdc-whistle-blower-full-audio
198 https://www.ncbi.nlm.nih.gov/pubmed/?term=Thompson+WW%5BAuthor%5D
199 https://cdn.voiceamerica.com/health/010278/arranga040814.mp3

4. HHS Defends Vaccines

After HHS licenses, effectively mandates, and promotes a vaccine to 78 million American children with virtually no safety data, *this very same government agency is mandated to defend against any claim that the vaccine caused harm*. There is no other product where the very agency responsible to regulate a product and assure its safety is statutorily required to defend against any claim it causes harm.

The Vaccine Injury Compensation Program (**VICP** or **Vaccine Court**) is effectively the only legal recourse in America to obtain compensation for a pediatric vaccine injury.[200] The injured must file a claim in the VICP and litigate against HHS and the DOJ in a quasi-judicial process filed under seal where the injured child effectively cannot obtain documents from or depose vaccine makers to prove how the vaccine caused injury.[201] There is no jury, nor even a judge; special masters play the role of trial judges, with the final say.[202] DOJ and HHS have the government's vast resources while the injured must secure a private attorney.[203] Moreover, an injured child's damages are limited to $250,000 for death and pain and suffering.[204]

Worst of all, despite these limitations, the injured child must *still* almost always prove "causation" – the biological mechanism by which the vaccine caused the claimed injury. Requiring an injured child to prove causation adds insult to injury because, sadly, had HHS conducted the vaccine safety science it demands as proof in the VICP before licensing a vaccine, the child's injury may have been avoided altogether.

There is a disconnect in requiring a child receiving a compulsory pharmaceutical product to medically prove how the vaccine caused his or her injury, where the science to understand vaccine injuries is not being done by the government agency tasked with this job.[205] As confirmed by the IOM, HHS has not conducted the basic science needed to even determine whether commonly claimed vaccine injuries are caused by vaccines.[206] It has failed to conduct even one properly sized study comparing vaccinated to unvaccinated children, despite all the resources at its disposal.[207] It therefore may not be surprising that the Federal Circuit Court of Appeals found, medical science is "a field bereft of complete and direct proof of how vaccines affect the human body."[208]

The Committee on Government Reform explained the devastating consequences suffered by families when children are injured by a vaccine:

> *Every year, a number of children are seriously injured by adverse reactions to vaccines. When such a tragedy befalls a family, they are faced with devastating emotional and financial consequences. As the devastation of adverse reactions can lead to paralysis, permanent disability and death, families without adequate insurance can face enormous expenses, including*

[200] 42 U.S.C. § 300aa-10 et seq.
[201] 42 U.S.C. § 300aa-12
[202] Ibid.
[203] 42 U.S.C. § 300aa-15
[204] Ibid.
[205] See Sections II and III above.
[206] See Section III(2) above.
[207] See Section III(6) above.
[208] *Althen v. Secretary of Health and Human Services*, 418 F.3d 1274 (Fed. Cir. 2005)

> *residential care, therapy, medical equipment, and drugs.*[209]

Yet it is left to the injured child to prove the physiological mechanics by which the vaccine caused injury.[210]

Moreover, Congress left HHS with the authority to set the rules for the VICP and so HHS has used this authority to shortcut its defense of claims for vaccine injuries by changing the rules in its favor. Indeed, the 1986 Act created a Vaccine Injury Table (the **Table**) which quickly compensated certain common injuries associated with each vaccine.[211] If the petitioner suffered an injury on the Table, the burden would shift to HHS to prove the vaccine did not cause the injury.[212] After passage of the 1986 Act, almost 90 percent of claims were Table claims and were quickly settled.[213] Soon after, in 1995 and 1997, HHS amended the Table such that 98% of new claims are off-Table.[214] This change greatly increased the difficulty of obtaining compensation for vaccine injuries.

