May 19, 2025

United State Senate Committee on
Homeland Security & Government Affairs
Permanent Subcommittee on Investigations
Chairman Ron Johnson
Hart Senate Office Building, Room SH-216

Re: *Hearing Regarding the Corruption of Science and Federal Health Agencies: How Health Officials Downplayed and Hid Myocarditis and Other Adverse Events Associated with the Covid-19 Vaccines*

Dear Chairman Johnson,

Thank you for the invitation to testify before the Permanent Subcommittee on Investigations on May 21, 2025, in the above-referenced hearing. This written statement is provided for circulation to the Subcommittee Members and Staff in advance of that hearing.

I am the managing partner of Siri & Glimstad LLP which has over 85 professionals. One part of our law firm handles consumer class actions which hold companies accountable when they fail to properly safeguard personal consumer information, including health, biometric, and genetic information, as well as for violations of privacy, religious, and other fundamental rights. The majority of our firm, however, focuses on vaccine-related work, including vaccine injury, exemptions, and policy. As far as I am aware, we have the largest vaccine practice in the country that does not represent pharmaceutical companies.

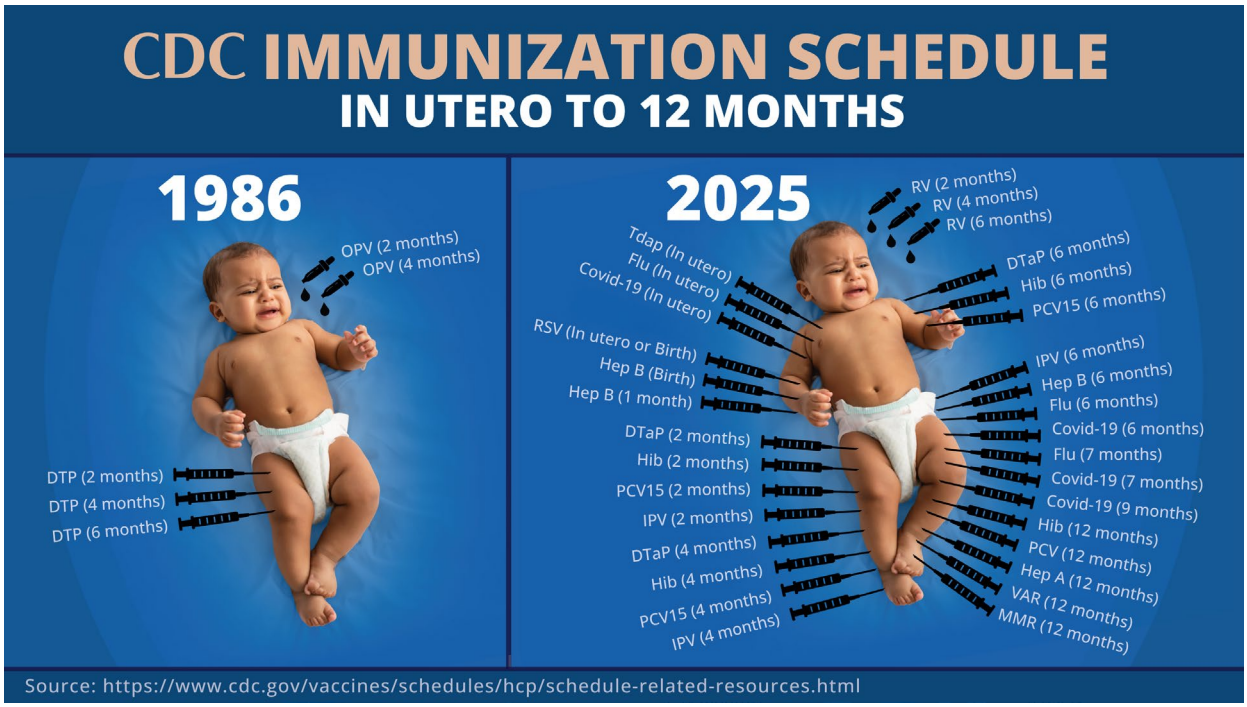
Our vaccine practice has included litigating to obtain transparency and accountability from federal government agencies. It also involves litigating vaccines injuries and issues regarding vaccine efficacy. In those lawsuits, we cannot appeal to medical credentials but rather must prove claims regarding these products with government and high impact journal data and sources.

This written submission provides a few points regarding Covid-19 vaccines we believe provide a broader framework in which to consider the corruption of science and how federal health agencies downplayed adverse events associated with the Covid-19 vaccines. These products did not just fall into a vacuum but rather into a well-established economic and regulatory framework that exists for vaccines in this country. Understanding that framework assists in putting what occurred with Covid-19 vaccines into context.

I. ECONOMIC FRAMEWORK FOR VACCINES

Prior to 1986, when there were only 3 routine vaccines totaling 7 injections,[1] the financial liability related to injuries from these products resulted in companies exiting the market.[2] Instead of allowing economic interests to drive innovation of safer vaccine products, the National Childhood Vaccine Injury Act of 1986 (the "1986 Act") gave pharmaceutical companies immunity for vaccine injuries for those products *and* any routine childhood vaccine added to CDC's schedule thereafter.[3]

As of 2025, CDC's maternal and childhood schedules lists 19 vaccines totaling 84 injections, virtually all of which were licensed after 1986 by companies conducting clinical trials with the full knowledge they would generally not be liable for any injuries caused by their vaccine products.[4] The following graphic reflects the vaccines, both injected and oral, an infant following the CDC's vaccine schedule would receive in utero and up to 12 months of age in 1986 versus 2025:



Clinical trials for both drugs and vaccines are conducted by the pharmaceutical company seeking licensure of each product. Because companies remain liable for injuries *drugs* cause after licensure,

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[1] https://www.cdc.gov/vaccines/schedules/images/schedule1983s.jpg.

[2] *Bruesewitz v. Wyeth*, 562 U.S. 223 (2011) ("the remaining manufacturer [of DTP] estimated that its potential tort liability exceeded its annual sales by a factor of 200"); Institute of Medicine, *Adverse Events Associated with Childhood Vaccines*, at 2 (1994), https://pubmed.ncbi.nlm.nih.gov/25144097/ (By 1986, "litigation costs associated with claims of damage from vaccines had forced several companies to end their vaccine research and development programs as well as to stop producing already licensed vaccines.").

[3] 42 U.S.C. § 300aa-11 ("No person may bring a civil action for damages … against a vaccine administrator or manufacturer … for damages arising from a vaccine-related injury or death associated with the administration of a vaccine"); *Bruesewitz v. Wyeth*, 562 U.S. 223 (2011) ("[W]e hold that the National Childhood Vaccine Injury Act pre-empts all design-defect claims against vaccine manufacturers brought by plaintiffs who seek compensation for injury or death caused by a vaccine side effects.").

[4] https://www.cdc.gov/vaccines/parents/by-age/pregnancy.html; https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf (assumes each vaccine given individually and Covid-19 vaccine given annually).

this provides an incentive to conduct long-term placebo-controlled trials to confirm the safety of drug products before licensure to avoid financial loss after licensure. For example, the following chart includes what are reported as the four most profitable drugs sold by Pfizer as of 2019, along with the control and safety duration in their licensure trial:

Pfizer's Four Most Profitable Drugs of All Time as of 2019[5]		
DRUG	**SAFETY FOLLOW UP**	**CONTROL USED**
Enbrel	6.6 years	Placebo
Eliquis	7.4 years+	Placebo
Lipitor	4.9 years+	Placebo
Lyrica	2 years+	Placebo

In contrast, for *vaccine* products, the economic incentive to assess safety prior to licensure was eliminated by the 1986 Act.[6] This is because long-term placebo-controlled trials for vaccine products do not make financial sense for companies seeking to maximize profits. In fact, while assuring safety in drug trials is aligned with a company's economic interest, it is in conflict when it comes to vaccine trials. This is why, in contrast to drug products, as will be detailed in the next section, virtually every routine childhood vaccine recommended by the CDC was licensed without a placebo control; was monitored for safety after administration for typically six months or less, sometimes only days or weeks; and often had too few participants to detect safety signals.

The purpose of discussing this framework is not to take issue with any particular vaccine but to provide context for the treatment of Covid-19 vaccines by pharmaceutical companies and by our federal health agencies. As will be discussed, our federal health agencies have a structural conflict that undermines their vaccine safety duties. This is because HHS's responsibility to promote and defend vaccines conflicts with its safety duties and (as will be manifest from the remainder of this statement) its promotion duties have sublimated its safety duties.

Indeed, because duties to promote an industry inherently conflict with duties to identify and address safety issues within that industry, outside of vaccines, these duties are often separated into independent agencies. For example, DOT promotes transportation while safety functions are handled by the independent NTSB.[7] Similarly, DOE promotes nuclear power while safety functions are handled by the independent NRC.[8] But with vaccines, these conflicting duties are handled by the same entity: HHS.

Moreover, HHS is statutorily required to and does vigorously defend against vaccine injury claims. Under the 1986 Act, one can bring a claim for a vaccine injury, but it is brought against the Secretary of HHS in the Vaccine Injury Compensation Program ("**VICP**"). This further conflicts HHS, including because any safety issues identified can be used against HHS in the VICP.[9]

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[5] https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm (*See* § 6.1 for each drug product); https://moneyinc.com/the-five-highest-selling-pfizer-drugs-of-all-time/.

[6] 42 U.S.C. §§ 300aa-1 through 300aa-34.

[7] https://www.ntsb.gov/about/history/pages/default.aspx.

[8] https://www.nrc.gov/about-nrc/history.html; https://www.energy.gov/ne/office-nuclear-energy.

[9] 42 U.S.C. § 300aa-12 ("In all proceedings brought by the filing of a petition [in VICP] the Secretary [of HHS] shall be named as the respondent."); https://www.congress.gov/106/crpt/hrpt977/CRPT-106hrpt977.pdf ("DOJ attorneys make full use of the apparently limitless resources available to them," "pursued aggressive defenses in compensation cases," "establish[ed] a cadre of

Vaccines are the only consumer product I am aware of where the government defends industry against consumers, instead of vice-versa.

These structural conflicts in regulating vaccines can result in regulators viewing and conducting themselves as partners with pharmaceutical companies rather than as regulators. Instances of this will be detailed in the remaining sections.[10] Moreover, once federal regulators have heavily promoted vaccine products, something they do not do with drug products, later admitting they cause harms could result in a loss of public confidence in HHS, the FDA, and the CDC and its vaccine schedule. It could also result in liability to HHS where it would need to pay out damages as the respondent to claims in the VICP and the Countermeasures Injury Compensation Program ("**CICP**"). These create intractable and dangerous structural conflicts with regard to HHS addressing vaccine safety.

The foregoing provides a quick summary of the economic and regulatory framework into which Covid-19 vaccines fell and should help provide context for the clinical trials relied upon to license these products and the post-licensure safety conduct by our federal health agencies with regard to these products.

II. COVID-19 VACCINE CLINICAL TRIALS

When our firm seeks to establish causation between a vaccine product and a claimed injury, the primary source for proving such claims are the data from clinical trials for that product. This is because most of the studies conducted after licensure are retrospective epidemiological studies which are not deemed reliable for supporting causation. Hence, obtaining and reviewing the clinical trial data for each vaccine has been an important part of our legal work.

Clinical trials are also critical for assuring safety, especially for vaccines. This is because after a vaccine is licensed, many consider it unethical to conduct a placebo-controlled trial and without a proper trial determining causation between a vaccine and a claimed adverse event is extremely difficult.

By way of background, the data relied upon to license a vaccine is collected during one or more clinical trials. Clinical trials are conducted by the pharmaceutical company seeking to license the

attorneys specializing in vaccine injury" and "an expert witness program to challenge claims."); https://uscfc.uscourts.gov/vaccine-programoffice-special-masters.

[10] In one instance, highlighted in a October 2024 report by the U.S. House of Representative's Committee on Energy and Commerce, Dr. Marion Gruber, Director of the FDA's Office of Vaccine Research and Review (OVRR) at the Center for Biologics Evaluation and Research, and Dr. Philip Krause, Dr. Gruber's deputy, resigned "in anger over the Biden administration's plan to roll out COVID-19 booster shots before officials had a chance to approve it." https://d1dth6e84htgma.cloudfront.net/We_Can_Do_This_NIH_PR_Campaign_Report_PUBLIC_82616d81eb.pdf at 36. In another instance, likewise highlighted in the October 2024 report, Dr. Rochelle Walensky made the "highly unusual" choice to "go against her own agency's advisers[']" recommendation that COVID-19 boosters be reserved for elderly and high risk individuals, in favor of her own broader recommendation that boosters be made available for healthy individuals at risk of occupational COVID-19 infection. *See id.* at 39. In yet another example, on December 21, 2021, Dr. Peter Marks launched an official FDA video series, titled *Just a Minute!*, in which he broadly promoted COVID-19 vaccines and boosters. *See, e.g.*, https://www.youtube.com/watch?v=GgTkc2v_CWk; https://www.youtube.com/watch?v=VmJ3s8DXIi0; https://www.youtube.com/watch?v=5kL9PIyru1w. This was despite the fact that, just two months prior, Dr. Marks had appointed himself Acting Director of OVRR, the FDA subagency responsible for "regulat[ing] all licensed and investigational vaccines for human use in the United States," after Dr. Gruber's and Dr. Krause's resignations for just such behavior. https://www.fda.gov/media/81708/download?attachment.

vaccine. The pharmaceutical company submits the clinical trial data to FDA which then reviews the data and decides whether the vaccine is safe and effective for licensure.

To determine the safety of a new product, a clinical trial compares the health outcomes of a group receiving the experimental product (the experimental group) to a group that does not receive this experimental product (the control group). The control group in clinical trials for a new drug will often receive a "placebo." As defined by the CDC, a "placebo" is: "A substance or treatment that has no effect on human beings."[11] Common examples include a saline injection or sugar pill.[12] The importance of a placebo control group is explained by the NIH as follows: "In undertaking a clinical trial, researchers … want to be as certain as possible that the results of the testing show whether or not a treatment is safe and effective. The 'gold standard' for testing interventions in people is the 'randomized, placebo-controlled' clinical trial. ... A placebo is an inactive substance that looks like the drug or treatment being tested."[13]

The clinical trials the FDA relies upon for licensure are known as the "pivotal trials." How well a pivotal trial can determine safety depends on, among other factors, (i) the duration safety is reviewed in the trial, (ii) the number of participants in the trial, and (iii) the use of a valid control, which should be a placebo or another vaccine for the same disease that has already been licensed based on a trial that properly assessed safety. Each of these factors is essential for a pivotal trial to be able to assess whether a vaccine causes one or more diseases. This is because:

- If the control group receives a control whose safety has not been established in a clinical trial, the control cannot be relied upon to provide a baseline of what is "safe."

- If the duration for which safety is reviewed is limited, the trial will miss safety issues that arise after the time for which safety is reviewed.

- If there are not enough participants, *i.e.* sufficient power, it will not detect safety issues that occur at a rate not detectible at that level of power.

With that background, as compared to the clinical trials relied upon to license routine childhood vaccines, the FDA and pharmaceutical companies would have no doubt viewed the trials relied upon to license Covid-19 vaccines as robust: the trials for Covid-19 vaccines had a placebo control (for a limited duration), reviewed safety for six months, and had larger numbers of participants compared to most childhood vaccine trials. Of course, as compared to the trials that often occur to licensure drugs, a product often given to sick adults, the trials for Covid-19 vaccines were incredibly anemic.

To better understand the framework in which Covid-19 vaccines were trialed and licensed by the FDA, it is helpful to look at some childhood vaccines that had previously been trialed and subsequently licensed by the FDA. In that regard, the following chart includes the control used and safety follow up after injection in the clinical trial FDA relied upon to license these childhood

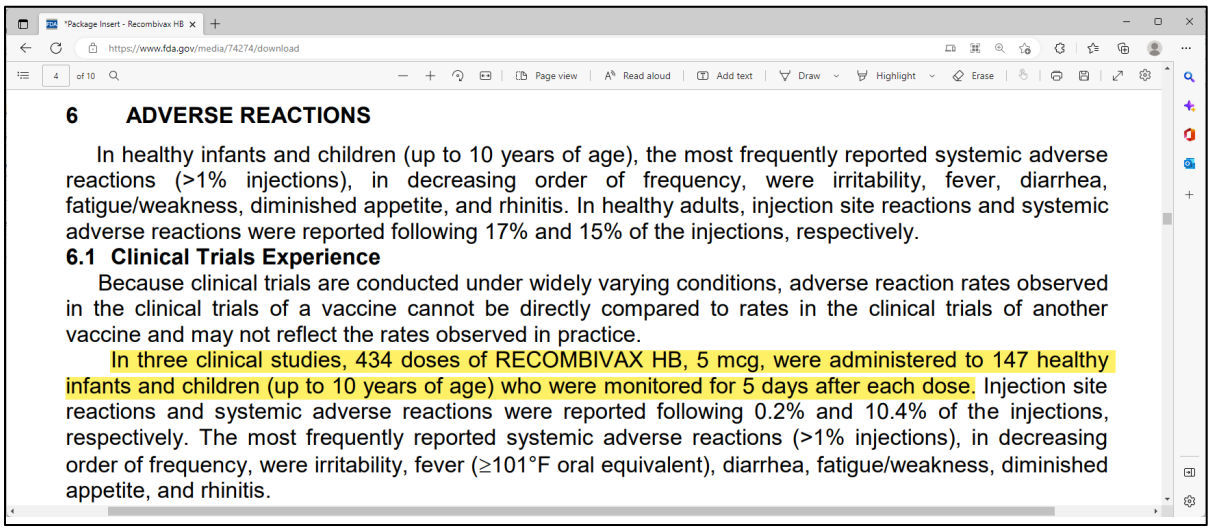
[11] https://www.cdc.gov/vaccines/terms/glossary.html.
[12] https://www.ncbi.nlm.nih.gov/pubmed/1330942 ("a placebo is a pharmacologically inactive substance").
[13] https://www.nia.nih.gov/health/why-are-placebos-important.

vaccines, each of which CDC recommends be injected three times each between birth and six months of age:[14]

VACCINE	SAFETY FOLLOW UP AFTER INJECTION	CONTROL USED
Hep-B (Merck)	5 days	None
IPV (Sanofi)	3 days	None
Hib (Merck)	3 days	Hib
DTaP (GSK)	28 days	DTP
Prevnar13 (Pfizer)	6 months	Prevnar

(The FDA citations for the above is provided below in the annotation regarding each vaccine. Note that when another vaccine was used as a control, that vaccine was also not licensed based on a placebo-controlled trial.)

Typically, the data for each clinical trial is easily obtained by reviewing the source material on FDA's website for each product. For example, below is a screenshot from Section 6.1 of the package insert for the Hep-B vaccine referenced in the chart above. (Section 6.1 is the section of each vaccine package insert required by federal regulations to include a summary of the clinical trial relied upon to find the vaccine was safe for licensure):



6 ADVERSE REACTIONS

In healthy infants and children (up to 10 years of age), the most frequently reported systemic adverse reactions (>1% injections), in decreasing order of frequency, were irritability, fever, diarrhea, fatigue/weakness, diminished appetite, and rhinitis. In healthy adults, injection site reactions and systemic adverse reactions were reported following 17% and 15% of the injections, respectively.

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a vaccine cannot be directly compared to rates in the clinical trials of another vaccine and may not reflect the rates observed in practice.

