

# 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



**1. 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 pharmaceutical company liability for injuries caused by their vaccine products.<sup>2</sup>

**2. Pharmaceutical Company Misconduct.** Since 1986, Merck, GSK, Sanofi and Pfizer have paid billions of dollars for misconduct and injuries related to their drug products.<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



**3. HHS Defends Against Any Claim of Vaccine Injury.** After eliminating liability for pharmaceutical companies, the 1986 Act established the Vaccine Injury Compensation Program (Vaccine Court), part of the U.S. Court of Federal Claims, to compensate people injured by vaccines.<sup>4</sup> Under the 1986 Act, the U.S. Dep't of Health & Human Services (HHS) is the defendant in Vaccine Court and is legally obligated to defend against any claim that a vaccine causes injury.<sup>5</sup> HHS is represented by the formidable resources of the U.S. Department of Justice (DOJ).<sup>6</sup> In nearly every case the injured person must prove the vaccine caused the injury.<sup>7</sup> Despite these hurdles, since 1986, HHS has paid over \$4 billion for vaccine injuries.<sup>8</sup>

**4. HHS Incriminates Itself if it Publishes or Admits a Vaccine Can Cause a Harm.** The Centers for Disease Control & Prevention (CDC) and Food & Drug Administration (FDA) are agencies within HHS. If HHS publishes any study supporting that a vaccine causes a harm, that study will then be used against HHS in Vaccine Court.<sup>9</sup> This greatly limits HHS's incentive to publish safety studies.

**5. CDC's Childhood Vaccine Schedule Was Created by Pharma Insiders.** Congress has repeatedly found that the members of the FDA and CDC committees responsible for approving most of the currently licensed and recommended childhood vaccines had serious conflicts of interests with pharmaceutical companies.<sup>10</sup>

## VACCINE SAFETY: CONCERNS & LIMITATIONS



**6. Pediatric Vaccine Clinical Trials (i) Lack Placebos and (ii) Are Too Short.** The pivotal clinical trials relied upon to license childhood vaccines do not include a placebo-control group and safety review periods in these clinical trials are typically only days or months.<sup>11</sup> The safety profile for a pediatric vaccine is therefore not known before it is licensed and routinely used in children.<sup>12</sup>

**7. Post-Licensure Safety.** After licensure and use by the public, federal law requires that the package insert for each vaccine include "only those adverse events for which there is some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event."<sup>13</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>14</sup>

**8. Prevalence of Vaccine Harm.** The CDC's Vaccine Adverse Events Reporting System (VAERS), to which doctors and patients may voluntarily report adverse vaccine events, received 61,232 reports in 2019, including 559 deaths, 1,436 permanent disabilities, and 4,660 hospitalizations.<sup>15</sup> An HHS-funded three-year review by Harvard Medical School of 715,000 patients stated that "fewer than 1% of vaccine adverse events are reported" to VAERS.<sup>16</sup> This could mean there are a hundredfold more adverse vaccine events than are not reported to VAERS. The CDC has nonetheless refused to mandate or automate VAERS reporting.<sup>17</sup>

**9. Children Susceptible to Vaccine Injury.** While the Institute of Medicine (IOM) has explained that "most individuals who experience an adverse reaction to vaccines have a preexisting susceptibility," HHS and CDC have failed to conduct studies to identify children susceptible to vaccine harms while at the same time recommending vaccines for all children.<sup>18</sup>

**10. Carcinogenicity, Mutagenicity & Infertility.** Most vaccines have never been evaluated for their potential to cause cancer, mutate genes or cause infertility.<sup>19</sup>

**11. Autism.** Autism is the most controversial of the claimed vaccine injuries and the one HHS and CDC declare they have thoroughly studied. Most parents with autistic children claim vaccines -- including DTaP, Hep B, Hib, PCV13, and IPV, each injected 3 times by 6 months -- are a cause of their child's autism.<sup>20</sup> The CDC tells these parents that "Vaccines Do Not Cause Autism."<sup>21</sup> The CDC was recently sued for copies of the studies which support that these vaccines do not cause autism.<sup>22</sup> In the end, the CDC identified 20 studies, 18 of which studied a different vaccine (MMR<sup>23</sup>) or an ingredient not in these vaccines (thimerosal), and one irrelevant study regarding antigens.<sup>24</sup> Incredibly, the final study the CDC identified explained it searched for but failed to identify any study to support that DTaP does not cause autism.<sup>25</sup>

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The same is true for Hep B, Hib, PCV13, and IPV.<sup>26</sup> Worse, HHS's primary autism expert in Vaccine Court recently testified that vaccines can cause autism in some children.<sup>27</sup> Given the lack of studies regarding vaccines and autism, it should not be surprising that few or no studies support the CDC's other vaccine safety claims.