While HHS changes the VICP rules in its favor, the Committee on Government Reform found "DOJ attorneys make full use of the apparently limitless resources available to them," "pursued aggressive defenses in compensation cases," and "establish[ed] a cadre of attorneys specializing in vaccine injury" and "an expert witness program to challenge claims."[215] The Committee even noted a VICP decision which stated:

> *In the special master's view, [HHS's] counsel's abrasive, tenacious, obstreperous litigation tactics were inappropriate in a program that is intended to be less adversarial; and hindered greatly a fair, expeditious resolution of the case. In addition, counsel lacks simply tact and compassion. Quite frankly; the special master is embarrassed that [HHS's] counsel and ... life care planner represented the United States Government in this case.*[216]

The length of time it has taken to adjudicate claims has also multiplied such that over half of claims now take over five years.[217]

Even with all the foregoing barriers to obtaining compensation for a vaccine injury – notably requiring injured children to prove causation and capping damages for pain and suffering and death at $250,000 – the VICP has paid over $2.1 billion dollars for vaccine injury claims since 2007 and over $3.7 billion since 1986.[218] Just a few of the serious vaccine injuries for which the VICP has paid include:

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[209] https://www.congress.gov/106/crpt/hrpt977/CRPT-106hrpt977.pdf

[210] Further compounding the above issues, babies are unable to describe their symptoms which may explain why most VICP claims are filed by adults. Most adults bring claims for injury after a single flu shot. (https://www.hrsa.gov/vaccinecompensation/data/vicpmonthlyreporttemplate8_1_17.pdf) In contrast, babies receive between five and seven injections of numerous vaccine doses at two months, four months, six months, etc. (See Section I above.) If babies could talk, they may be able to explain why they are crying inconsolably, have decreased activity/lethargy, drowsiness, irritability, fussiness, and loss of appetite – reactions that are considered "normal" side effects of vaccination. (See vaccine product inserts at https://www.fda.gov/biologicsbloodvaccines/vaccines/approvedproducts/ucm093833.htm) But since babies can't talk, the symptoms which would explain a neurological injury, for example, are not knowable until later in life when it is too late to assert a claim.

[211] https://www.hrsa.gov/vaccinecompensation/vaccineinjurytable.pdf

[212] 42 U.S.C. § 300aa-13

[213] Stevens v. Secretary of the Department of Health & Human Services, No. 99-594V (Office of Special Masters 2001)

[214] http://www.gao.gov/assets/670/667136.pdf

[215] https://www.congress.gov/106/crpt/hrpt977/CRPT-106hrpt977.pdf

[216] Ibid.

[217] http://www.gao.gov/assets/670/667136.pdf

[218] https://www.hrsa.gov/vaccinecompensation/data/vicpmonthlyreporttemplate8_1_17.pdf; 42 U.S.C.A. § 300aa-15(a)(2), (4)

> *Guillain-Barre Syndrome, Transverse Myelitis, Encephalopathy (disease altering brain function), Seizure Disorder, Death, Brachial Neuritis, CIDP (inflammation damaging the brain and spinal cord), Acute Disseminated Encephalomyelitis, Premature Ovarian Failure, Bell's Palsy, Idiopathic Thrombocytopenic Purpura (ITP) (autoimmune disease of the blood), Juvenile Diabetes, Rheumatoid Arthritis, Multiple Sclerosis, Fibromyalgia, Infantile Spasms, Anaphylaxis, Ocular Myasthenia Gravis (autoimmune condition causing visual impairments), Hypoxic Seizure*[219]

Recognizing the depths of the foregoing issues and conflicts, in 2006 a bi-partisan group of seven congressmen proposed a bill to create an entirely new government agency solely devoted to vaccine safety.[220] The primary sponsor of this bill explained the need for this bill as follows:

> *Federal agencies charged with overseeing vaccine safety research have failed. They have failed to provide sufficient resources for vaccine safety research. They have failed to fund extramural research. And, they have failed to free themselves from conflicts of interest that serve to undermine public confidence in the safety of vaccines.*
>
> *The American public deserves better and increasingly parents and the public at large are demanding better.*
>
> *I'm a physician. … When I first began working on this issue about seven years ago, I was shocked at the dearth of resources dedicated to vaccine safety research. …*
>
> *When I first tasked my staff with investigating this issue we got a lot of confused responses from federal agencies. The FDA told us to check in with the CDC, saying CDC did most of the vaccine safety research. The CDC referred us over to the NIH. Then, the NIH referred us back to the CDC. …*
>
> *Several issues relating to vaccine safety have persisted for years. The response from public health agencies has been largely defensive from the outset and the studies plagued by conflicts of interest. …*
>
> *Presently, vaccine safety research is an in-house function conducted predominantly by the CDC – the very agency that makes vaccine*

[219] *See, e.g.*, *Kuperus v. Sec'y of the HHS*, No. 01-0060V, 2003 U.S. Claims LEXIS 397 (Fed. Cl. Oct. 23, 2003) (Acute Disseminated Encephalitis from DTaP); *Lerwick v. Sec'y of HHS*, No. 06-847V, 2010 U.S. Claims LEXIS 398 (Fed. Cl. May 26, 2010) (Acute Disseminated Encephalitis from DTaP); *Price v. Sec'y of HHS*, No. 11-442V, 2015 U.S. Claims LEXIS 1554 (Fed. Cl. Oct. 29, 2015) (Anaphylaxis from DTaP); *Rodriguez v. Sec'y of the HHS*, No. 06-559V, 2007 U.S. Claims LEXIS 685 (Fed. Cl. Sep. 14, 2007) (Death from DTaP); *Harry Tembenis & Gina Tembenis v. Sec'y of HHS*, No. 03-2820V, 2010 U.S. Claims LEXIS 950 (Fed. Cl. Nov. 29, 2010) (Death from DTaP); *Agresti v. Sec'y of HHS*, No. 05-0752V, 2009 U.S. Claims LEXIS 517 (Fed. Cl. Mar. 17, 2009) (Encephalopathy from DTaP); *Corzine v. Sec'y of the HHS*, No. 01-230V, 2004 U.S. Claims LEXIS 116 (Fed. Cl. Apr. 23, 2004) (Hypoxic seizure leading to Death from DTaP); *Loving v. Sec'y of HHS*, No. 02-469V, 2013 U.S. Claims LEXIS 1570 (Fed. Cl. Sep. 20, 2013) (Infantile Spasms and Seizure Disorder from DTaP); *Herrell v. Sec'y of the HHS*, No. 08-123V, 2009 U.S. Claims LEXIS 577 (Fed. Cl. Jan. 6, 2009) (Idopathic Thrombocytopenic Purpura from MMR); *Zatuchni v. Sec'y of HHS (In re Snyder)*, No. 94-58V, 2006 U.S. Claims LEXIS 127 (Fed. Cl. May 10, 2006) (Fibromyalgia leading to death from MMR); *Francis v. Sec'y of the HHS*, No. 99-520V, 2007 U.S. Claims LEXIS 172 (Fed. Cl. May 23, 2007) (Ocular Myasthenia Gravis from Varicella).

[220] https://www.congress.gov/bill/109th-congress/house-bill/5887

> *recommendations and promotes their uptake. This should not be.*[221]

This bill did not get out of committee, a fact which likely reflects the ratio of over 1,000 pharma lobbyists in Washington D.C. to virtually no vaccine safety lobbyists.

Many parents, doctors and scientists, as well as politicians, are legitimately concerned about the process whereby vaccines are licensed, recommended, promoted and defended by the same department. This is not because of any conspiracy, or belief in an insidious intent. Rather, the problem is with the structural conflicts and incentive scheme this system creates. There is no incentive for research to uncover which long-term chronic conditions, including which immune and neurological disorders – which *can* clearly result from the current vaccination schedule – are caused by vaccines. Even worse is the disincentive to uncover susceptible populations to vaccine injury. The burden of judging whether a vaccine will seriously injure a child therefore falls on the child's parents. But unless parents can identify with scientific accuracy how a vaccine will injure their child, parents cannot obtain a medical exemption from vaccinating their child. Worse, when a child is injured, the burden again falls on the parent to prove how the vaccine injured their child. This system is inherently unfair and unjust.