In three clinical studies, 434 doses of RECOMBIVAX HB, 5 mcg, were administered to 147 healthy infants and children (up to 10 years of age) who were monitored for 5 days after each dose. Injection site reactions and systemic adverse reactions were reported following 0.2% and 10.4% of the injections, respectively. The most frequently reported systemic adverse reactions (>1% injections), in decreasing order of frequency, were irritability, fever (≥101°F oral equivalent), diarrhea, fatigue/weakness, diminished appetite, and rhinitis.

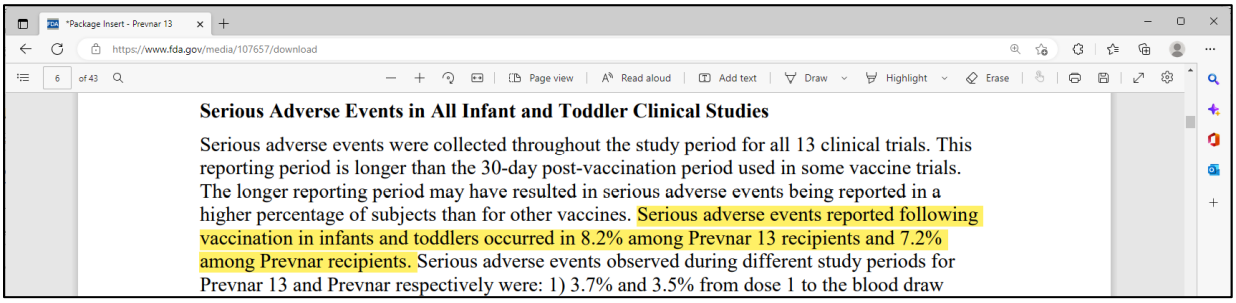
The trial reports submitted to FDA to license this Hep-B vaccine, which our firm obtained via Freedom of Information Act ("FOIA"), also confirm it was licensed for infants based on a trial with only 147 infants and children and only 5 days of safety monitoring after injection.[15] FDA is also over four years late in substantively responding to a petition regarding this patently inadequate trial.[16]

[14] https://www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states (See Section 6.1, titled "Adverse Reactions: Clinical Trial Experience," of the package insert for each product which, as required by federal regulations, describes the clinical trial relied upon to license the product).

[15] https://icandecide.org/wp-content/uploads/2020/09/COMBINED-02.pdf.

[16] https://www.regulations.gov/document/FDA-2020-P-1857-0001.

As another example, Prevnar 13 was licensed for babies based on a trial in which Prevnar was used as a control:[17]



Serious Adverse Events in All Infant and Toddler Clinical Studies

Serious adverse events were collected throughout the study period for all 13 clinical trials. This reporting period is longer than the 30-day post-vaccination period used in some vaccine trials. The longer reporting period may have resulted in serious adverse events being reported in a higher percentage of subjects than for other vaccines. Serious adverse events reported following vaccination in infants and toddlers occurred in 8.2% among Prevnar 13 recipients and 7.2% among Prevnar recipients. Serious adverse events observed during different study periods for Prevnar 13 and Prevnar respectively were: 1) 3.7% and 3.5% from dose 1 to the blood draw

Prior to that, Prevnar had been licensed based on a trial in which another experimental vaccine, an "Investigational meningococcal group C conjugate vaccine," was used as a control:[18]

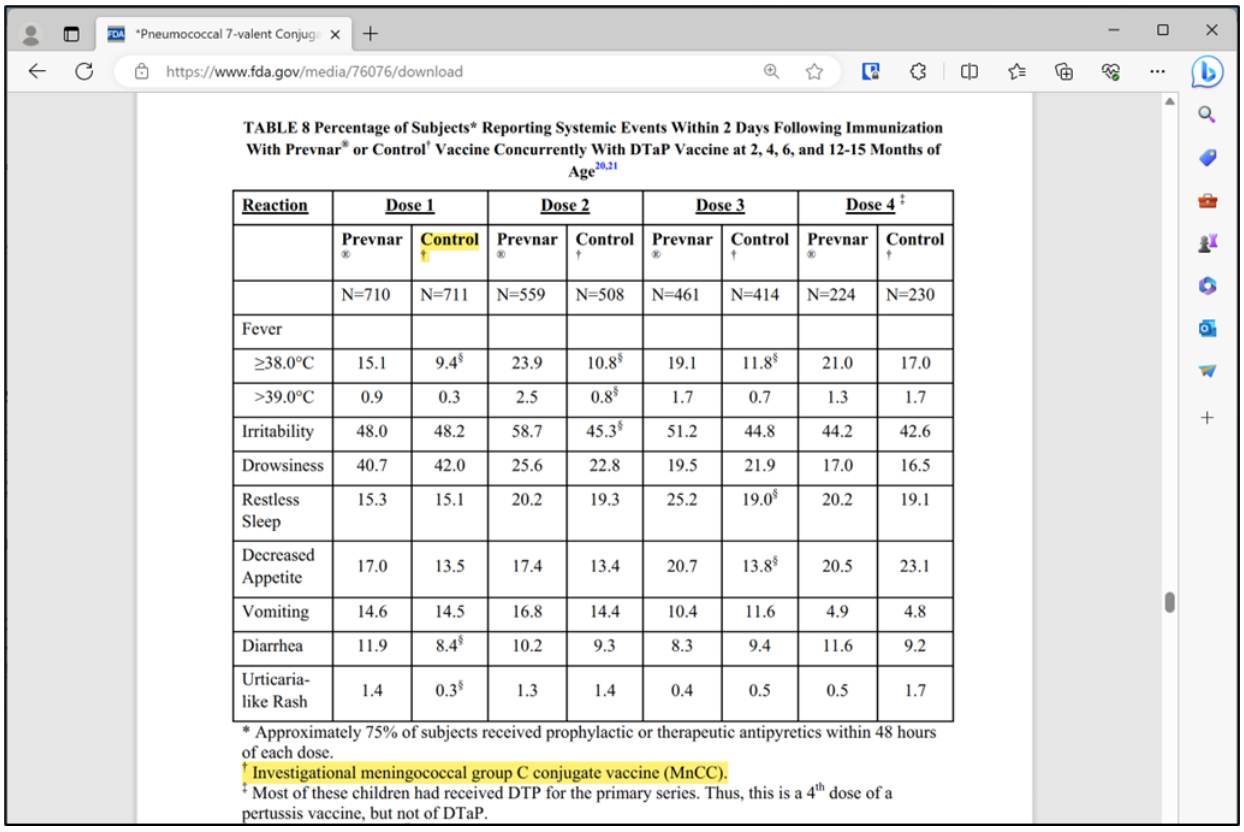


TABLE 8 Percentage of Subjects* Reporting Systemic Events Within 2 Days Following Immunization With Prevnar® or Control† Vaccine Concurrently With DTaP Vaccine at 2, 4, 6, and 12-15 Months of Age[20,21]

Reaction	Dose 1		Dose 2		Dose 3		Dose 4 ‡	
	Prevnar ®	Control †	Prevnar ®	Control †	Prevnar ®	Control †	Prevnar ®	Control †
	N=710	N=711	N=559	N=508	N=461	N=414	N=224	N=230
Fever								
≥38.0°C	15.1	9.4§	23.9	10.8§	19.1	11.8§	21.0	17.0
>39.0°C	0.9	0.3	2.5	0.8§	1.7	0.7	1.3	1.7
Irritability	48.0	48.2	58.7	45.3§	51.2	44.8	44.2	42.6
Drowsiness	40.7	42.0	25.6	22.8	19.5	21.9	17.0	16.5
Restless Sleep	15.3	15.1	20.2	19.3	25.2	19.0§	20.2	19.1
Decreased Appetite	17.0	13.5	17.4	13.4	20.7	13.8§	20.5	23.1
Vomiting	14.6	14.5	16.8	14.4	10.4	11.6	4.9	4.8
Diarrhea	11.9	8.4§	10.2	9.3	8.3	9.4	11.6	9.2
Urticaria-like Rash	1.4	0.3§	1.3	1.4	0.4	0.5	0.5	1.7

* Approximately 75% of subjects received prophylactic or therapeutic antipyretics within 48 hours of each dose.
† Investigational meningococcal group C conjugate vaccine (MnCC).
‡ Most of these children had received DTP for the primary series. Thus, this is a 4th dose of a pertussis vaccine, but not of DTaP.

A chart of each vaccine licensed by FDA that is on CDC's childhood schedule, along with the control, safety review period, and link to FDA source for each, is available at https://icandecide.org/no-placebo. This chart reflects that none of the vaccines on CDC's childhood schedule were licensed by FDA based on a long-term placebo-controlled trial and most were licensed with six months or less of safety follow up after injection, with often only days or

[17] https://www.fda.gov/media/107657/download.
[18] https://www.fda.gov/media/76076/download.

weeks of follow up. Hence, in comparison with the trials relied upon to license childhood vaccines, the trials for Covid-19 vaccines were robust. But again, in comparison with drug trials, these clinical trials were anemic.

What follows is every vaccine on the CDC's childhood vaccine schedule and a short discussion regarding the pivotal trial FDA relied upon to license each (with citation to the FDA sources):

- Hep B vaccine (CDC schedule: birth, 1 month, and 6 months)
  - **Recombivax HB (Merck)**: licensed for babies based on trials with no placebo control and 5 days of safety monitoring after injection.[19]
  - **Engerix B (GSK)**: licensed for babies based on trials with no placebo control and 4 days of safety monitoring after injection.[20]
- DTaP vaccine (CDC schedule: 2, 4, 6, and 15 months, and 4 years)
  - **Infanrix (GSK)**: licensed for babies based on trials with no placebo control (DTP vaccine used as a control) and up to 30 days of safety review after injection.[21] DTP, used as the control was not licensed in a placebo-controlled trial and DTP has, in most studies looking at this issue, repeatedly been found to increase mortality in infants, meaning DTP-vaccinated infants die at far higher rates than their equally situated non-vaccinated peers.[22]
  - **Daptacel (Sanofi)**: licensed for babies based on trials with no placebo control (DT or DTP vaccine used as control) and 2 months of safety review after injection, except one trial which had 6 months of safety review, no control, and 1,454 children. In that trial, "[w]ithin 30 days following any dose of DAPTACEL, 3.9% subjects reported at least one serious adverse event."[23] See Infanrix bullet point regarding DTP.
- PCV vaccine (CDC schedule: 2, 4, 6, and 12 months)
  - **Prevnar 13, PCV-13 (Wyeth, part of Pfizer)**: licensed for babies based on trials with no placebo control (Prevnar 7 used as a control, which was licensed based on a trial in which the control was an "Investigational meningococcal group C conjugate vaccine," meaning another experimental vaccine) and 6 months of safety review after injection which found, "[s]erious adverse events reported following vaccination in infants and toddlers occurred in 8.2% among Prevnar 13 recipients and 7.2% among Prevnar 7 recipients."[24]
  - **Vaxneuvance PCV-15 (Merck)**: licensed for babies based on trials with no placebo control (Prevnar 13 used as the control) and up to 6 months of safety review after injection finding that, "[a]mong children who received VAXNEUVANCE (N=3,349) or Prevnar 13 (N=1,814) … serious adverse events up to 6 months following vaccination with the 4-dose series were reported by 9.6% of VAXNEUVANCE recipients and by 8.9% of Prevnar 13 recipients." Deemed "safe"

[19] *See* Section 6.1 at https://www.fda.gov/media/74274/download.
[20] *See* Section 6.1 at https://www.fda.gov/media/119403/download.
[21] *See* Section 6.1 at https://www.fda.gov/media/75157/download.
[22] https://icandecide.org/wp-content/uploads/2021/06/2021.01.28-Letter-to-Special-Rapporteur-on-Poverty.pdf.
[23] *See* Section 6.1 at https://www.fda.gov/media/74035/download; https://www.fda.gov/safety/reporting-serious-problems-fda/what-serious-adverse-event.
[24] *See* Section 6.1 at https://www.fda.gov/media/107657/download; https://www.fda.gov/media/76076/download.

because, "[t]here were no notable patterns or numerical imbalances between vaccination groups."[25]

- **Prevnar 20, PCV-20 (Pfizer)**: licensed for babies based on trials with no placebo control (Prevnar 13 used as the control), up to 6 months of safety review after injection, and that showed high rates of serious events (this time broken up into two categories – "serious adverse events" and "newly diagnosed chronic medical conditions") in both vaccine groups (experimental and control) but deemed "safe" because "no notable patterns or imbalances between vaccine groups."[26] Meaning, PCV-20 was licensed based on a clinical in which PCV-15 was the control, PCV-15 was licensed based on a clinical trial in which PCV-13 was the control, PCV-13 was licensed based on a clinical trial in which PCV-7 was the control, and PCV-7 was licensed based on a clinical trial in which another experimental, unlicensed vaccine was the control, and in each of these trials the serious adverse events in both the control and experimental groups were similar which was sufficient for a finding of "safe" for licensure by the FDA.

- Polio vaccine (CDC schedule: 2, 4, and 6 months, and 4 years)
  - **IPOL (Sanofi)**: licensed in 1990 for babies based on trials with no placebo control and 3 days of safety review after injection. Sanofi reports that, "Although no causal relationship has been established, deaths have occurred in temporal association after vaccination of infants with IPV." [27] (Note that IPOL is a completely different product than the polio vaccine developed by Jonas Salk in the 1950s, which was discontinued in the 1960s, including because it is "grown in vero cells, a continuous line of monkey kidney cells cultivated on microcarriers." Hence, the Salk vaccine's safety or efficacy was not relied upon to license IPOL.[28])
- Hib vaccine (CDC schedule: 2, 4, 6, and 12 months)
  - **ActHIB (Sanofi)**: licensed for babies based on trials with no placebo control (Hepatitis B vaccine used as control) and 30 days of safety review after injection during which 3.4% experienced a serious adverse event but "[n]one was assessed by the investigators [Sonafi] as related to the study of vaccines."[29]
  - **Hiberix (GSK)**: licensed for babies based on trials with no placebo control (unlicensed Hib vaccines and HibTITER used as the control) and 31 days of safety review after injection.[30]
  - **Liquid PedvaxHIB (Merck)**: licensed for babies based on trials with no placebo control (Lyophilized PedvaxHIB used a control) and 3 days of safety review after injection.[31] (Note that Lyophilized PedvaxHIB was tested in a trial in which the

[25] *See* Section 6.1 at https://www.fda.gov/media/150819/download.
[26] *See* Section 6.1 at https://www.fda.gov/media/149987/download; https://www.fda.gov/media/150459/download?attachment.
[27] *See* pages 14-17 at https://www.fda.gov/media/75695/download.
[28] *See* pages 1 at https://www.fda.gov/media/75695/download; https://pubmed.ncbi.nlm.nih.gov/6740101/; https://admin.phe-culturecollections.org.uk/media/122249/vero-cell-line-profile.pdf; https://www.atcc.org/products/all/ccl-81.aspx#characteristics.
[29] *See* Section 6.1 at https://www.fda.gov/media/74395/download; *see* page 8 at http://wayback.archive-it.org/7993/20170723144656/https:/www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM244597.pdf.
[30] *See* Section 6.1 at https://www.fda.gov/media/77017/download; *see* pages 20-21 at http://wayback.archive-it.org/7993/20170722072902/https:/www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM182550.pdf.
[31] *See* page 6-8 at https://www.fda.gov/media/80438/download.

control group was given placebo, OPV, and DTP but there is no indication Lyophilized PedvaxHIB was ever licensed.[32])

- Rotavirus vaccine (CDC schedule: 2, 4, and 6 months) (Note that every vaccine on the CDC childhood schedule is given via injection, except for one flu vaccine given by nasal spray and the rotavirus vaccines, which are given by oral drops in the mouth.)
    - **Rotarix (GSK)**: licensed for babies based on trials without a placebo control (the control group received an oral drop that included Dextran, Sorbitol, Amino Acids, Dulbecco's Modified Eagle Medium, and Xanthan) and 31 days of safety review after oral dose and up to a year in some trials to watch for cases of intussusception. There were more deaths in the group receiving Rotarix than the control group. "During the entire course of 8 clinical studies (Studies 1 to 8), there were 68 (0.19%) deaths following administration of ROTARIX (n = 36,755) and 50 (0.15%) deaths following placebo administration (n = 34,454). The most commonly reported cause of death following vaccination was pneumonia, which was observed in 19 (0.05%) recipients of ROTARIX and 10 (0.03%) placebo recipients (RR: 1.74, 95% CI: 0.76, 4.23)."[33]
    - **RotaTeq (Merck)**: licensed for babies based on trials without a placebo control (the control group received an oral drop that included Polysorbate-80, Tissue Culture Medium, Fetal Bovine Serum, and Sodium Phosphate) and 42 days of safety review after each oral dose and up to a year to watch for cases of intussusception.[34]
- Covid-19 vaccine (CDC schedule: 6, 7, and 10 months, and then annually.)
    - **Comirnaty (Pfizer)**: licensed only for children 12 years of age and older (not for babies) and had a placebo control (note that the placebo controls were vaccinated during the trial), 6 months of safety review after injection, and a total of 3,014 participants.[35] Note that Pfizer failed to report a serious injury in at least one child participant in its trial who received the vaccine.[36]
    - **Spikevax (Moderna)**: licensed only for children 12 years of age and older (not for babies) and had a placebo control (note that the placebo controls were vaccinated during the trial), 6 months of safety review after injection, and a total of 3,726 participants.[37]
- Flu vaccine (CDC schedule: 6 and 7 months and then annually)
    - The formulation for each influenza vaccine changes annually and there is no clinical trial carried out for each new formulation. In any event, none of the clinical trials for the original formulation of any injected influenza vaccine for children had a placebo control group. In 1980, FDA licensed Fluzone (IIV3) without assessing

[32] *See* page 6-8 at https://www.fda.gov/media/80438/download.
[33] *See* Section 6.1 at https://www.fda.gov/media/163009/download (claims used a placebo); *see* pages 23-24 at http://wayback.archive-it.org/7993/20170722073219/https:/www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM133580.pdf (explains "placebo" included all the foregoing ingredients).
[34] *See* Section 6.1 at https://www.fda.gov/media/75718/download (claims used placebo); *see* page 445 *et al*. at https://icandecide.org/wp-content/uploads/2023/06/rotateq_placebo.pdf.
(explains the "placebo" included all the foregoing ingredients).
[35] *See* Section 6.1 at https://www.fda.gov/media/151707/download?attachment.
[36] https://icandecide.org/wp-content/uploads/2023/07/3-08-2022-Ltr-to-Dr.-Paul-Richards-FDA-re-Maddie-de-Garay.pdf.
[37] https://www.fda.gov/media/155675/download.

its safety against a placebo control.[38] Nonetheless, Fluzone (IIV3) was used as the control in the trials relied upon to license Afluria (IIV3) in 2007 and Fluzone (IIV4) in 2013 for children.[39] Then, Fluzone (IIV4), Fluarix (IIV3), or Havrix were used as the controls in the clinical trials supporting the licensure of FluLaval (IIV4).[40] The safety of these products therefore rests on the safety of Fluzone (IIV3) which was licensed for pediatric use based on a trial without any control, let alone a placebo control.[41] Similarly, Fluarix (IIV4) was licensed for children in 2012 based on a trial using Prevnar 13, Havrix and/or Varivax as controls; Fluarix (IIV4) was then used as the control to license Afluria (IIV4) in 2016.[42] This means Afluria (IIV4) was licensed because it was deemed as safe as Fluarix (IIV4), and that vaccine was licensed because it was deemed as safe as Prevnar 13, Havrix, or Varivax. However, the latter two were licensed without a placebo control; and Prevnar 13 was licensed because it was as safe as Prevnar, but that vaccine was only licensed because it was as safe as "an investigational meningococcal group C conjugate vaccine." Hence, none of those vaccines had its safety profile established based on any placebo-controlled clinical trial. The only exception is one inhaled influenza vaccine whose original trial had a placebo, but its formulation changes every year and is not safety tested in any trial.[43]

- MMR vaccine (CDC schedule: 12 months and 4 years)
    - **M-M-R-II (Merck)**: licensed based on a trial with a total of 834 children, no control group, and that reviewed safety for 42 days during which one-third of vaccinated participants developed gastrointestinal and a third respiratory issues.[44]
    - **Priorix (GSK)**: licensed based on trials with no placebo control (M-M-R-II used as the control) and 6 months of safety review after injection in which both vaccine groups had a high rate of serious adverse events (2.1% of Priorix group and 1.9% of M-M-R-II group), emergency room visits (10.1% of Priorix group and 10.4% of M-M-R-II group), and new onset of chronic diseases (e.g., autoimmune disorders,

[38] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM619664.pdf; (Research-ers did conduct one efficacy trial for Fluzone (IIV3) long *after* it was licensed which found that "the rate of hospitalization was actually higher in the vaccine group than in the placebo group" with 60% more vaccinated than unvaccinated children being hospitalized for insertion of ear draining tubes. https://www.ncbi.nlm.nih.gov/pubmed/14506120).

