# AN INTRODUCTION TO VACCINE SAFETY

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



### PHARMA HAS NO INCENTIVE TO ASSURE VACCINE SAFETY

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

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

### HHS CONFLICTED FROM ASSURING VACCINE SAFETY

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

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

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

### **PRE-LICENSURE VACCINE SAFETY**

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

### **POST-LICENSURE VACCINE SAFETY**

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

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



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# **POST-LICENSURE VACCINE SAFETY (CONTINUED)**

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

Autism. Autism is the most controversial of the claimed vaccine injuries and the one CDC declares to have thoroughly studied. Most parents with autistic children claim vaccines – including DTaP, Hep B, Hib, PCV13, and IPV, each injected 3 times by 6 months – are a cause of their child's autism.<sup>23</sup> CDC responds with "Vaccines Do Not Cause Autism."<sup>24</sup> ICAN had to sue CDC for the studies it claims supports that these vaccines do not cause autism.<sup>25</sup> CDC then identified 20 studies, 18 of which studied a different vaccine (MMR<sup>26</sup>) or an ingredient not in these vaccines (thimerosal), and one irrelevant study regarding antigens.<sup>27</sup> Incredibly, the final study CDC identified was a review of DTaP/ autism that found no studies supporting that DTaP doesn't cause autism (and one study that supported it does!).<sup>28</sup> Worse, HHS's own autism expert recently testified vaccines can cause autism in some children.<sup>29</sup> Given the lack of studies regarding vaccines and autism, it is unsurprising that few or no studies support CDC's other vaccine safety claims.

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

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

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

#### **UNINTENDED CONSEQUENCES**

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

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

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

# **ADDITIONAL INFORMATION**

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

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