CONCLUSION

We can do better. With hundreds of vaccines in the pipeline we must do better. Children susceptible to vaccine injury are as deserving of protection as any other child. Avoiding injury to these children is not only a moral and ethical duty, but will, in fact, strengthen the Vaccine Program. Every parent that does not witness their child suffer a serious reaction after vaccination, such as a seizure or paralysis, is another parent that will not add their voice to the growing chorus of parents opposed to the Vaccine Program due to safety concerns.

These parents and their kindred doctors, scientists and politicians, are also in fact correct that the system for vaccine safety is broken. While we know that vaccines can cause serious adverse reactions, the studies to quantify the rate at which it causes these harms have never been done. While we know that certain children are predisposed to serious injury from vaccines, the studies to identify which children are so disposed have never been done. While we know that valid pre-licensure safety trials take years and must use an inert placebo control, such pre-licensure safety trials are never done for any vaccine. While we know that post-licensure surveillance of vaccines captures less than one percent of adverse reactions, the CDC refused to cooperate to automate VAERS reporting.

In the zeal to protect the Vaccine Program the primary objective of protecting every child to the greatest extent possible from

[221] http://vaccine-safety.s3.amazonaws.com/Weldon_Statement_Vaccine_Safety_final.pdf

harm has been lost. Every child susceptible to a vaccine injury or injured by a vaccine deserves better.

The good news is that fixing this system is not complicated and would require a tiny fraction of the resources already devoted to the Vaccine Program. The quickest solution would be to repeal the 1986 Act and let normal market forces drive vaccine safety. Alternatively, the following actions would immediately correct many of the issues identified in this white-paper:

Reduce Conflicts

1. Prohibit any conflict waivers for members of HHS's vaccine committees.[222]

2. Prohibit HHS vaccine committee members or employees from accepting any compensation from a vaccine maker for twenty years.

3. Require that vaccine safety advocates comprise at least half of HHS's vaccine committees.

Increase Safety Profile

4. Conduct prospective double-blind saline-placebo controlled studies of each vaccine recommended by the CDC as well as the entire CDC vaccine schedule.

5. Conduct properly sized and controlled retrospective and prospective safety studies comparing total health outcomes between vaccinated children and completely unvaccinated children.

6. Create a vaccine safety agency independent of HHS with a budget equal to 50% of HHS's budget for promoting and purchasing vaccines.

7. Automate creation and transmission of adverse reactions reports at hospital/clinic to VAERS.

[222] HHS's vaccine committees include the Advisory Committee on Immunization Practices (ACIP), the Vaccine and Related Biological Products Advisory Committee (VRBPAC), the National Vaccine Advisory Committee (NVAC), and the Advisory Commission on Childhood Vaccines (ACCV).

APPENDIX: Vaccine Ingredients

Most pediatric vaccines do not contain live viruses.[223] For example, (i) polio vaccine (IPV) only contains a killed virus, (ii) hepatitis b vaccine contains a portion of a killed virus, and (iii) diphtheria vaccine contains only a modified toxin released by the diphtheria bacteria.[224] These pieces of killed bacteria or virus or modified toxins are commonly referred to as "antigens." An injection of antigen alone, with nothing more, produces a weak immune response insufficient for creating long-term immunity.[225]

Therefore, many vaccines also contain an "adjuvant," an immune-stimulating substance that increase the immune response to the antigen, so that immunity is created. Aluminum compounds are by far the most commonly used adjuvants in vaccines. They are made of particles of aluminum hydroxide, aluminum phosphate or aluminum sulfate, or mixtures thereof.[226]

It is universally accepted that aluminum is a potent neurotoxin, and toxic to all life.[227] Accordingly, the FDA has established strict limits for aluminum in intravenous feeding solutions (.000005 grams per kg body weight per day). Exposure in infants exceeding this limit causes long term cognitive impairment.[228]