[39] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM263239.pdf (placebo control only used in adult trials but never in trials to license this vaccine for children); https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM356094.pdf.

[40] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM619548.pdf.

[41] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM619664.pdf.

[42] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM220624.pdf (44% and 45% of the Fluarix (IIV4) and comparator vaccine group, respectively, reported an unsolicited adverse event within 28 days and 3.6% and 3.3%, respectively, reported a serious adverse reaction).

[43] https://www.fda.gov/media/160349/download?attachment; https://www.fda.gov/media/73706/downloads.

[44] *See* clinical trial reports for M-M-R-II at https://www.sirillp.com/wp-content/uploads/2023/07/MMRII-FOIA.pdf. package insert; *see* package insert for M-M-R-II https://www.fda.gov/media/75191/download (The package insert for M-M-R-II does not list any pivotal trial as a basis for determining this product was safe for licensure, presumably because the trial relied upon to license this product could not establish it was safe for licensure.); *see*https://icandecide.org/wp-content/uploads/2023/08/MMR-I-clinical-trials-safety-tables.pdf (The original MMR's clinical trial was also underpowered, among other deficiencies, and showed a similarly high rate of gastrointestinal, respiratory and other issues, as compared to the small untreated control group. Also note that the original MMR was a different product that did not include millions of pieces of human DNA and cellular debris, as does M-M-R-II.).

asthma, type I diabetes, vasculitis, celiac disease, thrombocytopenia, and allergies) (3.4% of Priorix group and 3.7% of M-M-R-II group).[45]

- Varicella vaccine (CDC schedule: 12 months and 4 years)
  - **Varivax (Merck)**: licensed based on trials with no placebo control (the purported "placebo" was actually an injection of 45 mg of neomycin per milliliter) and 70 days of safety review after injection which included only one controlled trial of 956 children in which approximately half received Varivax and half received the injection of 45 mg of neomycin per milliliter, and there was one trial in which 32 children received Varivax and 29 children received nothing and then received Varivax eight weeks later; during this eight-week period, the Varivax group had double the rate of ear infection and a 50% increase in respiratory infection. As for serious adverse events, Merck did not consider any related to Varivax.[46]
- Hep A vaccine (CDC schedule: 12 and 18 months)
  - **Havrix (GSK)**: licensed based on trials with no placebo control (Engerix-B was used as a control) and 31 days of safety review after injection with a phone call follow-up at 6 months.[47] Note, as discussed above, Engerix-B was licensed for babies based on trials with no placebo control and 4 days of safety monitoring after injection.[48]
  - **Vaqta (Merck)**: licensed based on trials with no placebo control (an injection of AAHS, an aluminum adjuvant, and thimerosal, a form of mercury, were used as a control) and up to 42 days of safety review after injection.[49] Note that no placebo control was used despite the fact the trials for Havrix and Vaqta occurred at roughly the same time when there was no licensed Hepatitis A vaccine yet licensed.
- Tdap vaccine (CDC schedule: 11 years)
  - **Adacel (Sanofi)**: licensed based on trials with no placebo control (Td, for adult use, was used as a control) and up to 6 months of safety review after injection.[50]
  - **Boostrix (GSK)**: licensed based on trials with no placebo control (DECAVAC or Adacel was used as a control) & up to 6 months of safety review after injection.[51]
- HPV vaccine (CDC schedule: 9 and 9 ½ years)
  - **Gardasil 9 (Merck)**: licensed based on trials in which safety was reviewed after injection for 1 month in five of the clinical trials, 6 months in a lot consistency trial, and 4 years in one trial of women aged 16 to 26 years. These Gardasil 9 trials were either not controlled or used Gardasil 4 as the control, except for one trial in which 306 participants received a placebo but only after receiving the full series of Gardasil 4 injections.[52] (Note that in Gardasil 4's clinical trial, controls received an aluminum adjuvant, AAHS, except 320 people labeled "Saline Placebo" who

[45] *See* Section 6.1 at https://www.fda.gov/media/158941/download; *see* page 12 at https://pmc.ncbi.nlm.nih.gov/articles/instance/7192400/bin/piz010_suppl_supplementary_materials.docx.
[46] *See* Section 6.1 at https://www.fda.gov/media/76000/download; *see* page 2 at https://pubmed.ncbi.nlm.nih.gov/6325909/; *see* Varivax clinical reports at https://www.sirillp.com/wp-content/uploads/2023/07/Varivax-clinical-trials.pdf.
[47] *See* Section 6.1 at https://www.fda.gov/media/119388/download.
[48] *See* Section 6.1 at https://www.fda.gov/media/119403/download.
[49] *See* Section 6.1 at https://www.fda.gov/media/74519/download (using term "placebo"); *see* clinical trial report at 454 https://www.nejm.org/doi/pdf/10.1056/NEJM199208133270702?articleTools=true (explains the purported "placebo" included the foregoing ingredients).
[50] *See* Section 6.1 at https://www.fda.gov/media/119862/download.
[51] *See* Section 6.1 at https://www.fda.gov/media/124002/download.
[52] See pages 17-19 at https://wayback.archive-it.org/7993/20190423065200/https:/www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM429166.pdf.

actually received all vaccine ingredients except antigens and AAHS; and across all these trials, 2-3% of participants receiving vaccine or aluminum adjuvant – a substance used to induce autoimmunity in lab animals – had a suspected autoimmune disorder.[53]

- Men4 vaccine (CDC schedule: 11 and 16 years)
  - **Menactra (Sanofi)**: licensed based on trials with no placebo control (Menomune used as the control) and up to 6 months of safety review after injection.[54] Note Menomune was licensed without a placebo-controlled trial; rather, the safety section of the package insert for Menomune lists the same trial used to license Menactra as the basis for the safety of Menomune despite the fact Menomune was used as a control in that trial.[55]
  - **Menveo (GSK)**: licensed based on trials with no placebo control (Menactra, Boostrix, or other vaccines used as a control) and up to 6 months of safety review after injection.[56]
  - **MenQuadfi (Sanofi)**: licensed based on trials with no placebo control (Menveo or other vaccines used as a control) and up to 6 months of safety review after injection.[57] Thus, Menomune was licensed without a placebo-controlled trial and was then used as the control to license Menactra; Menactra is then used as the control to license Menveo; and then Menveo is used as the control to license MenQuadfi.
- MenB vaccine (CDC schedule: 10 years and older if indicated)
  - **Bexsero (GSK)**: licensed based on trials in which controls were administered aluminum hydroxide and, in one trial with 120 adolescents, saline injection followed by injection of Menveo. FDA labels this an "active control," not a "placebo control" trial.[58]
  - **Trumenba (Pfizer)**: licensed based on trials with no placebo control group other than 12 people in a dose-ranging phase II study (otherwise the controls were injection of Gardasil+placebo, dTaP-IPV+placebo, HepA+placebo, or Menactra+Adacel+placebo and 30 days of safety review after injection for one of the three trials and up to 11 months in the other two trials.[59]
- PPSV23 vaccine (2Y+ if indicated)

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[53] *See* https://www.fda.gov/media/74350/download; https://pubmed.ncbi.nlm.nih.gov/27417999/.
[54] *See* Section 6.1 at https://www.fda.gov/media/75619/download.
[55] *See* https://archive.org/details/menomune-a-c-y-w-135-prescribing-information.
[56] *See* Section 6.1 at https://www.fda.gov/media/78514/download.
[57] *See* Section 6.1 at https://www.fda.gov/media/137306/download.
[58] *See* pages 14-15 at https://wayback.archive-it.org/7993/20190425012223/https:/www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM434748.pdf; *see* page 40 at https://wayback.archive-it.org/7993/20190423064855/https:/www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM434714.pdf. *See* pages 14-15 at https://wayback.archive-it.org/7993/20190425012223/https:/www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM434748.pdf; *see* page 40 at https://wayback.archive-it.org/7993/20190423064855/https:/www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM434714.pdf.
[59] *See* page 4 at https://wayback.archive-it.org/7993/20190425012035/https:/www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM548305.pdf; *see* pages 9-10 at https://wayback.archive-it.org/7993/20190423065758/https:/www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM424626.pdf.

- **Pneumovax 23 (Merck)**: licensed for children 2 years and older although there is no indication that there was any clinical trial involving anyone younger than 16 years of age that the FDA relied upon to license this vaccine.[60]

- Dengue vaccine (6Y+ if previously had dengue and live in area dengue is endemic)
  - **Dengvaxia (Sanofi)**: licensed based on a trial with 11,474 children receiving a placebo control (saline injection), over 35,000 children in the trial, and 5 years of safety review after injection. Meaning, the last listed vaccine on the CDC's childhood vaccine schedule is the only vaccine that underwent a longer-term placebo-controlled trial prior to licensure with a larger number of children.[61] Careful study of this vaccine revealed that children under 6 years old had an increased risk of severe harm and death from this vaccine and that children older than 6 who had never had dengue and received this vaccine likewise had a seriously increased risk of severe harm and death. Hence, this vaccine is only indicated for older children who have previously had dengue. "Those not previously infected are at increased risk for severe dengue disease when vaccinated and subsequently infected with dengue virus."[62] This vaccine is only recommended for children in endemic dengue areas and dengue is not endemic in the U.S.[63]

The FDA source material for each vaccine, as set forth above, reflects:

- **None of the childhood vaccines currently recommended for routine use by the CDC (save Covid-19 vaccine) were licensed based on a placebo-controlled trial nor a trial where the vaccine used as a control was licensed based on a placebo-controlled trial**. Rather, in each trial, there was either no control or another vaccine or vaccine ingredient was used as a control, and none of the control vaccines were licensed based on a placebo-controlled trial. (It is noted that there was one non-routine vaccine licensed based on a placebo-controlled trial, dengue vaccine.)
- **None of the childhood vaccines currently recommended for routine use by the CDC (save for one limited HPV trial) were licensed based on trials that had long-term safety follow-up after administration.** Rather, safety was reviewed for a limited period, often no more than months, and often only days or weeks after administration. (It is noted that there was one non-routine vaccine licensed based on a long-term trial, dengue vaccine.)
- **None of the childhood vaccines currently recommended for routine use by the CDC were licensed based on trials which were appropriate to assess whether the vaccine causes more harm than it prevents**. This is because, as seen from the FDA source material, their pivotal trial typically had only hundreds or a few thousand children, severely limiting the power of these trials to assess safety and was not sufficient to conclude, statistically, they prevent more serious harms and deaths then they cause.

When taken together, the lack of appropriate controls, the safety review durations, and the power of each reflect that the pivotal trials relied upon to license every currently-recommended childhood

[60] See Sections 6.1 and 14.1 https://www.fda.gov/media/80547/download
[61] *See* page 10 at https://www.fda.gov/media/125481/download; *see* page 4 at https://www.fda.gov/media/124379/download.
[62] https://www.fda.gov/media/124379/download.
[63] https://www.usgs.gov/faqs/what-constitutes-united-states-what-are-official-definitions.

vaccine, with the exception of dengue vaccine which is not routinely recommended, were not designed and did not rule out that these products are contributing to the chronic diseases that have rapidly risen over the preceding decades.

The FDA documentation also reflects that, as the Secretary of Health and Human Services, Robert F. Kennedy Jr., has previously explained, none of the routine vaccines on the CDC childhood schedule (which would not include the dengue vaccine as it's not routine) underwent a long-term placebo-controlled trial, nor just a placebo-controlled trial (or even a trial where the vaccine used as a control was previously established as safe in a long-term placebo-controlled trial).

Critical for this submission, it also reflects why pharmaceutical companies and the FDA viewed the Covid-19 vaccine clinical trials as robust – they *were* when stood next to childhood vaccine trials. But they were, from a real-world perspective, patently insufficient to assess the actual safety of these products for licensure.

The limited safety required in vaccine trials reflects FDA's bias and assumption, which we have seen repeatedly in our legal work, that these products are safe. Even experimental vaccines that have not yet been licensed. This bias was also reflected in how FDA allowed the clinical trials for Covid-19 vaccines to be conducted. For example, clinical trials are supposed to be statistical comparisons of the outcomes of those in the experimental group as compared to those in the placebo group. This avoids, *inter alia*, the introduction of bias by the pharmaceutical company conducting the trial. But this did not occur with regard to deaths in Pfizer's Covid-19 vaccine trial.

Deaths In Experimental v. Placebo Groups in Pfizer Covid-19 Vaccine Trial

This statistical comparison approach was used when comparing symptomatic cases in the experimental group (8 cases) and in the placebo group (162 cases) in Pfizer's Covid-19 vaccine trial to arrive at the 95% efficacy figure.[64] (It is noted there were 3,410 suspected but unconfirmed cases not included in this analysis, the impact of which remains unknown.[65]) However, when it came to deaths in the trial, the statistical comparison approach was abandoned and instead each death was judged subjectively.

In July 2021, Pfizer's published study reported 15 deaths in the vaccinated group and 14 in the placebo group (including 9 cardiovascular deaths in the vaccinated group versus 5 cardiovascular related deaths in the placebo group).[66] In November 2021, FDA's published report of Pfizer's trial stated that "there were a total of 38 deaths, 21 in the COMIRNATY [Pfizer's Covid-19 vaccine] group and 17 in the placebo group. None of the deaths were considered related to vaccination."[67]

Hence, a statistical comparison was conducted when the data supported the desired conclusion but a subjective assessment when it didn't. We therefore asked the FDA: "Why are the death data from a randomized controlled trial ('RCT') treated like a clinical case-series rather than an RCT when

[64] https://blogs.bmj.com/bmj/2021/01/04/peter-doshi-pfizer-and-modernas-95-effective-vaccines-we-need-more-details-and-the-raw-data/.
[65] *Id.*
[66] https://www.nejm.org/doi/full/10.1056/NEJMoa2110345.
[67] https://www.fda.gov/media/151733/download.

it comes to assessing causality?"[68] FDA responded that it was "unable to respond substantively at this time due to resource constraints and the ongoing pandemic response."[69]

Pfizer Fails to Disclose Serious Adverse Events, FDA Takes No Action

Another example of FDA's bias is the harms suffered by Maddie de Garay, 11 years old at the time, as a participant in Pfizer's Covid-19 clinical trial for 12-15-year-olds, which included only 1,131 children who received the shot.[70] Maddie's injuries left her wheelchair-bound and reliant upon a feeding tube, yet Pfizer classified her severe injuries as mere "functional abdominal pain" in its emergency use authorization submission to FDA.[71] On behalf of Maddie, my firm wrote to FDA four times and provided her medical records,[72] and the de Garays submitted their own comment to FDA about this.[73] Neither our firm nor the de Garays received any response until February 26, 2022, 128 days after we first contacted FDA.[74] FDA's response contained no explanation for the agency's over 4-month-long delay in responding and, instead, merely suggested that the de Garays file a VAERS report. The de Garays had already done so,[75] which raises serious concern about the claim that "FDA takes all reports of adverse events potentially related to vaccines seriously" as it contends.

We separately commenced a lawsuit on September 3, 2022 against HHS for FDA's internal communications related to Maddie de Garay.[76] It revealed that on June 24, 2021, in response to inquiries from the public, FDA finally asked Pfizer about Maddie de Garay. On June 30, 2021, Pfizer for the first time disclosed to FDA Maddie's serious adverse events, including being wheelchair bound and needing a feeding tube. But Pfizer's report concluded that "the PI [principal investigator] did not feel that the subject's symptology [sic] was consistent with a vaccine related adverse event."[77] As reflected in the email chain, FDA appears to simply accept this conclusion.

All adverse events in a clinical trial, whether the sponsor considers them related to the product or not, must be reported to FDA. That the Pfizer Covid-19 vaccine causes an injury should not be surprising – injuries from pharmaceutical products occur. What is concerning is that FDA appears unfazed by Pfizer's failure to adequately disclose this serious injury. FDA's role as a regulator is to take serious issue with this conduct, but its failure to do so is reflective of the close partnership between FDA and Pfizer. That Pfizer faced no ramifications for failing to accurately and adequately disclose Maddie's adverse event, in a clinical trial in which just over 1,000 children received the investigational vaccine, leaves open the question of how many other serious injuries

[68] https://icandecide.org/wp-content/uploads/2022/02/Ltr-re-Pfizer-death-discrepancies_2021_11_16.pdf.
[69] https://icandecide.org/wp-content/uploads/2022/07/Pfizer-death-discrepancy-email.pdf.
[70] https://www.nejm.org/doi/full/10.1056/NEJMoa2107456.
[71] https://www.sirillp.com/wp-content/uploads/2022/03/nr_EUA-27034.132-Review-Memo-Pfizer-BioNTech-COVID-19-Vaccine_RE-4dc738480420dad83663dbb169bd3fd3.pdf.
[72] https://sirillp.com/Letter-10-22-2021; https://sirillp.com/Letter-10-25-2021; https://sirillp.com/Letter-01-03-2022; https://sirillp.com/Letter-01-14-2022.
[73] https://www.sirillp.com/wp-content/uploads/2022/03/Attachment-5-Oct.-25-2021-Comment-to-FDA-from-de-Garays-8a01a5168186b3b86ccaca837aaca387.pdf.
[74] https://www.sirillp.com/wp-content/uploads/2022/03/Paul-Richards-email-response_2022_02_26_Redacted-33b881e4534f7fc2af8e5872c01984ea.pdf.
[75] https://www.sirillp.com/wp-content/uploads/2022/03/Attachment-6-VAERS-Report-45f531e089effee94bec01a9a9b4a0f9.pdf.
[76] https://www.sirillp.com/de-Garay.
[77] https://www.sirillp.com/wp-content/uploads/2024/04/FDA-emails-with-Pfizer-about-M.-deGaray-c6f24607aa9781481eae01d0d073b684.pdf.

were omitted from the data reported by Pfizer to FDA. To date, FDA still has not produced records in its possession concerning Pfizer's 12–15-year-old trial in which Maddie participated.