**12. HHS Refuses to Publish Vaccinated Vs. Unvaccinated Studies of Vaccine Schedule.** A true epidemic in the U.S. is the fact that 1 in 2 children have an autoimmune, developmental, neurological, or chronic disorder.<sup>28</sup> These conditions have sharply risen in lock-step with the increases in the CDC's vaccine schedule.<sup>29</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>30</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>31</sup> In another study, children received influenza vaccine or a saline placebo; while both groups had a similar rate of influenza, the vaccinated group had a 440% increased rate of non-influenza infections.<sup>32</sup> A recent pilot study from the School of Public Health at Jackson State University found that 33% of vaccinated preterm babies had a neuro-developmental disorder compared to 0% of the unvaccinated preterm babies; and vaccinated children in this study had an increased risk of 290% for eczema, 390% for allergies, 420% for ADHD, 420% for autism, and 520% for learning disabilities.<sup>33</sup> Nonetheless, HHS and CDC refuse to publish any studies comparing the health outcomes between vaccinated and unvaccinated children.<sup>34</sup>

**13. HHS Fails to Perform Basic Vaccine Safety Requirements.** After eliminating the market forces that assured vaccine safety, Congress made HHS directly responsible for vaccine safety pursuant to a section of the 1986 Act entitled the "Mandate for safer childhood vaccines."<sup>35</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>36</sup>

**14. Eliminating Measles Has Increased Cancer Rates.** The mortality rate from measles declined by over 98% between 1900 and 1962 as living conditions improved in this country.<sup>37</sup> In 1962, a year before the first measles vaccine, the CDC reported a total of 408 deaths.<sup>38</sup> That amounts to 1 in 500,000 Americans at a time when measles infected nearly every American.<sup>39</sup> Eliminating measles has, however, increased cancer rates. For example, the International Agency for Research on Cancer found that individuals who never had measles had a 66% increased rate of Non-Hodgkin Lymphoma and a 233% increased rate of Hodgkin Lymphoma.<sup>40</sup> Combined, these cancers killed 20,960 Americans in 2018.<sup>41</sup> As another example, individuals who never had measles, mumps or rubella had a 50% increased rate of ovarian cancer.<sup>42</sup> In 2018, ovarian cancer killed 14,070 Americans.<sup>43</sup> Eliminating measles in this country has caused more deaths from cancer.

**15. Eliminating Mumps and Measles Has Increased Heart Disease.** A 22-year prospective study of over 100,000 individuals in Japan revealed that "measles and mumps, especially in case of both infections, were associated with lower risks of mortality from atherosclerotic CVD [heart disease]."<sup>44</sup> Heart disease killed 610,000 Americans in 2018.<sup>45</sup> Eliminating our ecological relationship with measles, mumps and rubella has had serious unintended consequences.

**16. DTaP Vaccine.** The FDA and university scientists have only recently discovered 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>46</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>47</sup>

**17. Chicken Pox Vaccine.** The immunity from the chicken pox vaccine wanes and, absent natural boosting from exposure to chicken pox virus, can lead to shingles.<sup>48</sup> The incidence of shingles in the U.S. has exploded since introducing this vaccine.<sup>49</sup> The increased risk of shingles from this vaccine is why countries, such as the U.K., have not added it to their routine vaccine schedule.<sup>50</sup>

**18. 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 in certain vaccines.<sup>51</sup>

## ADDITIONAL INFORMATION

The right to be informed about the risks before consenting to a vaccine should not be crushed. Prior to any medical procedure, HHS explains that the "voluntary consent of the human subject is absolutely essential."<sup>52</sup> Coercion invalidates informed consent.<sup>53</sup> Mandating liability-free vaccines to children has created a moral hazard.