A significant safety problem with aluminum adjuvants is that, because they are made of microscopic particles, they can travel into the brain.[229] Once in the brain, aluminum adjuvants cause long term chronic inflammation.[230] Inflammation in the brain is a cause of neurodevelopmental disorders (e.g. autism) and mental illnesses (e.g. schizophrenia).[231] The resulting mental illness can occur years or decades after the inflammation starts.[232]

Exposure to aluminum adjuvants has increased dramatically in the last 50 years, in parallel with the increasing incidence of neurodevelopmental disorders in children.[233]

Some vaccines also contain other biological matter, both intended and unintended.[234] These include cell lines from aborted human fetuses and biological material from animal tissue.[235] Before being killed in the vaccine manufacturing process, the virus, disease, or toxin (against which the vaccine is supposed to protect) is grown on these human and biological mediums.[236]

Human cell portions in vaccines disclosed by the CDC include "human albumin, human diploid cell cultures (WI-38), human embryonic lung cultures, WI-38 human diploid lung fibroblasts, MRC-5 (human diploid) cells, MRC-5 cells, residual components of MRC-5 cells including DNA and protein, [and] recombinant human albumin."[237] These human cell portions also include billions of strands of human DNA from these aborted fetal cells lines that are of a length capable of inserting themselves into DNA to which they are exposed.[238]

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[223] https://www.vaccines.gov/basics/types/index.html
[224] Ibid.
[225] https://www.cdc.gov/vaccinesafety/concerns/adjuvants.html
[226] Ibid.
[227] https://www.ncbi.nlm.nih.gov/pubmed/2940082; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2819810/; https://www.ncbi.nlm.nih.gov/pubmed/23932735
[228] https://www.ncbi.nlm.nih.gov/pubmed/9164811
[229] https://www.ncbi.nlm.nih.gov/pubmed/23557144
[230] https://www.ncbi.nlm.nih.gov/pubmed/27908630; https://www.ncbi.nlm.nih.gov/pubmed/19740540
[231] https://www.ncbi.nlm.nih.gov/pubmed/27540164; https://www.ncbi.nlm.nih.gov/pubmed/25311587
[232] Ibid.
[233] https://www.cdc.gov/vaccines/schedules/past.html; https://www.ncbi.nlm.nih.gov/pubmed/20159870
[234] https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/b/excipient-table-2.pdf
[235] Ibid.
[236] Ibid.
[237] Ibid.
[238] http://soundchoice.org/research/dna-fragments-research/; http://soundchoice.org/wp-content/uploads/2012/08/DNA_

The CDC's list of ingredients for the vaccines also includes the following animal parts:

> *monkey kidney cells, vero (monkey kidney) cells, embryonic guinea pig cell cultures, lactose, chick embryo cell culture, bovine calf serum, bovine serum albumin, calf serum protein, fetal bovine serum*[239]

These fragments of cultured human tissue and animal tissue, which have also been found to include various monkey, retro and other unintended viruses, are injected into the muscle tissue of babies and children, along with the adjuvant intended to generate a sustained immune response to the biological matter in the vaccine.[240]

Contaminants_in_Vaccines_Can_Integrate_Into_Childrens_Genes.pdf

[239] https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/b/excipient-table-2.pdf

[240] https://www.fda.gov/biologicsbloodvaccines/scienceresearch/biologicsresearchareas/ucm127327.htm; https://www. ncbi.nlm.nih.gov/pubmed/20375174. Vaccines also contain, among other ingredients, the following: *2-phenoxethanol, complex fermentation medium, detergent, 5rdimethyl 1-beta-cyclodextrin, Eagle MEM modified medium, enzymes, formaldehyde, gelatin, glutaraldehyde, hemin chloride, hydrolyzed galtin, lactalbumin hydrolysate, Medium 199, Minimum Essential Medium, modified Mueller's growth medium, modified Stainer-Scholte liquid medium, neomycin, neomycin sulfate, phenol polymyxin B, polymyxin B sulfate, polysorbate 80, soy peptone, Stainer-Scholte medium, streptomycin, yeast, yeast protein*