III. POST-LICENSURE SAFETY

Given the severe limitations in assessing safety during the Covid-19 vaccine trials, this left assessing safety, as with virtually every other vaccine, to the post-licensure period. The same economic and regulatory factors that limited safety review in vaccine clinical trials also impacted the post-licensure safety environment. To provide context for the post-licensure safety conducted for Covid-19 vaccines, this submission will first review the safety conducted post-licensure for childhood vaccines.

"Vaccines Do Not Cause Autism"

Autism is one of many chronic diseases that parents and stakeholders have claimed are caused by vaccines. For decades, parents have made claims that DTaP, PCV, Hep B, Hib, and IPV (given in the first year of life) and MMR (given in the second year of life) caused their child's autism. Autism is also the claimed vaccine injury that federal health authorities have repeatedly assured the public they have thoroughly studied and concluded is *not* connected with vaccination. As the CDC website categorically asserts: "Vaccines do not cause autism."[78]

Because autism is the claimed injury to have been most thoroughly studied in relation to vaccines, this section begins by reviewing the post-licensure safety literature that supports this claim.

While autism was relatively uncommon in the early 1980s, it was a serious enough concern that in the 1986 Act, Congress required that the federal health authorities review the scientific literature regarding whether there is a connection between pertussis-containing vaccines and autism. As provided in the 1986 Act:

> Review of Pertussis Vaccines and Related Illnesses and Conditions. –Not later than 3 years after the effective date of this title, **the Secretary of Health and Human Services shall complete a review of all relevant medical and scientific information … on the nature, circumstances, and extent of the relationship, if any, between vaccines containing pertussis** (including whole cell, extracts, and specific antigens) **and … Autism**."[79]

HHS in turn commissioned the IOM to conduct this review. When that review was published in 1991, the IOM explained that it could not identify any study to support the claim that pertussis vaccines do not cause autism. As explained by the IOM: "No data were identified that address the question of a relation between vaccination with DPT or its pertussis component and autism."[80]

The IOM committee included the following warning in its 1991 report:

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[78] https://beta.cdc.gov/vaccine-safety/about/autism.html.
[79] https://nap.nationalacademies.org/read/12796/chapter/12#268 (emphasis added).
[80] https://www.nap.edu/read/1815/chapter/1#v.

> In the course of its review, the committee found many gaps and limitations in knowledge bearing directly and indirectly on the safety of vaccines. … If research capacity and accomplishment in this field are not improved, future reviews of vaccine safety will be similarly handicapped.[81]

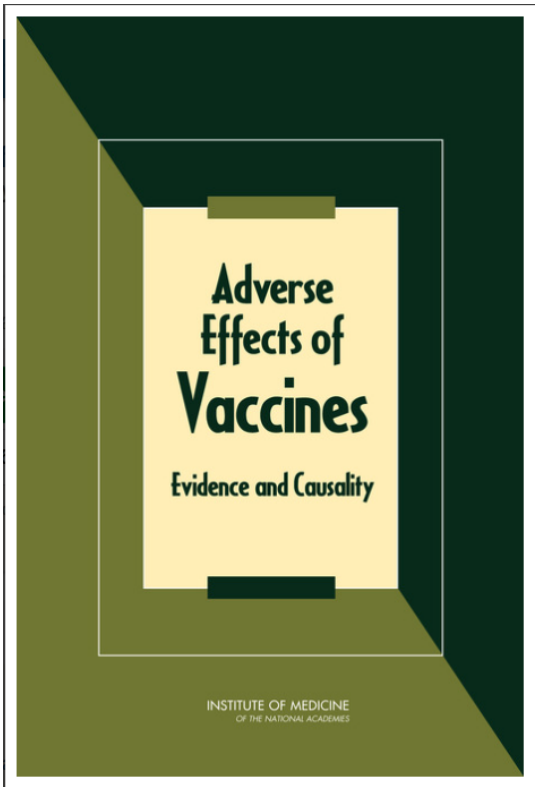
Two decades later, in 2012, the IOM issued another report on vaccine safety, this time commissioned by the CDC and its sister agency, the Health Resources and Services Administration (**HRSA**). The CDC and HRSA asked the IOM to again assess the evidence bearing on whether pertussis vaccines, including DTaP, cause autism. It did so because, according to the CDC and HRSA, autism remained one of the most commonly claimed injuries from this vaccine.[82] This time, the request to the IOM also included reviewing whether tetanus and diphtheria vaccines can cause autism.

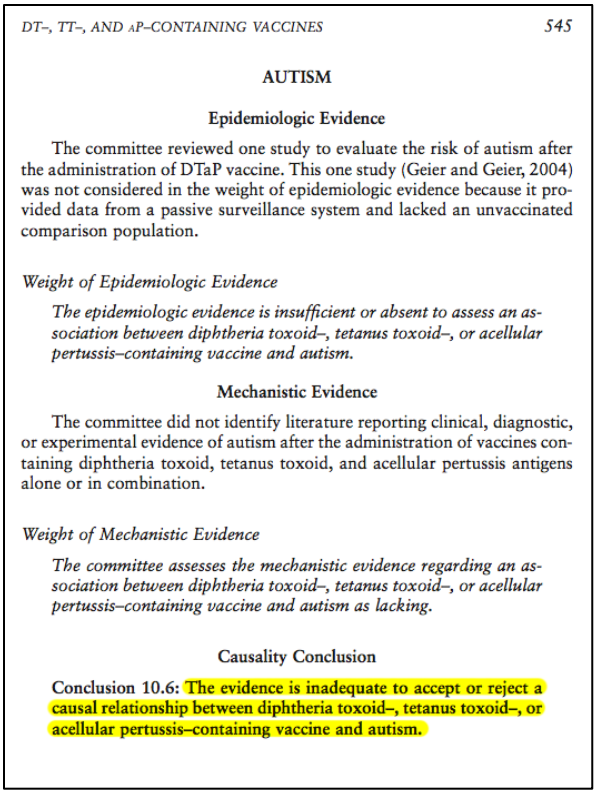
The IOM again convened a committee composed of individuals with expertise in pediatrics, internal medicine, neurology, immunology, immunotoxicology, neurobiology, rheumatology, epidemiology, biostatistics, and law to answer this question.[83]

As in 1991, the IOM again was unable to locate a study supporting the claim that DTaP does not cause autism. The IOM concluded in its 2012 report: "The evidence is inadequate to accept or reject a causal relationship between diphtheria toxoid–, tetanus toxoid–, or acellular pertussis–containing vaccine and autism."[84]

The following is the IOM's full explanation for this finding in its 2012 report:

[81] https://www.nap.edu/read/1815/chapter/9.
[82] https://www.nap.edu/read/13164/chapter/2#2.
[83] https://www.nap.edu/read/13164/chapter/1#v.
[84] https://www.nap.edu/read/13164/chapter/12#545.





DT-, TT-, AND aP-CONTAINING VACCINES 545

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.

The 2012 report from the IOM also looked at whether MMR vaccine, recommended for routine administration after one year of age, can cause autism.[85] The IOM identified 22 studies that evaluated the connection between MMR vaccine and autism, but did not rely on 17 of them due to lack of "unvaccinated comparison population," "individual-level data," or "methodological limitations."[86] Based on the remaining five studies, none of which were with children in the United States, the IOM concluded that, "The evidence favors rejection of a causal relationship between MMR vaccine and autism."[87] This conclusion reflects that studies can be conducted which the IOM is willing to rely upon to reach a conclusion that a particular vaccine does not cause autism. That said, the IOM's conclusion regarding MMR vaccine and autism does not support the much broader claim that "vaccines do not cause autism," as it only addresses whether the MMR vaccine can cause autism, not whether any other vaccines, especially those given to infants, can cause autism.[88]

Two years later, in 2014, the Agency for Healthcare Research and Quality ("**AHRQ**") conducted a review which again included looked at any study regarding pertussis, tetanus, and diphtheria vaccines, including DTaP, and autism.[89] HHS has explained in 2018 that this report represented "the most comprehensive review to date of published studies on the safety of routine vaccines recommended for children in the United States."[90] As with the IOM reports from 1991 and 2012,

[85] https://nap.nationalacademies.org/read/13164/chapter/6#145.
[86] https://nap.nationalacademies.org/read/13164/chapter/6#145.
[87] https://nap.nationalacademies.org/read/13164/chapter/6#145.
[88] https://nap.nationalacademies.org/read/13164/chapter/6#145.
[89] https://www.ncbi.nlm.nih.gov/books/NBK230053/pdf/Bookshelf_NBK230053.pdf.
[90] https://icandecide.org/wp-content/uploads/2019/09/HHS-Response-1.pdf.

the "comprehensive review" published by AHRQ in 2014 again concluded that it could not identify a study to support the claim that DTaP, administered at 2, 4, and 6 months of age, does *not* cause autism.[91]

AHRQ also reviewed autism and Hep B vaccine, administered at 1 day, 1 month, and 6 months of age, and did not identify a study to support the claim that this vaccine does *not* cause autism.[92] Instead, the only study meeting AHRQ's criteria for reliability was from the Stony Brook University Medical Center which found a 300% increased rate of autism among newborns receiving a Hep B vaccine at birth compared to those who did not get this vaccine at birth. AHRQ's 2014 review summarizes the results of this study as follows:

> Result was significant for the risk of autism in children who received their first dose of Hepatitis B vaccine during the first month of life (OR 3.00, 95% CI 1.11, 8.13), compared with those who received the vaccination after the first month of life or not at all.[93]

AHRQ therefore identified one study that showed an association, and no studies to support that Hep B vaccine does not cause autism, yet it concluded it does not know whether the Hep B vaccine causes autism.[94]

On May 31, 2017, the White House convened a meeting at the NIH in which the published agenda included, "Causes of autism, including genetic and environmental influences."[95] In attendance at that meeting were approximately a dozen individuals; on one side of the table was Robert F. Kennedy Jr. along with individuals he invited to join him, and on the other side of the table were the following NIH officials: Dr. Francis Collins, Director (NIH); Dr. Anthony Fauci, Director, National Institute of Allergy and Infectious Diseases (NIAID); Dr. Joshua Gordon, Director, National Institute of Mental Health (NIMH) and Chairman, Interagency Autism Coordinating Committee (IACC); Dr. Diana Bianchi, Director, Eunice Kennedy Shriver Institute of Child Health and Human Development (NICHD); and Dr. Linda Birnbaum, Director, National Institute of Environmental Health Sciences (NIEHS).

During that meeting, Dr. Gordon asserted that vaccines do not cause autism. Following the meeting, there were several follow-up communications with Dr. Gordon and CDC officials requesting the studies that support this claim – specifically for the vaccines given to infants: DTaP, Hep B, Hib, PCV13 and IPV. None of them were able to identify a single relevant study.[96]

A subsequent October 12, 2017 letter sent to HHS and signed by Robert F. Kennedy Jr. and others explained that there are no published studies supporting that the vaccines given in the first year of life do not cause autism. The letter asked HHS to "identify the specific studies on which HHS bases its blanket claim that no vaccines cause autism."[97] The letter also cited to studies which did

[91] https://www.ncbi.nlm.nih.gov/books/NBK230053/pdf/Bookshelf_NBK230053.pdf.
[92] https://www.ncbi.nlm.nih.gov/books/NBK230053/pdf/Bookshelf_NBK230053.pdf.
[93] https://www.ncbi.nlm.nih.gov/books/NBK230053/pdf/Bookshelf_NBK230053.pdf.
[94] https://www.ncbi.nlm.nih.gov/books/NBK230053/pdf/Bookshelf_NBK230053.pdf.
[95] https://archive.org/details/may-31-2017-agenda.
[96] https://archive.org/details/gordon-emails-with-attachments.
[97] https://icandecide.org/wp-content/uploads/2019/09/ICAN-HHS-Notice-1.pdf .

find an association between one or more of these vaccines and autism and provided scientific support and letters from world-leading aluminum scientists on how vaccines containing this ingredient could cause autism.[98]

On January 18, 2018, HHS sent a response which provided various links to CDC webpages but neither those links nor the content of those webpages identified a study which supports the claim that the vaccines given to babies do not cause autism.[99] This was explained in a follow-up letter to HHS which again requested any supporting studies and again reiterated the data regarding how aluminum adjuvants can cause autism.[100] It also specifically asked HHS the following:

> The following white paper provides the peer reviewed scientific support for how aluminum adjuvants injected into the body travel to the brain, can cause IL-6 production and microglial activation in the brain, and that this in turn can cause autism: http://icandecide.org/white-papers/ICAN-AluminumAdjuvant-Autism.pdf. Please clearly and specifically explain which steps in this chain of causation or any other aspect of this white paper HHS disputes.[101]

No response from HHS was ever provided to rebut these studies or scientific findings.[102]

On December 31, 2019, the CDC was sued in federal court for failing to provide studies in response to a Freedom of Information Act request submitted to the CDC seeking studies it relied upon to support that the vaccines the CDC recommends be given in the first year of life—DTaP, Hep B, Hib, PCV13, and IPV, individually and collectively—do not cause autism.[103]

To resolve the lawsuit, the CDC provided a list of the 16 studies and 4 reviews it claimed support the claim that the foregoing vaccines do not cause autism. This list was memorialized in a signed stipulation with the CDC on February 28, 2020, and then entered as an order of the Court on March 2, 2020.[104] The stipulation and order provided in relevant part as follows:[105]

> WHEREAS, the Institute for Autism Science and Informed Consent Action Network **("ICAN")** commenced the above-captioned lawsuit against the Centers for Disease Control and Prevention **("CDC")** regarding six Freedom of Information Act requests (the **"FOIA Requests");**
>
> WHEREAS, the FOIA Requests were as follows:

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[98] https://icandecide.org/wp-content/uploads/2019/09/ICAN-HHS-Notice-1.pdf.
[99] https://icandecide.org/wp-content/uploads/2019/09/HHS-Response-1.pdf.
[100] https://icandecide.org/wp-content/uploads/2019/09/ICAN-Reply-1.pdf.
[101] https://icandecide.org/wp-content/uploads/2019/09/ICAN-Reply-1.pdf.
[102] https://icandecide.org/wp-content/uploads/2020/08/ICAN-Follow-Up-Final.pdf.
[103] https://ecf.nysd.uscourts.gov/doc1/127026118709 (https://www.courtlistener.com/docket/16644712/1/institute-for-autism-science-v-centers-for-disease-control-and-prevention/); https://ecf.nysd.uscourts.gov/doc1/127126484251.
[104] https://ecf.nysd.uscourts.gov/doc1/127126484251 (https://www.courtlistener.com/docket/16644712/15/institute-for-autism-science-v-centers-for-disease-control-and-prevention/).
[105] https://ecf.nysd.uscourts.gov/doc1/127126484251 (https://www.courtlistener.com/docket/16644712/15/institute-for-autism-science-v-centers-for-disease-control-and-prevention/).

- "All studies relied upon by CDC to claim that the DTaP vaccine does not cause autism."
- "All studies relied upon by CDC to claim that neither Engerix-B nor Recombivax HB do not cause autism."
- "All studies relied upon by CDC to claim that Prevnar 13 does not cause autism."
- "All studies relied upon by CDC to claim that Hib vaccines do not cause autism."
- "All studies relied upon by CDC to claim that inactivated polio vaccine ('IPV') does not cause autism."
- "Copies of the studies the CDC relies upon to claim that the cumulative exposure of vaccines it recommends that babies be administered during the first six months of life do not cause autism."

WHEREAS, after conducting a search of its records, the CDC identified the following studies responsive to the FOIA Requests:

1. Madsen KM, Hviid A, Vestergaard M, Schendel D, Wohlfahrt J, et al. A population-based study of measles, mumps, and mbella vaccination and autism. N Engl J Med. 2002;347 (19):1477-1482.
2. IOM (Institute of Medicine). 2012. Adverse Effects of Vaccines: Evidence and Causality. Washington, DC: The National Academies Press.
3. IOM (Institute of Medicine). 2004. Immunization Safety Review: Vaccines and Autism. Washington, DC: The National Academies Press.
4. IOM (Institute of Medicine). 2013. The childhood immunization schedule and safety: Stakeholder concerns, scientific evidence, and future studies. Washington, DC: The National Academies Press.
5. Frombonne E, Zakarian R, Bennett A, et al. Pervasive developmental disorders in Montreal, Quebec, Canada: prevalence and links with immunizations. Pediatrics. 2006;118(1):el39-50.
6. Taylor LE, Swerdfeger AL, Eslick GD. Vaccines are not associated with autism: An evidence based meta-analysis of case-control and coh01t studies. Vaccine. 2014;32:3623-3629.
7. Ball L, Ball R, Pratt RD. An assessment of thimerosal in childhood vaccines. Pediatrics. 2001;107:1147-1154.
8. Hviid A, Stellfeld M, Wohlfahrt J, Melbye M. Association between thimerosal-containing vaccine and autism. JAMA. 2003;290:1763-6.

9. Madsen KM, Lauritsen MB, Pedersen CB, et al. Thimerosal and the occurrence of autism: negative ecological evidence from Danish population-based data. Pediatrics. 2003;112(3 Pt 1):604-6.
10. Stehr-Green P, Tull P, Stellfeld M, et al. Autism and thimerosal-containing vaccines: lack of consistent evidence for an association. Am JPrev Med. 2003;25(2):101-6.
11. Verstraeten T, Davis RL, Destefano F, et al. Safety of thimerosal-containing vaccines: a two phased study of computerized health maintenance organization databases. Pediatrics. 2003;112(5):1039-48.
12. Andrews N, Miller E, Grant A, et al. Thimerosal exposure in infants and developmental disorders: a retrospective cohort study in the United Kingdom does not supp01t a causal association. Pediatrics. 2004;114(3):584-91.
13. Thompson WW, Price C, Goodson B, et al. Early thimerosal exposure and neuropsychological outcomes at 7 to 10 years. N Engl JMed. 2007;357(13):1281-92.
14. McMahon AW, Iskander Il(, Haber P, Braun MM, Ball R. Inactivated influenza vaccine (IIV) in children <2 years of age: Examination of selected adverse events reported to the Vaccine Adverse Event Reporting System (VAERS) after thimerosal-free or thimerosal-containing vaccine. Vaccine. 2008 Jan; 26(3):427-429.
15. Schechter R, Grether Il(. Continuing increases in autism repmted to California's developmental services system: Mercury in retrograde. Arch Gen Psychiatry. 2008;65:19-24.
16. DeStefano F. Thimerosal-containing vaccines: evidence versus public apprehension. Expe1t Opin Drug Saf. 2009;8(1):1-4.
17. Tozzi AE, Bisiacchi P, Tarantino V, et al. Neuropsychological performance 10 years after immunization in infancy with thimerosal-containingvaccines. Pediatrics. 2009;123(2):475-482.
18. Price CS, Thompson WW, Goodson B, et al. Prenatal and infant exposure to thimerosal from vaccines and immunoglobulins and risk of autism. Pediatrics. 2010;126(4):656-64.
19. Barile JP, Kuperminc GP, Weintraub ES, et al. Thimerosal exposure in early life and neuropsychological outcomes 7-10 years later. J Pediatr Psychol. 2012;37(1):106-18.
20. Destefano F, Price CS, Weintraub ES. Increasing exposure to antibody-stimulating proteins and polysaccharides in vaccines is not associated with risk of autism. J Pediatr. 2013;163(2):561-7.