For more information visit [www.icandecide.org](http://www.icandecide.org)

## UNINTENDED CONSEQUENCES



- [1 <https://www.nap.edu/read/2138/chapter/2#2>](https://www.nap.edu/read/2138/chapter/2#2) ("The litigation costs associated with claims of damage from vaccines had forced several companies [by 1986] to... stop producing already licensed vaccines.")
- [2 \[42 U.S.C. § 300aa-11\]\(https://www.ncbi.nlm.nih.gov/pubmed/25398603\)](https://www.ncbi.nlm.nih.gov/pubmed/25398603) "No person may bring a civil action ... in the amount greater than \$1,000 ... against a vaccine administrator or manufacturer ... for damages arising from a vaccine-related injury or death."); [Bruesewitz v. Wyeth LLC, 562 U.S. 223, 243 \[2011\]](https://www.eas.gov/assets/670/667136.pdf) ("The 1986 Act preempts all design-defect claims against vaccine manufacturers brought by plaintiffs who seek compensation for injury or death caused by vaccine side effects")
- [3 <https://www.citizen.org/sites/default/files/2408.pdf>](https://www.citizen.org/sites/default/files/2408.pdf)
- [4-6 \[42 U.S.C. § 300aa-12\]\(https://www.congress.gov/106/crpt/hrpt977/CRPT-106hrpt977.pdf\); <https://www.congress.gov/106/crpt/hrpt977/CRPT-106hrpt977.pdf>](https://www.congress.gov/106/crpt/hrpt977/CRPT-106hrpt977.pdf) (HHS amended the Vaccine Court rules to make it extremely difficult to obtain compensation and "DOJ attorneys make full use of the [r] apparently limitless resources," "pursued aggressive defenses," "establish[ed] a cadre of attorneys specializing in vaccine injury" and "an expert witness program to challenge claims.")
- [7 The 1986 Act created a Vaccine Injury Table \(the Table\) which was intended to permit the Vaccine Court to quickly compensate certain common injuries. \[42 U.S.C. § 300aa-12\]\(https://www.ncbi.nlm.nih.gov/pubmed/21570014\). For Table injuries, the burden shifts to HHS to prove the vaccine is not the cause. \[42 U.S.C. § 300aa-13\]\(https://www.ncbi.nlm.nih.gov/pubmed/21570014\). After passage of the 1986 Act, almost 90% of claims were Table claims and quickly settled. Stevens v. Secretary of HHS, No. 99-594V \(Office of Special Masters 2001\). However, in the 1990s, HHS amended the Table such that now 98% of new claims are off-Table. <http://www.eas.gov/assets/670/667136.pdf>. As a result, injured children "must prove that the vaccine was the cause" in almost all cases. <https://www.ncbi.nlm.nih.gov/pubmed/21570014>](https://www.ncbi.nlm.nih.gov/pubmed/21570014)
- [8 <https://www.hrsa.gov/sites/default/files/hrsa/vaccine-compensation/data/monthly-stats-february-2019.pdf>](https://www.hrsa.gov/sites/default/files/hrsa/vaccine-compensation/data/monthly-stats-february-2019.pdf)
- [9 See fn. 4 and 7.](https://www.fda.gov/oc/2019/02/2019-02-20)
- [10 <https://www.vaccinesafetycommission.org/pdfs/Conflicts-Govt-Reform.pdf>](https://www.vaccinesafetycommission.org/pdfs/Conflicts-Govt-Reform.pdf)
- [11-12 <https://www.icandecide.org/hhs/CAN-Reply.pdf>](https://www.icandecide.org/hhs/CAN-Reply.pdf) (see Section I)
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- [25 <https://www.nap.edu/read/13164/chapter/12?term=autism#545>](https://www.nap.edu/read/13164/chapter/12?term=autism#545)
- [26 <https://www.icandecide.org/hhs/CAN-Reply.pdf>](https://www.icandecide.org/hhs/CAN-Reply.pdf) (see Section VI)
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- [34 <https://www.icandecide.org/hhs/CAN-Reply.pdf>](https://www.icandecide.org/hhs/CAN-Reply.pdf) (see Section VII)
- [35 \[42 U.S.C. § 300aa-27\]\(https://www.ncbi.nlm.nih.gov/pubmed/21570014\)](https://www.ncbi.nlm.nih.gov/pubmed/21570014)
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