None of these 20 studies or reviews identified by the CDC included a study to support the claim that the vaccines on the CDC's childhood vaccine schedule given to infants—DTaP, Hep B, Hib, PCV13, and IPV—do not cause autism. Instead, these 20 studies or reviews include:

- 15 studies and 3 reviews concerning MMR and/or thimerosal;
- 1 study concerning antigen (not vaccine) exposure; and
- 1 review concerning MMR, thimerosal, and DTaP.

Hence, only one of the 20 studies and reviews identified by the CDC involved a single vaccine given to infants, DTaP. This was the review the IOM published in 2012, discussed above, which failed to identify a study to support that DTaP does not cause autism. Instead, it found only one study regarding DTaP vaccine and autism, and that study found an association between this vaccine and autism. Hence, the only study or review out of 20 identified by the CDC that reviewed a vaccine given during the first year of life was a study which *did find* an association between DTaP vaccine and autism.

On August 25, 2020, the head of CDC's Clinical Immunization Safety Assessment (CISA) Project, one of the four vaccine safety systems listed on the CDC's website, also confirmed that there are no studies to support that infant vaccines do not cause autism when questioned under oath in a case specifically about autism and vaccines:

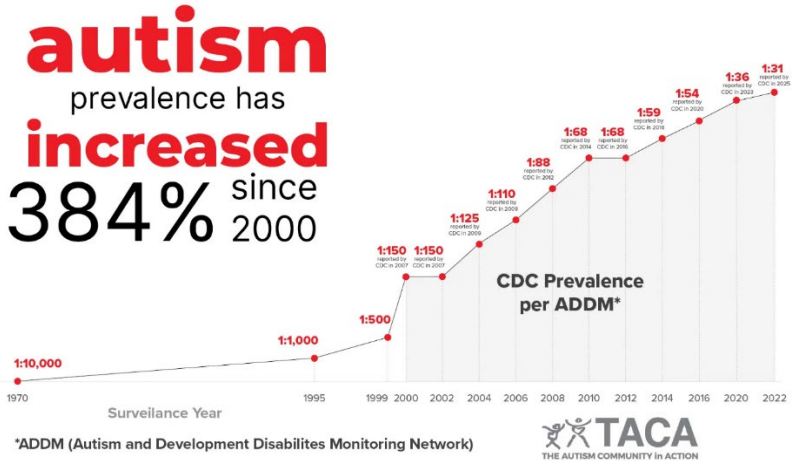
> Q: [A]ccording to your profile, you have done most of the clinical trials relied upon to license many of the vaccines, correct, on the market?
> A: Yes, sir.
> Q: Okay. So you're highly experienced at conducting clinical trials; correct?
> A: I am highly experienced conducting clinical trials.
> Q: ... And you're familiar with many of the clinical trials that -- relied upon to license many of the vaccines currently on the market; correct?
> A: I am.
> Q: Okay. In your opinion, did the clinical trials relied upon to license the vaccines that [the child] received, many of which are still on the market today, were they designed to rule out that the vaccine causes autism?
> A: No. …
> Q: [I]n the expert disclosures for this case, it asserts that among other things you will testify that, quote, the issue of whether vaccines cause autism has been thoroughly researched and rejected, end quote. …
> Q: … It's your testimony that MMR vaccine cannot cause autism?
> A: That's correct.
> Q: It's your testimony the HepB vaccine cannot cause autism?
> A: That's correct.
> Q: It's your testimony that IPOL cannot cause autism?
> A: Yes.
> Q: It's your testimony that Hib vaccine cannot cause autism?
> A: Yes.
> Q: It's your testimony that varicella vaccine cannot cause autism?
> A: Yes.

Q: It's your testimony that Prevnar vaccine cannot cause autism?
A: Yes.
Q: And it's your testimony that DTaP vaccine cannot cause autism?
A: Yes. …
Q: And do you have a study that supports that DTaP doesn't cause autism?
A: I have -- I do not have a study that -- that DTaP causes autism, so I don't have either.
Q: … Do you have any study one way or another of whether IPOL causes autism?
A: No, I do not, sir.
Q: Do you have any study one way or another of whether Engerix-B causes autism?
A: I do not have any evidence that it causes autism, nor that it does not.
Q: And what about HibTITERs vaccine, any evidence one way or another of whether it causes autism?
A: No. …
Q: … And what about Prevnar vaccine? Any evidence, one way or another?
A: No, sir. No, sir. …
Q: … And how about varicella vaccines … are there any studies one way or another that support whether it does or doesn't cause autism?
A: [As p]art of MMR, but not as varicella by itself, no sir. No studies that say it does or no studies that say it doesn't.
Q: … There have been studies that have found an association between hepatitis B vaccine and autism; correct?
A: Not studies that I feel are credible.
Q: Okay. Which study -- which study … are you referring to when you say that?
A: Well, why don't you show me the study and then I'll say whether I agree with it.[106]

As the foregoing reflects, and as explained by the Secretary of Health and Human Services, Robert F. Kennedy Jr., the CDC cannot claim that vaccines given in the first year of life do not cause autism. It cannot do so because the studies to disprove that the vaccines given to infants do not cause autism have not been conducted.

The need for studies regarding whether these vaccines have contributed to the autism epidemic is acute. Since the 1980s, the rise in cases of autism has occurred in lockstep across all geographic areas of the United States and across all racial, ethnic, and religious groups.[107]

[106] https://archive.org/details/kathryn-edwards-full-pdf-transcript.
[107] *See* The CDC's Autism and Developmental Disabilities Monitoring (ADDM) Network, https://www.cdc.gov/ncbddd/autism/addm.html, the U.S. Department of Education data collected pursuant to the Individuals with Disabilities Act (IDEA), https://sites.ed.gov/idea/data/, and the California Department of Developmental Services (CDDS), https://www.dds.ca.gov/transparency/autism/.



Given the steep rise, the cause of autism is an environmental change that has occurred throughout the United States since the early 1980s. A study published in *Environmental Health* out of the University of Colorado reviewed the correlations between numerous environmental factors suspected of potentially causing autism and the change in the level of their exposure during childhood since the 1980.[108] The environmental exposure in the study showing the highest statistical correlation with autism rates was the increasing doses of vaccination. The following charts are from this study. The circles represent the number of vaccine doses and the triangles represents the rate of autism:

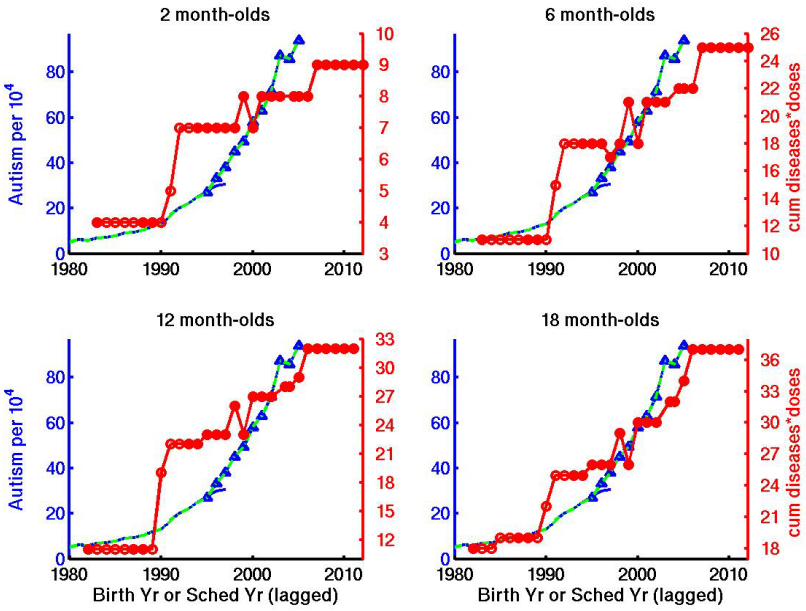


Figure S8. Temporal trend in autism compared to temporal trend in cumulative number of immunizations administered to U.S. infants

[108] https://pubmed.ncbi.nlm.nih.gov/25189402/.

> and toddlers by 2, 6, 12 and 18 months via immunization according to the CDC recommended schedule.[109]

Correlation does not equal causation, but it does provide a safety signal that merits investigation, including because numerous studies support immune dysfunction as a cause of autism and vaccines are intended to and do systemically modify the immune system. Additionally, a significant proportion of parents of children with autism identify vaccines as what they believe caused their child's autism, including pointing to the vaccines given in the first six months of life.[110]

IOM Reviews of Vaccine Safety

While autism is the chronic disease that federal health authorities assert they have most thoroughly studied in relation to vaccination, this sub-section will now review the state of the science regarding vaccines as a potential cause of many other serious health conditions parents have claimed were caused by vaccines. To assess the thoroughness of the post-licensure vaccine safety literature, this section will review IOM reviews on vaccine safety paid for by HHS, the CDC, and/or other federal health agencies.

In 1991, at HHS's request per the 1986 Act, the IOM issued a report that evaluated 22 reported serious injuries from pertussis and rubella vaccines.[111] The IOM located sufficient science to support that 6 serious injuries are causally related to these vaccines, including acute encephalopathy (brain damage) and chronic arthritis.[112] The IOM, however, found that studies had not been conducted in order for it to conclude whether or not these vaccines caused 12 other commonly reported serious injuries, including:

> Autism, Aseptic Meningitis, Chronic Neurological Damage, Guillain-Barre Syndrome, Juvenile Diabetes, Learning Disabilities, Attention-Deficit Disorder, Thrombocytopenia[113]

In 1994, again at HHS's request per the 1986 Act, the IOM evaluated 54 commonly reported serious injuries and vaccines for diphtheria, tetanus, measles, mumps, polio, hep B, and Hib.[114] The IOM located sufficient science to support that 12 serious injuries are causally related to these vaccines, including death, thrombocytopenia, and GBS.[115] The IOM, however, found that studies had not been conducted in order for it to conclude whether or not these vaccines caused 38 other commonly reported serious injuries, including:

> Arthritis, Aseptic Meningitis, Demyelinating diseases of the central nervous system, Insulin-Dependent Diabetes Mellitus, Myelitis, Neuropathy, Residual Seizure Disorder, Sensorineural Deafness,

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[109] https://pubmed.ncbi.nlm.nih.gov/25189402/.
[110] https://www.ncbi.nlm.nih.gov/pubmed/16685182; https://www.ncbi.nlm.nih.gov/pubmed/25398603; https://www.ncbi.nlm.nih.gov/pubmed/16547798; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1448378/.
[111] https://nap.nationalacademies.org/read/1815/chapter/1.
[112] https://nap.nationalacademies.org/read/1815/chapter/2#7.
[113] https://nap.nationalacademies.org/read/1815/chapter/2#7.
[114] https://www.nap.edu/read/2138/chapter/2#12.
[115] https://www.nap.edu/read/2138/chapter/2#12.

> Sudden Infant Death Syndrome, Sterility, Transverse Optic Neuritis[116]

The IOM explained: "The lack of adequate data regarding many of the adverse events under study was of major concern to the committee. Presentations at public meetings indicated that many parents and physicians share this concern."[117]

Fifteen years later, in 2012, the CDC and HRSA, paid the IOM to review what they stated were the 158 most common injuries claimed to be caused by various childhood vaccines.[118] The IOM located science to support that 18 serious injuries were causally related to these vaccines, including pneumonia, meningitis, MIBE, and febrile seizures.[119] The IOM, however, found that studies had not been conducted in order for it to conclude whether or not these vaccines caused 135 other commonly reported serious injuries, including:

> Acute Disseminated Encephalomyelitis, Afebrile Seizures, Amyotrophic Lateral Sclerosis, Arthralgia, Autoimmune Hepatitis, Brachial Neuritis, Cerebellar Ataxia, Chronic Headache, Chronic Inflammatory Demyelinating Poly-neuropathy, Chronic Urticaria, Encephalitis, Encephalopathy, Erythema Nodosum, Fibromyalgia, Guillain-Barré Syndrome, Hearing Loss, Immune Thrombocytopenic Purpura, Infantile Spasms, Juvenile Idiopathic Arthritis, Multiple Sclerosis, Neuromyelitis Optica, Optic Neuritis, Polyarteritis Nodosa, Psoriatic Arthritis, Reactive Arthritis, Rheumatoid Arthritis, Seizures, Small Fiber Neuropathy, Stroke, Sudden Infant Death Syndrome, Systemic Lupus Erythematosus, Thrombocytopenia, Transverse Myelitis[120]

This means that even among the 158 serious injuries that the CDC and HRSA (an agency which defends against vaccine injury claims) identified as the most commonly claimed injuries from vaccines, the CDC nor the greater scientific community have conducted the studies necessary to rule out vaccines as a cause for over 86% of these commonly claimed vaccine harms. [121]

AHRQ's "Comprehensive Review" of Vaccine Safety is Equally Concerning

HHS asserted that a 2014 report by the Agency for Health Research and Quality (**AHRQ**) is "the most comprehensive review" of the literature on vaccine safety.[122]

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[116] https://www.nap.edu/read/2138/chapter/2#12.
[117] https://www.nap.edu/read/2138/chapter/12.
[118] https://www.nap.edu/read/2138/chapter/12.
[119] https://www.nap.edu/read/13164/chapter/2#3.
[120] https://www.nap.edu/read/13164/chapter/2#3.
[121] https://www.nap.edu/read/13164/chapter/2#3.
[122] https://www.ncbi.nlm.nih.gov/books/NBK230053/ (HHS's 2014 review also added the following vaccine-injury pairs to the list of what it asserts are the most commonly-claimed vaccine injuries: spontaneous abortion from HPV vaccine and meningitis from MMR vaccine.).

The report reviewed the entire body of published literature regarding vaccine safety and only identified 97 studies that are applicable to children that it found to be reliable.[123] Of those studies, 77 were directly funded and/or authored, typically both, by the same pharmaceutical company whose vaccine(s) the study reviewed.[124] As for the remaining 20 studies, almost all were funded and/or authored by agencies and/or individuals that directly or indirectly receive funding from the pharmaceutical company whose vaccine(s) the study reviews.[125]

AHRQ's comprehensive review of vaccine safety *excluded* a rare randomized, double-blind, placebo-controlled study comparing respiratory infections between children receiving a saline injection and children receiving inactivated influenza vaccine (**TIV**).[126] This study carefully tracked these children for nine-months. The result was that:

> There was no statistically significant difference in the risk of confirmed seasonal influenza infection between recipients of TIV or placebo. … However, participants who received TIV had higher risk of ARI [acute respiratory illness] associated with confirmed noninfluenza respiratory virus infection (RR, 4.40; 95% CI, 1.31–14.8).[127]

Meaning, both groups had a similar rate of influenza, but the vaccinated group had 440% more cases of noninfluenza acute respiratory illness.[128] Getting the flu shot, as the study explained, appears to have significantly "reduced immunity to noninfluenza respiratory viruses."[129] In contrast, the review included, as just one example, a study funded by GSK and conducted by GSK employees which compared 199 infants receiving PHiD-CV, DTPa, HBV, IPV and Hib (test group) with 101 infants receiving DTPa, HBV, IPV and Hib (control group).[130]

The review also begins by explaining its concern that "vaccination rates remain well below established Healthy People 2020 targets for many vaccines," "[i]ncreasing vaccination rates remains critically important," "public concerns about vaccine safety continue to persist" despite "the rigorous processes new vaccines must undergo before receiving approval" and that the vaccines meet "stringent criteria for safety."[131] Hence, the review made clear that it began by assuming vaccines were safe.

Despite the review starting with the assumption that vaccines are safe, and only accepting as reliable less than one hundred studies with regard to vaccine safety for all childhood vaccines, it concluded that childhood vaccines can cause, among other serious adverse reactions, febrile seizures, arthralgia (pain in the joints), thrombocytopenic purpura (the immune system attacking

[123] The review lists the study, Zaman K. et al. (2012), twice in Table 22 and the study, Khatun S. et al. (2012), twice in Table 25.
[124] https://www.ncbi.nlm.nih.gov/books/NBK230053/.
[125] https://www.ncbi.nlm.nih.gov/books/NBK230053/.
[126] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3404712/.
[127] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3404712/.
[128] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3404712/.
[129] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3404712/.
[130] https://www.ncbi.nlm.nih.gov/pubmed/23432812.
[131] https://www.ncbi.nlm.nih.gov/books/NBK230053/.

the body's own platelets), meningitis (inflammation of the membranes surrounding the brain and spinal cord), and encephalitis (inflammation of the brain).[132]

But like the IOM reports, for a vast majority of the reported harms it reviewed, it could not identify studies it could rely upon to conclude they were *not* caused by one or more childhood vaccines.[133]

The foregoing comprehensive reviews of vaccine safety, as conducted by the IOM and AHRQ, reflect that the post-licensure vaccine safety literature is severely limited even for the health conditions that federal health officials assert are most common.

Harms Pharmaceutical Companies Have a Basis to Believe Are Causally Related to One or More Childhood Vaccines

While AHRQ and the IOM, in reports commissioned by HHS and the CDC, have found the published literature on vaccine safety lacking, pharmaceutical companies selling these products have access to internal safety data that is unavailable to the public.

Federal law requires pharmaceutical companies to disclose, in the package insert for each vaccine, "*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."[134] With access to safety data that is unavailable to the public or health authorities, the pharmaceutical companies are able to identify what injuries may be caused by vaccines that committees within HHS, IOM, and AHRQ cannot do without access to such data.

These adverse events identified by pharmaceutical companies are typically listed in Section 6.2 of each vaccine's package insert. Only adverse events for which these companies have a basis to believe have a "causal relationship" with the vaccine are to be listed pursuant to federal law. Adverse events for which there is only a correlation with the administration of the vaccine should therefore not be listed.

Many of the chronic diseases currently plaguing children in this country have been disclosed on one or more package inserts by pharmaceutical companies.[135] The following is a list of some of the injuries disclosed in one or more vaccine package inserts:

Immune System Disorders

Alopecia	*autoimmune skin disease causing loss of hair on the scalp and body.*
Anaphylactic Shock	*rapid onset of severe allergic reaction that causes sudden drop in blood pressure and narrowing of airway that can lead to seizures, shock, and death.*
Angioedema	*potentially life-threatening swelling underneath the skin.*

[132] https://www.ncbi.nlm.nih.gov/books/NBK230053/.
[133] https://www.ncbi.nlm.nih.gov/books/NBK230053/.
[134] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=201.57.
[135] https://www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states.

Arthritis	*painful and disabling autoimmune disease that includes joint pain, swelling and progressive stiffness in the fingers, arms, legs and wrists.*
Autoimmune Disease	*disease caused by the immune system mistakenly attacking the body's own tissue.*
Guillain-Barré Syndrome	*autoimmune disease where the immune system attacks the nerves in the legs, upper body, arms and/or face.*
Hemolytic Anemia	*red blood cells are destroyed faster than they can be replaced.*
Henoch-Schonlein Purpura	*abnormal immune response causing inflammation of microscopic blood vessels which can lead to multiple organ damage.*
Lupus Erythematosus	*autoimmune disease in which the immune system attacks multiple organs, including skin, joints, kidney, and brain.*
Multiple Sclerosis	*autoimmune disease in which the immune system attacks nerve fibers, causing them to deteriorate.*
Myasthenia	*autoimmune disease causing chronic weakness of the skeletal muscles, including arms and legs, vision problems, and drooping eyelids or head.*
Myositis	*chronic muscle inflammation that damages the muscle fibers causing weakness, and may affect the arteries and blood vessels that pass through muscle.*
Polyarteritis Nodosa	*systemic vasculitis that affect medium-sized and small muscular arteries resulting in ruptures and other damage.*
Stevens-Johnson's Syndrome	*severe autoimmune reaction in which the top layer of skin is burned off and dies.*
Thrombocytopenia	*low blood platelet count which can result in easy bruising and excessive bleeding from wounds or bleeding in mucous membranes.*
Vasculitis	*inflammation of the blood vessels, potentially leading to loss of function of affected tissues and organ damage.*

Nervous System Disorders

Acute Disseminated Encephalomyelitis	*acute, widespread inflammation in the brain and spinal cord that damages myelin.*
Ataxia	*brain damage resulting in loss of full control of bodily movement, impaired speech, eye movement, and swallowing.*
Bell's Palsy	*disfiguring paralysis or weakness on one side of the face.*
Encephalitis	*inflammation of the brain, which can result in permanent injury.*
Encephalomyelitis	*inflammation of the brain and spinal cord.*
Encephalopathy with EEG Disturbances	*damage or malfunction of the brain with severity ranging from altered mental state to dementia, seizures and coma.*
Grand Mal Convulsion	*loss of consciousness and violent muscle contractions.*
Hypotonia	*low muscle tone.*
Hypotonic-Hypo-responsive Episode	*sudden and unexpected loss of tone, unresponsiveness and color change.*

Meningitis	*inflammation of protective membranes covering the brain and spinal cord.*
Migraine	*sudden and severe, pounding headaches, upset stomach, and sometimes disturbed vision.*
Motor Neuron Disease	*neurological disorder that destroys motor neurons that control essential voluntary muscle activity such as speaking, walking, breathing, and swallowing.*
Myelitis	*inflammation of spinal cord that can involve nerve pain, paralysis and incontinence.*
Nerve Deafness	*hearing loss from damage to the nerve that runs from the ear to the brain.*
Neuralgia	*intense painful sensation along a nerve or group of nerves.*
Neuropathy	*nerve problem that causes pain, numbness, tingling, swelling, or muscle weakness in different parts of the body.*
Ocular Palsies	*damage to the nerve of the eye that controls eye movement.*
Optic Neuritis	*inflammation causing eye pain and partial or complete vision loss.*
Paralysis	*inability to move part or all of the body.*
Radial Nerve and Recurrent Nerve Paralysis	*nerve injury to the radial nerve that can cause weakness or difficulty moving the wrist, hand or fingers.*
Radiculopathy	*compressed or pinched nerve.*
Retrobulbar Neuritis	*inflammation and damage to the optic nerve between the back of the eye and the brain.*
Seizures	*sudden, uncontrolled body movements and changes in behavior that occur because of abnormal electrical activity in the brain.*
Stroke	*blood flow blocked to the brain or bleeding in the brain, which can lead to brain damage, long-term disability, or death.*
Subacute Sclerosing Panencephalitis (SSPE)	*progressive neurological disorder affecting the central nervous system leading to mental deterioration, loss of motor function, and ultimately leading to a vegetative state followed by death.*
Syncope	*decrease in blood flow to the brain causing a loss of consciousness and muscle strength.*
Transverse Myelitis	*inflamed spinal cord which may result in paralysis.*

Other Disorders and Chronic Disorders

Aseptic Meningitis	*acute inflammation of the brain and spinal cord.*
Aplastic Anemia	*damage to the bone marrow that slows or shuts down the production of new blood cells.*
Cellulitis	*infection of the deep tissues of the skin and muscles that cause the skin to become warm and tender.*
Cyanosis	*bluish skin discoloration due to low oxygen saturation.*
Death	*permanent end of life.*
Deep Vein Thrombosis	*formation of a blood clot in a deep vein that can break off and block blood flow to organs.*
Diabetes Mellitus	*chronic condition affecting ability to use energy from food.*

Dysphonia	*impairment in the ability to speak.*
Epididymitis	*inflammation of the testicle tube, which can lead to abscess formation, testicular pain, painful urination, tissue death, and decreased functionality of gonads.*
Mental Disorders	*unusual thoughts, perceptions, emotions, behavior, and relationship with others.*
Myalgia	*muscle pain that can become chronic.*
Orchitis	*inflammation of one or more testicles that can cause infertility, testicular atrophy, and severe pain.*
Pancreatitis	*inflammation of the pancreas due to damage by digestive enzymes.*
Pneumonia	*infection in one or both lungs.*
Respiratory Infection	*infection of the respiratory tract.*
Retinitis	*inflammation of the retina which can permanently damage the retina, leading to blindness.*
Rhinitis	*irritation and inflammation of nasal mucous membranes impacting ability to breathe properly.*
Sudden Infant Death Syndrome	*sudden death of infant in good health.*
Tachycardia	*an abnormally rapid heart rate.*
Uveitis	*inflammation of the eye leading to vision loss.*
Vertigo	*problem with the vestibular portion of the inner ear causing dizziness.*

Many of these medical conditions are the same conditions that have risen since the 1980s but have still not been properly studied by the CDC or other public health agencies.

Vaccinated v. Unvaccinated Studies

Properly assessing the safety of a product typically requires comparing an exposed group to an unexposed group and assessing their health outcomes, i.e., comparing a group that receives the product with a group that does not receive the product. Regarding vaccines, that requires comparing the health outcomes between vaccinated (one or more vaccines) and unvaccinated (zero vaccines) children. This can be accomplished by using existing databases that contain this health data.

In 2013, the IOM published a report after having been commissioned by HHS to review the overall safety of the CDC childhood schedule "to identify health outcomes associated with some aspect of the childhood immunization schedule," including "asthma, autoimmunity, autism, other neurodevelopmental disorders (e.g., learning disabilities, tics, behavioral disorders, and intellectual disability), seizures, and epilepsy."[136] This was a different IOM report than the ones previously discussed above as it did not focus on individual vaccines but rather on the safety of the CDC childhood vaccine schedule as a whole.

[136] https://www.nap.edu/read/13563/chapter/2#5.

Instead of answers, the IOM found that no studies had ever been conducted which compared the health outcomes of children receiving the CDC's childhood vaccine schedule with children that had not been vaccinated:

> [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. …
>
> [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.[137]

Even when the IOM committee expanded its search for any evidence that could help it assess the safety of the CDC's childhood vaccine schedule, it stated that it "found a paucity of information, scientific or otherwise, that addressed the risk of adverse events in association with the complete recommended immunization schedule."[138]

Due to the lack of studies regarding the safety of the CDC's vaccine schedule, the best the IOM could do was conclude: "There is no evidence that the schedule is not safe."[139] This also means the IOM's conclusion was that there is no evidence that the schedule is safe because it was not able to find studies that directly address the question.

The IOM's report from 2013 did assert that it "is possible to make this comparison [between vaccinated and unvaccinated children] through analyses of patient information contained in large databases such as VSD [the Vaccine Safety Datalink]."[140] Subsequently, the CDC commissioned a 64-page white paper, published in April 2016, that discussed how to conduct such studies using the VSD.[141] But no such study has even been published by the CDC despite the fact this white paper acknowledges that many chronic disorders children are experiencing today in epidemic numbers are biologically plausible outcomes from exposure to CDC's childhood vaccine schedule but have not yet been properly studied. [142]

While CDC- and pharmaceutical-funded scientists have never published such a study, a few such studies have been published.

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[137] https://www.nap.edu/read/13563/chapter/2#5.
[138] https://www.nap.edu/read/13563/chapter/6?term=paucity#70.
[139] https://www.nap.edu/read/13563/chapter/2#12.
[140] https://www.nap.edu/read/13563/chapter/2#13.
[141] https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf.
[142] https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf.

A pilot study, based on parental surveys of homeschool children, from the School of Public Health at Jackson State University, published in 2017, found that 33% of vaccinated preterm babies had a neurodevelopmental disorder while 0% of the unvaccinated preterm babies had a neurodevelopmental disorder;[143] and another study by the same group found that vaccinated children, compared to unvaccinated children (receiving no vaccines), had a 74% decreased risk of chicken pox and a 70% decreased risk of pertussis, *but* had an increased risk of 290% for allergies, 320% for ADHD, 320% for autism, 190% for eczema, 420% for learning disabilities, and 270% for any neuro-developmental delay.[144]

In another study aggregating data from three medical practices in the United States, the health outcomes of vaccinated and unvaccinated children born between 2005 and 2015 were compared; this study found that vaccinated children, compared to unvaccinated children, had a statistically significant increased rate of 218% for developmental delay, 449% for asthma, and 213% for ear infections.[145]

Mandate for Safer Childhood Vaccines

There is another avenue to assess the diligence of our federal health agencies in assuring vaccine safety. When Congress passed the 1986 Act, it removed the economic interest that incentivize companies profiting from vaccine products to assure the safety of these products. The 1986 Act instead made HHS responsible for vaccine safety in a section of law titled the Mandate for Safer Childhood Vaccines (the **Mandate**), codified at 42 U.S.C. § 300aa-27.[146]

This mandate underpins and encompasses the vaccine safety obligations of HHS and hence the safety of vaccines in this country. Below is the full text of the Mandate:

> **(a) General rule**
> In the administration of this part and other pertinent laws under the jurisdiction of the Secretary, the Secretary shall—
> **(1)** promote the development of childhood vaccines that result in fewer and less serious adverse reactions than those vaccines on the market on December 22, 1987, and promote the refinement of such vaccines, and
> **(2)** make or assure improvements in, and otherwise use the authorities of the Secretary with respect to, the licensing, manufacturing, processing, testing, labeling, warning, use instructions, distribution, storage, administration, field surveillance, adverse reaction reporting, and recall of reactogenic lots or batches, of vaccines, and research on vaccines, in order to reduce the risks of adverse reactions to vaccines.

[143] https://www.oatext.com/pdf/JTS-3-187.pdf.
[144] https://www.oatext.com/pdf/JTS-3-186.pdf.
[145] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7268563/.
[146] 42 U.S.C. § 300aa-27.

(b) Task force
(1) The Secretary shall establish a task force on safer childhood vaccines which shall consist of the Director of the National Institutes of Health, the Commissioner of the Food and Drug Administration, and the Director of the Centers for Disease Control.
(2) The Director of the National Institutes of Health shall serve as chairman of the task force.
(3) In consultation with the Advisory Commission on Childhood Vaccines, the task force shall prepare recommendations to the Secretary concerning implementation of the requirements of subsection (a).

(c) Report
Within 2 years after December 22, 1987, and periodically thereafter, the Secretary shall prepare and transmit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report describing the actions taken pursuant to subsection (a) during the preceding 2-year period.

The first part of the Mandate requires HHS to make vaccines safer in almost every possible manner. A pharmaceutical company would normally be responsible for and have an economic interest in assuring these safety obligations in the normal course of their business dealings since they develop, manufacture, and sell these products and want their products to be profitable. But since these companies no longer have an economic interest to assure safety, and in fact have a financial *dis*incentive to assure safety, these safety responsibilities were transferred to HHS.

The second part of the Mandate created a Task Force on Safer Childhood Vaccines, comprised of the heads of NIH, CDC, and FDA, to make recommendations to HHS on how to achieve the safety responsibilities set forth in part one of the Mandate.

The third part of the Mandate requires HHS to send a report to Congress every two years detailing what has been done to improve safety pursuant to part one of the Mandate.

Starting with the third part of the Mandate, since the passage of the 1986 Act, there should have been at least 17 biannual reports submitted to Congress on how HHS has improved safety in the preceding two years. HHS, however, has never produced or sent a report to Congress even one report as required by part one of the Mandate.[147]

[147] https://ecf.nysd.uscourts.gov/doc1/127021989890 [https://archive.org/details/complaint-ICAN-NIH]; https://ecf.nysd.uscourts.gov/doc1/127122796564 [https://archive.org/details/complaint-ICAN-HHS]; https://icandecide.org/wp-content/uploads/2023/05/2023-01-04-IR0012_Final-Response-No-Records_HHS.pdf.

As for the second part of the Mandate, to make recommendations on how to improve vaccine safety, this task force only once made recommendations on April 19, 1996, and "the Task Force for Safer Childhood Vaccines was disbanded in 1998."[148]

Making recommendations to improve vaccine safety (part 2 of the Mandate) and submitting a biannual report to Congress on what improvements were made (part 3 of the Mandate) are the relatively easy obligations under the Mandate. The far more difficult obligations are the requirements to improve vaccine safety pursuant to part 1 of the Mandate and the above reflects how well HHS has fulfilled those critical obligations that underpin vaccine safety in this country.

As discussed above, structural conflicts within HHS appear to drive this outcome. HHS's duties to both promote and defend vaccines conflict with its safety duties, and its promotion duties have sublimated its safety duties as seen above.

Because duties to promote an industry inherently conflict with duties to identify and address safety issues within that industry, these duties are often separated into independent agencies. For example, DOT promotes transportation while safety functions are handled by the independent NTSB.[149] Similarly, DOE promotes nuclear power while safety functions are handled by the independent NRC.[150] But with vaccines, these conflicting duties are handled by the same entity: HHS.

Moreover, HHS is statutorily required to and does vigorously defend against vaccine injury claims. Under the 1986 Act, one can bring a claim for a vaccine injury, but it is brought against the Secretary of HHS in the Vaccine Injury Compensation Program (**VICP**). This further conflicts HHS, including because any safety issues identified can be used against HHS in the VICP.[151] Vaccines are the only consumer product where the government defends industry against consumers, instead of vice-versa.

The foregoing conflicts may explain why HHS has failed to perform its safety duties pursuant to the Mandate for Safer Childhood Vaccines, which underpins vaccine safety in our country, and more broadly. Also, regarding the FDA and the CDC's independent vaccine advisory committees, VRBPAC and ACIP,[152] prior reports have found its members have serious conflicts of interest, including a House Report which found that with regard to VRBPAC, for example, "[t]he overwhelming majority of members, both voting members and consultants, have substantial ties to the pharmaceutical industry."[153]

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[148] https://icandecide.org/wp-content/uploads/2023/06/task-force-safer-childhood-vaccines.pdf; https://icandecide.org/wp-content/uploads/2023/05/Meetings-held-by-the-Task-Force-for-Safer-Childhood-Vaccines.pdf.

[149] https://www.ntsb.gov/about/history/pages/default.aspx.

[150] https://www.nrc.gov/about-nrc/history.html; https://www.energy.gov/ne/office-nuclear-energy.

[151] 42 U.S.C. § 300aa-12 ("In all proceedings brought by the filing of a petition [in VICP] the Secretary [of HHS] shall be named as the respondent."); https://www.congress.gov/106/crpt/hrpt977/CRPT-106hrpt977.pdf ("DOJ attorneys make full use of the apparently limitless resources available to them," "pursued aggressive defenses in compensation cases," "establish[ed] a cadre of attorneys specializing in vaccine injury" and "an expert witness program to challenge claims."); https://uscfc.uscourts.gov/vaccine-programoffice-special-masters.

[152] *E.g.*, https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-june-5-2024-meeting-announcement ("Advisory committees provide independent expert advice to the FDA on broad scientific topics or on certain products to help the agency make sound decisions based on the available science.").

[153] https://icandecide.org/wp-content/uploads/2023/01/OGR-Majority-Report-1.pdf; https://icandecide.org/press-release/cdc-stacks-its-vaccine-committee-with-pharma-affiliated-members-ahead-of-june-2024-vote-on-covid-19-vaccines/.

As noted above, these structural conflicts in regulating vaccines can result in regulators viewing and conducting themselves like partners with pharmaceutical companies rather than like regulators when it comes to vaccines. As seen from the foregoing, this is precisely what has occurred.

As a recap of post-licensure safety: Federal health agencies are unable to identify any studies to support that infant vaccines do not cause autism and autism is the disease federal health agencies claimed to have most thoroughly studied in relation to vaccines. The IOM reports reflect that of the most commonly claimed injuries, according to the CDC, over 86% have not been studied to determine whether they are causally related to vaccines. AHRQ's "comprehensive review" of vaccine safety reflects the same and reveals that there are less than 100 childhood vaccine safety studies it deems reliable. The injuries pharmaceutical companies say they have a basis to believe are *caused* by their childhood vaccines match the health conditions that have increased precipitously over the last few decades. The handful of studies and data sources that have assessed health outcomes between children exposed to vaccines and those not exposed have found non-vaccinated children have higher rates of pertussis and chicken pox, for example, but that vaccinated children have multiple times the rate of various chronic health conditions that are at the center of this report. All of this to say that the bar for post-licensure vaccine safety was very low when Covid-19 vaccines were released and hence the status quote would have been for harms claimed to result from Covid-19 vaccines to also not be properly studied.

IV. FDA AND CDC CONCEAL CONCERNING POST-LICENSURE SAFETY DATA

Covid-19 vaccines were developed, authorized, promoted, and licensed in this existing framework. Thus, it should not come as a surprise that FDA and CDC – both viewed themselves as partners with pharmaceutical companies and actively promoted these products and mislead and concealed from the public critical Covid-19 vaccine safety data, especially with regard to data contained in and their analysis of data in their primary vaccine safety systems: VAERS, VSD and V-safe.

VAERS

The Vaccine Adverse Events Reporting System (**VAERS**) is jointly administered by the CDC and the FDA. It is a passive reporting system to which anyone can submit reports of an injury after vaccination. However, the vast majority of reports are submitted by pharmaceutical companies, health care providers, and state immunization programs.[154]

The CDC explains that VAERS cannot establish causation between a vaccine and an injury and that, at best, it can be used for signal detection. Hence, CDC argues that it should not be used to reach a causality conclusion regarding a claimed injury from one or more vaccines. But it can provide potential signals of vaccine harm based on the volume and type of reports received.

Reviewing the period prior to Covid-19 vaccines, between 2013 and 2018, VAERS received 261,294 reports of adverse vaccine events, including 2,081 deaths, 5,477 permanent disabilities, and 20,778 hospitalizations.[155]

[154] https://web.archive.org/web/20150615195821/http://vaers.hhs.gov/about/faqs.
[155] https://wonder.cdc.gov/vaers.html.

A study of VAERS reporting commissioned by the AHRQ stated that "fewer than 1% of vaccine adverse events are reported."[156] In this study, AHRQ provided a $1 million grant to create a software program at Harvard Pilgrim Health Care that would automate reporting injuries after vaccination to VAERS.[157] The result was the successful creation of a system at Harvard Pilgrim which automatically created adverse vaccine event reports:

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.[158]

Meaning, after they used an automated system to capture injuries after vaccination instead of a passive system, they found 35,570 reportable reactions in 376,452 vaccine recipients.[159]

Regrettably, the CDC did not cooperate with making this new program functional. After creating a software program that automatically created VAERS reports, the system's developers 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.[160] But as the Harvard researchers 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.[161]

VAERS cannot be used to determine whether a vaccine causes a harm because, while VAERS can provide the number of people harmed (numerator), it cannot provide the total number of people vaccinated (denominator) from which to calculate a rate of harm. Automating VAERS reports from a fixed pool of people would have made calculating a rate and thus reaching a causality conclusion on any given harm possible. That type of automation has still not been implemented for VAERS.

With that backdrop regarding VAERS, on December 4, 2020, before the first Covid-19 vaccine was rolled out, CDC released the VAERS Standard Operating Procedures for Covid-19 ("**VAERS SOP**"), which stated in relevant part:

> The analyses for **COVID-19 vaccine safety signals** will focus on identifying deviations from preliminary safety data, and possibly from other vaccines, using disproportionality analyses and comparisons of reporting rates.

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[156] https://healthit.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf.
[157] https://healthit.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf.
[158] https://healthit.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf.
[159] https://healthit.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf.
[160] https://healthit.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf.
[161] https://healthit.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf.

> **Two main approaches to data mining are Proportional Reporting Ratios (PRRs) and Empirical Bayesian Geometric Means**. Both have published literature suggesting criteria for detecting "signals". **PRR will be used at CDC for potential signal detection; Empirical Bayesian data mining will be performed by FDA**.[162]

This SOP made clear that CDC planned to conduct safety signal monitoring using Proportional Reporting Ratios ("**PRR**") and FDA planned to conduct safety signal monitoring using Empirical Bayesian ("**EB**") data mining.

Our firm requested the PRR signal detection data from CDC through FOIA and was denied. In the denial letter, CDC stated that it had not conducted PRR analyses; it instead highlighted the superiority of and historical use of EB data mining, calling it the "gold standard" and the "superior method" with which to detect safety signals. However, on September 2, 2022, then-CDC Director Rochelle Walensky sent a letter to Senator Ron Johnson acknowledging that PRR had in fact been used: "CDC performed PRR analysis between March 25, 2022, through July 31, 2022, to corroborate the results of EB data mining. Notably, **results from PRR analysis were generally consistent with EB data mining**, revealing no additional unexpected safety signals." Our firm then sued CDC based on this admission and ultimately received 51 excel files containing PRR data. [163] These files showed that CDC's own threshold for triggering a signal for adverse events was more than met for numerous serious adverse events, including as seen in the following CDC tables noting that CDC had set anything above a "2" in the PRR row as a safety signal:[164]

[162] https://www.cdc.gov/vaccinesafety/pdf/VAERS-COVID19-SOP-4-Dec-2020-508.pdf
[163] https://www.sirillp.com/wp-content/uploads/2024/06/Response-to-FDA-Stay-b390d697ad6bc29544ff90e607957c03.pdf.
[164] https://icandecide.org/cdc-proportional-reporting-ratio/ (All PRR data is available for download at this site).

N>=3 (Current Week), PRR>=2.00 (Ratio of			
MedDRA Codes ALL Reports (18+)	12/14/2020-05/06/2022 COVID19 mRNA N=632725	12/14-05/06 Chi-Square	12/14-05/06 PRR
CEREBRAL THROMBOSIS	194	69.78	73.46
INTERMENSTRUAL BLEEDING	1323	481.57	62.62
CEREBRAL VENOUS SINUS THROMBOSIS	155	55.02	58.69
HEAVY MENSTRUAL BLEEDING	4246	1543.71	53.59
INTENTIONAL PRODUCT USE ISSUE	141	49.72	53.39
POSITIVE AIRWAY PRESSURE THERAPY	789	283.64	49.79
PULMONARY THROMBOSIS	610	218.11	46.20
DISEASE RECURRENCE	227	79.98	42.98
HYPERPYREXIA	111	38.38	42.03
POSTMENOPAUSAL HAEMORRHAGE	521	184.41	39.46
POLYMENORRHOEA	684	241.57	37.00
RIGHT VENTRICULAR DYSFUNCTION	96	32.71	36.35
INTENTIONAL DOSE OMISSION	94	31.96	35.59
ABNORMAL UTERINE BLEEDING	82	27.43	31.05
OLIGOMENORRHOEA	564	196.16	30.51
CEREBELLAR STROKE	80	26.68	30.29
SUSPECTED COVID-19	550	190.86	29.75
CEREBRAL MASS EFFECT	75	24.79	28.40
RIGHT VENTRICULAR DILATATION	73	24.04	27.64
DYSMENORRHOEA	1821	631.80	27.58
THROMBECTOMY	348	118.98	26.35
MYOCARDIAL STRAIN	64	20.65	24.23
HAEMOFILTRATION	62	19.90	23.48
IMPLANTABLE CARDIAC MONITOR INSERTION	61	19.52	23.10
TRANSVERSE SINUS THROMBOSIS	60	19.15	22.72
MATERNAL EXPOSURE DURING BREAST FEEDING	292	97.84	22.11
BODY HEIGHT DECREASED	57	18.02	21.58
MENSTRUAL DISORDER	2435	822.34	20.96
MENSTRUATION IRREGULAR	3240	1094.66	20.79
MESENTERIC VEIN THROMBOSIS	54	16.90	20.45
NIH STROKE SCALE ABNORMAL	54	16.90	20.45
NIH STROKE SCALE	53	16.52	20.07
CORONARY ARTERY DISSECTION	52	16.15	19.69
JUGULAR VEIN THROMBOSIS	52	16.15	19.69
LEFT VENTRICULAR DILATATION	51	15.77	19.31
ANOSMIA	3546	1186.66	19.18
NEUROLOGIC NEGLECT SYNDROME	50	15.40	18.93
CEREBRAL ARTERY OCCLUSION	98	31.29	18.55
VITAL SIGNS MEASUREMENT	146	47.19	18.43
ILLNESS	4279	1423.54	18.21
INTRACARDIAC THROMBUS	95	30.16	17.99
LYMPHOPENIA	94	29.79	17.80
THROMBOEMBOLECTOMY	47	14.28	17.80
VACCINATION SITE URTICARIA	322	104.80	17.42
COR PULMONALE ACUTE	46	13.90	17.42
HEPATIC MASS	46	13.90	17.42
WRONG PATIENT	45	13.53	17.04
PREMENSTRUAL PAIN	44	13.16	16.66
PRODUCT RECONSTITUTION QUALITY ISSUE	44	13.16	16.66
TOTAL LUNG CAPACITY DECREASED	44	13.16	16.66
PERIPHERAL ARTERY OCCLUSION	43	12.78	16.28
ANTICOAGULANT THERAPY	3684	1204.20	16.22
COLON CANCER	41	12.04	15.53
SYMPTOM RECURRENCE	163	51.45	15.43
ACUTE CARDIAC EVENT	40	11.67	15.15
PERIPHERAL ARTERY THROMBOSIS	78	23.79	14.77
CARDIOVASCULAR SYMPTOM	39	11.29	14.77

When the CDC was confronted with the above data that it sought to hide from the public, it advised Senator Johnson that it was no longer relying upon PRR and instead would only rely upon FDA's EB data mining; as the CDC Director wrote to Senator Johnson:

> CDC and the Food and Drug Administration (FDA) chose to rely on Empirical Bayesian (EB) data mining—a more robust technique used to analyze disproportionate reporting—rather than PRR

> calculations to mitigate potential false signals. . . . Given the strength of the EB data mining method, CDC and FDA plan to continue relying upon EB data mining moving forward.[165]

Given that it now decided to abandon the PRR data and rely upon the EB data, our firm requested the EB data mining results from FDA through FOIA and was denied. Hence, we commenced litigation and the FDA filed a motion requesting that the litigation be stayed for at least 18 months due to the agency being overwhelmed as a result of another court order, issued to our client and litigated by our firm, that ordered FDA to disclose all of the clinical trial documents related to the Pfizer and Moderna Covid-19 vaccines' licensures. The Court granted the stay for 6 months and then recently granted an additional 6 months. During the stay of the litigation, the FDA unilaterally decided to make public what appears to be a cherry-picked portion of the EB data mostly related to the Janssen Covid-19 vaccine.[166] From this limited and unexplained data, we have learned the following regarding the Janssen Covid-19 vaccine:

- The first EB data mining report is dated 1/12/2021 and the last report is dated 7/5/2022. The reports were run weekly but the FDA did not release reports for the weeks of 1/19/2021, 1/26/2021, 2/9/2021, 2/16/2021, 4/6/2021, 5/4/2021, 12/28/2021, 1/18/2022, 4/26/2022, and 5/31/2022.

- Signals for menstruation issues for the Janssen Covid-19 vaccine showed up on the reports from 4/27/2021 through 5/25/2021.

- Beginning on 4/20/2021 and continuing through the rest of the production, the reports consistently show signals for numerous types of blood clotting issues (e.g., thrombosis, pulmonary embolism, cerebral venous sinus thrombosis, deep vein thrombosis, transverse sinus thrombosis, "fibrin D dimer," etc.) for the Janssen vaccine. The pause during the Janssen trial had been lifted on 4/23/2021.

- "Death" appears on every report from 3/8/2022 through 7/5/2022 for the Janssen vaccine. In the "Comment" column for "Death" it says "Reviewed, Regulatory Action." The FDA has not explained what this means.

To date, the FDA has refused to produce the remainder of the EB data mining results, and all communications concerning the EB data mining results, to the public despite the concerning results shown in the PRR data and despite the fact that the health authorities made clear that both the CDC and the FDA were relying upon EB data mining to monitor safety in these products.

VSD

The next system the CDC lists as a vaccine safety surveillance tool is the Vaccine Safety Datalink (**VSD**). While this system could be helpful in assessing vaccine safety, that is not currently the case. Until around 2001, the VSD was maintained at the CDC. Thus, independent scientists were able to obtain access to the VSD at the request of members of Congress and through other legal

[165] https://www.documentcloud.org/documents/23940343-sen-johnson-letter-to-fda-on-eb-data-mining.
[166] https://www.fda.gov/media/184988/download.

means. The studies these independent scientists published identified various harms associated with vaccination. CDC then moved the VSD to an industry trade association starting in 2001 which took it out of the reach of the Freedom of Information Act and also limited the data to only scientists and studies it approved.[167] This resulted in selection bias with regard to studies that were allowed to access and be published using the VSD. Moreover, every study published using the VSD violates scientific standards because the underlying data is almost never available for inspection by the public and other scientists.[168] Refusal to make this data available raises serious concerns regarding reproducibility and transparency. HHS regulations provide severe penalties if researchers, using HHS funding, refuse to share data underlying their studies, but the CDC does not apply this same standard to its own VSD studies.[169]

Putting these issues aside, the VSD is not typically used to study long term health conditions. While the CDC has acknowledged that public stakeholders "have expressed more concerns about long-term than short-term health outcomes" and that "long-term health outcomes have been less well-studied in the context of vaccine safety," VSD is geared toward assessing short-term, and not long-term, health outcomes:

> The current safety surveillance systems such as the VSD … already have extensive systems in place to assess short-term outcomes … [despite the fact] the childhood immunization schedule is essentially a long-term exposure, occurring over 18 to 24 months, [and hence] long-term adverse events may be more biologically plausible than short-term events.[170]

The deidentified data in the VSD, paid for by taxpayers, should be available to the public so that independent scientists can conduct vaccine safety studies. There are at least 359 published studies that have relied upon VSD data with a large majority of those studies concluding that vaccines are "safe and effective."[171] One such study, for example, titled *Safety of COVID-19 mRNA Vaccination Among Young Children in the Vaccine Safety Datalink*, stated: "In this interim analysis of children aged 5 years and younger, safety surveillance of more than 245,000 COVID-19 mRNA vaccine doses over 9 months did not detect a safety signal for any outcome during the 21 days after vaccination. Importantly, no cases of myocarditis or pericarditis occurred after vaccination… These results can provide reassurance to clinicians, parents, and policymakers alike."[172] However, until that data is released and any claimed results using this data replicated, it is an improper tool to reach any conclusion regarding vaccine safety.

V-safe

CDC's V-safe vaccine safety system is a smartphone-based program which uses "text messages and web surveys to ask how [users] feel, including if [users] experience any side effects after

[167] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4708093/.
[168] https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vsd/accessing-data.html.
[169] https://www.federalregister.gov/documents/2016/09/21/2016-22379/nih-policy-on-the-dissemination-of-nih-funded-clinical-trial-information.
[170] https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf.
[171] https://www.ncbi.nlm.nih.gov/myncbi/browse/collection/64309023/.
[172] https://publications.aap.org/pediatrics/article/152/1/e2023061894/191478/Safety-of-COVID-19-mRNA-Vaccination-Among-Young?autologincheck=redirected.

vaccination."[173] It was first developed and used with COVID-19 vaccines but has since been expanded for other vaccines. As explained by the CDC, the program "helps CDC gather important information and monitor any potential side effects in real time so scientists can quickly study them and determine if there is a safety concern with a particular vaccine."[174] The CDC explains that "[t]his information helps [it] communicate timely and transparent information about the safety of vaccines to public health officials, healthcare providers, and the public."[175]

On November 19, 2020, the CDC published a protocol for developing V-safe titled "V-safe active surveillance for COVID-19 vaccine safety" (**V-Safe Protocol**).[176] The V-Safe Protocol explains that "[t]he purpose of v-safe surveillance is to rapidly characterize the safety profile of COVID-19 vaccines when given outside a clinical trial setting and to detect and evaluate clinically important adverse events and safety issues that might impact policy or regulatory decisions."[177]

V-safe was launched simultaneously with the release of the first COVID-19 vaccine in December 2020. Approximately 10 million individuals signed up for v-safe, around 9 million of whom registered between December 2020 and April 2021.[178]

This period from December 2020 to April 2021 was a period when there were no Covid-19 vaccine mandates yet and there was high public interest in receiving this product. The data submitted by 10 million V-safe users is likely a good reflection of the experience of the larger population of 265 million Americans who received at least one dose of a COVID-19 vaccine.

V-safe collected data from users in two ways. The first was check-the-box options limited to (a) symptoms and (b) health impacts. The second was using free-text fields.

With regard to check-the-box symptoms, V-safe users were asked to select one or more of 10 listed symptoms that occurred within the first week after vaccination. These symptoms are those that the CDC explains are normal after vaccination and are a sign the vaccine is working by producing an immune response. As the CDC explains: "Any side effects from getting the vaccine are normal signs the body is building protection."[179] Meaning, the check-the-box symptoms data collected by V-safe had effectively no value in assessing safety of the COVID-19 vaccines. Indeed, the 10 million V-safe users reported over 70 million check-the-box symptoms, and this did not raise concerns for the CDC as seen from the studies the CDC published reflecting these high rates of check-the-box symptoms.[180]

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[173] *See* https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety.html (listing v-safe as one of the ways "CDC expanded and strengthened the country's ability to monitory vaccine safety").
[174] *Id.*
[175] *Id.* (emphasis added).
[176] https://web.archive.org/web/20210102024902/https://www.cdc.gov/vaccinesafety/pdf/V-safe-Protocol-508.pdf.
[177] *Id.* at 1.
[178] https://data.cdc.gov/Public-Health-Surveillance/v-safe-COVID-19/dqgu-gg5d/about_data.
[179] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/how-they-work.html.
[180] *See e.g.*, https://www.cdc.gov/mmwr/volumes/71/wr/mm7107e1.htm; https://www.cdc.gov/mmwr/volumes/70/wr/mm7039e4.htm; https://www.cdc.gov/mmwr/volumes/70/wr/mm7018e2.htm; https://jamanetwork.com/journals/jama/fullarticle/2778441; https://www.cdc.gov/mmwr/volumes/70/wr/mm7008e3.htm; https://www.cdc.gov/mmwr/volumes/70/wr/mm705152a1.htm; https://www.cdc.gov/mmwr/volumes/70/wr/mm7031e1.htm.

The only other check-the-box safety information collected (other than the 10 listed symptoms) was whether users reported needing medical care, missed school or work, or could not perform normal daily activities following their vaccination (**health impact data**). If a user selected that he or she needed medical care, the user was then also asked to select whether he or she sought telehealth, urgent care, emergency care, or was hospitalized.

The health impact data was collected during the first week, then weekly for the first six weeks, and then at 3, 6, and 12 months after injection. In contrast, the check-the-box symptoms data was collected for only the first week after injection. Since the CDC dubbed V-safe a "real time" surveillance program, presumably the health impact data is the data the CDC intended to use to rapidly detect any safety issues.[181]

Since 2021, the CDC published dozens of studies to support its claim that COVID-19 vaccines are safe. Primary data used in these studies is V-safe's health impact data, with a focus on the rate of people who reported needing medical care after the vaccine. The studies form a core of the CDC's support for the safety of COVID-19 vaccines. However, the studies only report the first week of health impact data after injection despite the fact injuries from COVID-19 vaccines can occur after the first week.[182]

When the CDC released the check-the-box data to the public, after over two years of litigation by a non-profit group seeking the data, it reflected that 7.7% of V-safe users reported needing medical care after a COVID-19 vaccine and an additional 25% of V-safe users reported missing school or work or being unable to perform normal activities after receiving a COVID-19 vaccine.[183]

That finding was not in accord with what the CDC had been reporting to the public, as it reflected that nearly 1 in 13 individuals in the V-safe system sought medical care after a COVID-19 vaccine, and on average, users sought medical care two to three times each. Since V-safe was supposed to assess safety, and the only metric that appears to have provided any such measure was when users reported seeking medical care, it is unclear what measure of vaccinees having to seek medical would have needed to occur in order to raise a safety concern for the CDC.

Furthermore, the CDC could have designed V-safe to be a rapid and useful safety system by including check-the-box options for harms that COVID-19 vaccines can or were suspected to cause. For example, a check-the-box option for myocarditis or for chest pain. As reflected in the first version of the V-safe Protocol, prior to the program's launch, it listed adverse events of special interest (**AESI**) in a chart titled Prespecified Medical Conditions:

[181] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety.html ("These platforms give CDC scientists information about the safety of COVID-19 vaccines in real time.").
[182] For example, myocarditis can arise at least 42 days after vaccination. *See* https://pubmed.ncbi.nlm.nih.gov/34614329/ at Figure 1. Thrombosis with thrombocytopenia syndrome (TTS), which can also be caused by the COVID-19 vaccine, can arise up to 18 days after vaccination. *See* https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-12-16/02-COVID-See-508.pdf at slide 16.
[183] https://icandecide.org/v-safe-data/.

Attachment 2: Adverse Events of Special Interest

Prespecified Medical Conditions
Acute myocardial infarction
Anaphylaxis
Coagulopathy
COVID-19 Disease
Death*
Guillain-Barré syndrome
Kawasaki disease
Multisystem Inflammatory Syndrome in children[1]
Multisystem Inflammatory Syndrome in adults[2]
Myocarditis/Pericarditis
Narcolepsy/Cataplexy
Pregnancy and Prespecified Conditions
Seizures/Convulsions
Stroke
Transverse Myelitis

* Capture of deaths through v-safe will be limited.

This list included acute myocardial infarction, anaphylaxis, coagulopathy, COVID-19 Disease, death, Guillain-Barre Syndrome, Kawasaki disease, Multisystem Inflammatory Syndrome in Children, Multisystem Inflammatory Syndrome in adults, myocarditis/pericarditis, narcolepsy/cataplexy, pregnancy and prespecified conditions, seizures/convulsions, stroke, and transverse myelitis.

The CDC also identified all but two (pregnancy and coagulopathy) of these AESIs in an October 22, 2020 presentation titled "CDC post-authorization/post-licensure safety monitoring of COVID-19 vaccines."[184] Many of these AESIs were also identified in a July 2020 NEJM study,[185] as well as in an October 16, 2020 JAMA article.[186]

Nonetheless, the CDC did not include in the V-safe system any check-the-box options for these harms *or* for common symptoms from these harms. Had the agency done so, it would have enabled the CDC and the scientific community to calculate a rate for which V-safe users had myocarditis, or other adverse events that had been prespecified by the CDC as potential problems (*e.g.*, strokes, seizures, etc.). Instead, the CDC limited potential reporting of such adverse events to free-text fields to which fewer people would report issues and which would be more difficult to standardize.

V-safe was plainly designed to reach a finding that COVID-19 vaccines are safe rather than designed to assess whether COVID-19 vaccines are safe. It only included symptoms that the CDC considers normal and reflect the vaccine is creating immunity, which is also reflected by the fact it only tracked those symptoms for one week after administration. It did not include on the list of symptoms and conditions those that it listed as ones of concern/special interest. It also did not, of its own accord, reveal the health impact data to the public, which appears to be the only actual useful data for assessing safety; only after years of legal demand and litigation did it release the data, which revealed that 7.7% of V-safe users reported seeking medical care after a COVID-19 vaccine, and on average two to three times per user.

[184] *See* https://cacmap.fda.gov/media/143530/download at 31.
[185] *See* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7377258/#ap2.
[186] *See* https://jamanetwork.com/journals/jama/fullarticle/2772137.

V-safe also collected "free text" data from a few fields (limited to 250 characters each) for users to provide additional safety information. CDC received approximately 7.8 million free-text entries from V-safe users. CDC refused to disclose the free-text data to the American public and again we had to sue the agency and get a court order before the agency eventually produced the data over the course of approximately one year. That production was recently completed in mid-January.[187] These free-text entries provide the most critical and informative dataset available for assessing the safety and efficacy of the existing COVID-19 vaccines because they were collected from a known universe of users directly reporting their symptoms and reactions. Thus, the rate at which an adverse event is reported can be calculated and relied upon as it would be, at best, an underestimation as free text fields are less likely to be completed than check the box forms. Moreover, unlike other safety data the government has relied upon, V-safe data is not filtered through the companies selling the vaccines which, in turn, removes conflicts of interest that could potentially influence the data. The data shows, for example, that 49,783 registrants reported chest pain; 784 registrants reported pericarditis; and 366 registrants reported myocarditis. These numbers are likely a severe undercount as V-safe users only had a certain timeframe in which they could submit data and that likely elapsed before anyone received an official diagnosis, and, as noted, users are less likely to complete free text fields than check the box options.

CISA

CDC regularly claims that the Clinical Immunization Safety Assessment ("**CISA**") is a critical part of the safety monitoring of vaccines. CDC describes CISA as: "a national collaborating network of vaccine safety experts from the CDC's Immunization Safety Office (ISO), eight medical research centers, and other partners" that was established "to improve the understanding of adverse events following immunization at the individual patient level."[188] CISA, like the other safety surveillance programs, is also problematic for a few reasons.

For one, as CDC states, "CISA provides consultations for U.S. healthcare providers with complex vaccine safety questions about their patients."[189] Our firm has heard time and again during the Covid-19 vaccine rollout that many people who suffered adverse events after their vaccination were not believed or being treated by their doctors. No one in the medical field would acknowledge that the injury could potentially be a vaccine injury and so those people were unable to utilize CISA as it provides consultations only to healthcare providers and not to individual patients.

Moreover, the Principal Investigator of CISA, Dr. Kathryn Edwards,[190] has also been a paid advisor to Pfizer, was compensated by numerous other pharmaceutical companies as consultant and/or advisor and also was one of five members of Pfizer Covid-19 vaccine trial's data safety monitoring board.[191] As explained by bioethicist Arthur Caplan, these boards are "very powerful. They're key guardians of science and safety and are as important if not more important than the FDA."[192] Dr. Edwards had a close look at the Pfizer vaccine trial and the ability to stop the trial if

[187] https://icandecide.org/v-safe-data/ (Provides downloads of all V-safe data and a searchable dashboard containing all of the data).
[188] https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html.
[189] *Id.*
[190] https://www.vumc.org/vvrp/person/kathryn-m-edwards-md.
[191] https://www.cbsnews.com/news/covid-19-vaccine-when-will-be-available-ready/.
[192] https://www.cnn.com/2020/10/03/health/dsmb-role-coronavirus-vaccine-trial/index.html.

there were safety concerns. Following the release of that same product, she was consulting with healthcare providers as to whether or not that same product was the cause of their patients' serious injuries. This conflict casts, at best, serious doubt on the entire CISA program.

Myocarditis – A Specific Adverse Event About Which Health Authorities Were Not Transparent

The following timeline demonstrates how our federal health authorities failed in timely and effectively identifying myocarditis as a risk to Covid-19 vaccination and then compounded that failure with a lack of transparency.

October 16, 2020 (pre-Covid vaccine)

- The article *Postapproval Vaccine Safety Surveillance for COVID-19 Vaccines in the US* published in *JAMA* mentions myocarditis/pericarditis as an adverse event of special interest.[193]

October 30, 2020 (pre-Covid vaccine)

- The CDC identified myocarditis as an adverse event of special interest in an October 30, 2020 presentation titled "CDC post-authorization/post-licensure safety monitoring of COVID-19 vaccines."[194]

January 28, 2021 (Covid vaccine now has EUA and is being administered to the public)

- ICAN obtained a copy of the CDC's January 28, 2021, V-safe protocol which reveals a series of 15 "Adverse Events of Special Interest."[195] One of those events of special interest was "Myocarditis/Pericarditis." The next version of the V-safe protocol, dated May 20, 2021, again lists the same series of 15 "Adverse Events of Special Interest"[196] but the V-safe program still did not track these adverse events.

Feb. 18, 2021

- Safety signal for myocarditis triggered in VAERS using CDC-endorsed method called Proportional Reporting Ratio.[197]

April 26, 2021 (CDC denying signal for myocarditis)

- Tom Shimabukuro (CDC) stated in an internal CDC email, "Yes, we have been briefed by the Israeli MOH on their myocarditis cases and DoD also has a myocarditis case series that they have submitted for publication. Myocarditis/pericarditis is a VAERS AESI and a VSD pre-specified outcome for active surveillance. After 220 million doses of mRNA vaccines nationwide and over 5 million doses administered in VSD, **we don't see any evidence of a safety problem with myocarditis or pericarditis**. I can't speak to the Israeli MOH or

[193] https://jamanetwork.com/journals/jama/fullarticle/2772137.
[194] https://stacks.cdc.gov/view/cdc/97350 (at slide 17).
[195] https://icandecide.org/wp-content/uploads/2022/10/Earlier-V-safe-Protocol-v2-012821.pdf#page=58.
[196] https://icandecide.org/wp-content/uploads/2022/10/Pages-from-0522-v-safe-Productions-Through-2022-07-12-2.pdf#page=55.
[197] https://medalerts.org/vaersdb/findfield.php?SNAPSHOT=20210218&PRR=ONESYM&SYMPTOMS=Myocarditis+%28100 28606%29&VAX=COVID19. *See also* https://www.theepochtimes.com/health/timeline-covid-19-vaccines-and-myocarditis-5317 985.

the DoD data, but **from CDC's perspective we don't have evidence of a safety signal for myocarditis or pericarditis**."[198]

April 27, 2021 (Walensky denying signal for myocarditis)

- Walensky at a White House briefing about myocarditis reports: "And after hearing about these reports, we, again, looked back in our vaccine safety data, and we have not seen any reports of those. Those have since been reported to us, and so those investigations are ongoing. But, you know, it is a — it is a different demographic than we normally see, and we will be working with DOD to understand what is happening in those 14 cases. We have not seen a signal, and we've actually looked intentionally for the signal in the over 200 million doses we've given."[199]

May 3-6, 2021 (Europe asks pharmaceutical companies for more data about myocarditis)

- EMA PRAC Meeting (Pharmacovigilance Risk Assessment Committee) - stated about myocarditis: "However, PRAC has requested the marketing authorisation holder to provide further detailed data, including an analysis of the events according to age and gender, in the context of the next pandemic summary safety report."[200]

May 18, 2021 (FDA finds one of its surveillance programs is not sufficient to assess myocarditis)

- CBER Sentinel Program Sufficiency Assessment Memo
    - This FDA memo specifically evaluated the ability of the Sentinel Program—"FDA's national electronic system [used to] monitor the safety of FDA-regulated medical products"—to evaluate the risk for myocarditis and pericarditis following receipt of the Pfizer vaccine. It found:

      "The CBER Sentinel Program is NOT sufficient to assess the serious risks of myocarditis and pericarditis, and subclinical myocarditis associated with COMIRNATY (BNT162b2) in lieu of PMR safety studies under FDAAA. At the time of BLA approval, the data sources in the CBER Sentinel Program are not sufficient to identify the outcomes due to lack of sufficient power to assess the magnitude of risk in patients 12-30 years of age. In addition, CBER Sentinel Program is not sufficient to follow up cases for recovery status and long-term sequelae, or for identification and characterization of subclinical myocarditis cases."[201]

May 19, 2021 (Cardiologists reaches out to CDC about rising cases of myocarditis in young people)

- No one at the CDC seemed surprised/concerned about this email from Dr. Ali Sharifian, Chief of Cardiology, Evergreen Health: "I am reaching out to you in regards to the **rising cases of myocarditis in our community**. **For the past week, I have admitted 5 cases of myocarditis in young males ages 18-27 the day after receiving their first dose of Pfizer**

[198] https://ican-public.s3.us-east-1.amazonaws.com/documents/24-00007-LT.pdf#page=1396

[199] https://www.whitehouse.gov/briefing-room/press-briefings/2021/04/27/press-briefing-by-white-house-covid-19-response-team-and-public-health-officials-32/.

[200] https://www.ema.europa.eu/en/news/meeting-highlights-pharmacovigilance-risk-assessment-committee-prac-3-6-may-2021.

[201] https://icandecide.org/wp-content/uploads/2023/11/127_Courtesy-Copy_BLA-125742-0_CBER-Sentinel-Program-Sufficiency-Memo-COMIRNATY.pdf#page=7 (emphasis added).

COVID vaccination. I have also talked to my colleagues at Overlake hospital and they have shared their concerns with same symptoms following this vaccine in this age bracket. **This is definitely not a coincidence** and I hope immediate actions are taken to ensure the safety of the teenagers and young adults in our community."[202]

May 21, 2021 (AAP coordinates with CDC on myocarditis messaging)

- The American Academy of Pediatrics reached out to CDC to **coordinate messaging** before publishing a study concerning myocarditis in adolescents after getting the Pfizer covid vaccine. Once again, CDC seems to be well aware of the situation with myocarditis.[203]

June 7-10, 2021 (Europe again asks for more data to determine causal connection for myocarditis)

- EMA PRAC [Pharmacovigilance Risk Assessment Committee] Meeting: "Currently, further analysis is needed to conclude whether there is a causal relationship with the vaccines, and PRAC is requesting additional data from the companies marketing them…. For Comirnaty and COVID-19 Vaccine Moderna, the PRAC is reviewing cases of myocarditis and pericarditis in the context of a safety signal, under an accelerated timetable (finalisation expected in July)." [204]

June 10, 2021 (FDA advisory committee shares data of high rate of myocarditis cases)

- VRBPAC Meeting: Slide 17 Shows dramatically higher observed vs expected
  - 35.0 cases per 1 million in ages 16-17 for Pfizer and Moderna
  - 20.6 cases per 1 million in ages 18-24 for Pfizer and Moderna[205]

June 13, 2021 (Pfizer report given to FDA says no causal association)

- May Pfizer SMSR covering April 30 – May 31 and published June 13
  - Page 7387: Myocarditis/pericarditis: "The rate at which these events are reported (even without applying the diagnostic certainty criteria) do not exceed the expected background rate…. Given the totality of the data, a causal association between the vaccine and myocarditis or pericarditis cannot be established."
  - Page 7385: All observed/expected ratios are under 1.0[206]

June 23, 2021 (CDC advisory committee working group admits data suggest an association)

- ACIP VaST Work Group Meeting: "Data available to date suggest likely association of myocarditis with mRNA vaccination in adolescents and young adults ▪ Clinical presentation of myocarditis cases following vaccination has been distinct, occurring most often within one week after dose 2, with chest pain as the most common presentation."[207]

July 12, 2021 (CDC aware of agency-confirmed cases of myocarditis)

- An internal CDC email forwarded from John Su contained the "Director's Daily Brief Bullets from VTF [Vaccine Task Force]."

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[202] https://ican-public.s3.us-east-1.amazonaws.com/documents/24-00007-LT.pdf#page=1366.
[203] https://ican-public.s3.us-east-1.amazonaws.com/documents/24-00007-LT.pdf#page=904.
[204] https://www.ema.europa.eu/en/news/meeting-highlights-pharmacovigilance-risk-assessment-committee-prac-7-10-june-2021.
[205] https://www.fda.gov/media/150054/download.
[206] https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/100123/19736_S0366_M1_smsr-30apr2021-31may2021.pdf#page=7387.
[207] https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-06/04-COVID-Lee-508.pdf.

- According to this update, there were 1047 reports of myopericarditis among persons 30 years of age and younger; 357 were under review and 633 met the CDC working definition for myocarditis.
- For ages 18-24, the expected number of myocarditis cases was 2-22 and instead there were 211 reported.[208]

July 14, 2021 (Pfizer report given to FDA says FDA proposed label changes concerning myocarditis)

- Pfizer June SMSR covering June 1 – 30 and published July 14
  - Page 13 – "FDA initiated proposed revisions to the BNT162b2 EUA labels regarding myocarditis and pericarditis cases following vaccination."
  - Page 82 – "After the DLP [data lock point], based on PRAC [Pharmacovigilance Risk Assessment Committee] Assessment on the updated signal assessment on myocarditis and pericarditis with BNT162b2 (Procedure Number: SDA 032), the MAH [marketing authorization holder] was requested to include myocarditis and pericarditis as important identified risks in the EU RMP [risk management plan]. The MAH is addressing this request currently."
  - Page 8740 – Table: Myocarditis observed/expected ratio – suddenly many are above 1.0.[209]

March-July 2022 (CDC's PRR identifies myocarditis as a signal)

- PRR Safety Signal Reports: ICAN obtains the CDC's Proportional Reporting Ratio (PRR) reports from March-July 2022, performed to identify adverse events reported in VAERS that are disproportionately reported relative to other adverse events. A "safety signal" is defined as a condition that has a PRR>=2.00, N>=3, and Chi-Square>=4.00.
- Myocarditis results:
  - Ages 5-11 years: PRR=18.84, N=14, Chi-Square=47.97
  - Ages 12-17 years: PRR of 130.22, N=709, Chi-Square=1,525.71
  - Ages 18+ years: PRR of 3.62, N=1905, Chi-Square=404.84[210]

December 2023 (Veteran Affairs data shows increase in myocarditis cases)

- ICAN's received a FOIA production from the Department of Veterans Affairs (VA), providing a detailed account of disability compensation claims made by servicemembers—active, reserve, and National Guard—including the periods of 2015-2019[211] and 2020-2023.[212] The VA data points to a worrying increase in myocarditis and pericarditis, as well as encephalitis, Guillain-Barré syndrome, and other illnesses starting in 2021, a rise mirrored across active-duty personnel, reservists, and National Guard members. For example, the number of myocarditis claims among active-duty soldiers rose from 50 in 2019 to 196 in 2023—an increase of 292%. The number of pericarditis claims rose from 294 to 476—an increase of approximately 62%.

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[208] https://icandecide.org/wp-content/uploads/2025/05/24-01012-IR1097B-Production-Part3.pdf#page=115.
[209] https://pdata0916.s3.us-east-2.amazonaws.com/pdocs/100123/19736_S0408_M1_smsr-01jun2021-30jun2021.pdf.
[210] https://icandecide.org/cdc-proportional-reporting-ratio/. *See also* https://icandecide.org/press-release/icans-two-lawsuits-so-far-for-cdc-and-fdas-vaers-safety-signal-analyses-set-to-blow-lid-off-their-misconduct/.
[211] https://icandecide.org/wp-content/uploads/2025/05/24-18564-F-VA-Disability-Claims-2015-1019.pdf.
[212] https://icandecide.org/wp-content/uploads/2025/05/24-14811-F-VA-Disability-Claims-2020-2024.pdf.

	2016	2017	2018	2019	2020	2021	2022	2023
Pericarditis	278	307	295	294	255	319	332	476
Myocarditis	51	56	76	50	66	73	131	196
Encephalopathy or Encephaliti	236	246	276	250	171	184	225	287
Guillian-Barre Syndrome	113	96	104	82	56	85	82	164
Brachial Neuritis	64	63	56	40	44	41	38	72
Thrombocytopenia Purpura	47	68	64	58	40	52	49	78
Transverse Myelitis	45	45	54	40	32	36	41	60

V. PREVENTING TRANSMISSION, AN EXAMPLE OF DOGMA DRIVING POLICY

In addition to failing to properly surveil and report on the safety of Covid-19 vaccines, health authorities were not straightforward with the public about the vaccines' efficacy either. They represented that those who were vaccinated would not be able to become infected with or transmit SARS-Cov-2.[213] CDC and FDA, however, should not have been surprised the Covid-19 vaccines did not prevent transmission because even most vaccines mandated for school do not prevent infection and transmission, including inactivated polio vaccine,[214]acellular pertussis vaccine,[215] tetanus vaccine,[216]and meningococcal vaccine.[217] Nor are we aware of a single non-live vaccine for a respiratory infection, like Covid-19 vaccines, that prevents transmission and infection.

As the FDA explains, "FDA's authorization and licensure standards for vaccines do not require demonstration of the prevention of infection or transmission."[218] FDA nonetheless promoted the belief that the Covid-19 vaccines products could do just that, including in the numerous "Just a Minute" promotional videos released by Dr. Peter Marks in late 2021 and early 2022.[219]

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[213] For example, *see* https://www.msnbc.com/transcripts/transcript-rachel-maddow-show-3-29-21-n1262442?utm_content=buffer7fb12&utm_medium=Arianna&utm_source=LinkedIn&utm_campaign=Buffer (March 29, 2021 statement by then-CDC Director Walensky stating: "[O]ur data from the CDC today suggests, you know, that vaccinated people do not carry the virus, don`t get sick, and that it`s not just in the clinical trials but it`s also in real world data.").

[214] https://www.cdc.gov/vaccines/vpd/polio/index.html ("Inactivated polio vaccine (IPV) is the only polio vaccine that has been given in the United States since 2000."); https://www.cdc.gov/orr/polioviruscontainment/diseaseandvirus.htm ("IPV… protects people from polio disease but does not stop transmission of the virus.") *linking to* CDC, *et al.*, Polio Global Eradication Initiative webpage https://polioeradication.org/polio-today/polio-prevention/the-vaccines/ipv/ ("IPV induces very low levels of immunity in the intestine. As a result, when a person immunized with IPV is infected with wild poliovirus, the virus can still multiply inside the intestines and be shed in the feces … IPV does not stop transmission of the virus.")

[215] https://www.cdc.gov/mmwr/preview/mmwrhtml/mm4902a4.htm (In 1999, CDC provided for "exclusive use of acellular pertussis vaccines for all doses of the pertussis vaccine series."); https://pubmed.ncbi.nlm.nih.gov/24277828/; https://pubmed.ncbi.nlm.nih.gov/31333640/ ("Mucosal immunity is essential to prevent colonization and transmission of B. pertussis organisms. … [P]reventive measures such as aPVs [acellular pertussis vaccine] that do not induce a valid mucosal response can prevent disease but cannot avoid infection and transmission. … aPV pertussis vaccines do not prevent colonization. Consequently, they do not reduce the circulation of *B. pertussis* and do not exert any herd immunity effect.").

[216] https://www.cdc.gov/tetanus/about/index.html ("Tetanus … does not spread from person to person.").

[217] https://www.cdc.gov/vaccines/vpd/mening/public/index.html ("Rates of meningococcal disease have declined in the United States since the 1990s and remain low today. Much of the decline occurred before the routine use of MenACWY vaccines. … [D]ata suggest MenACWY vaccines have provided protection to those vaccinated, but probably not to the larger, unvaccinated community (population or herd immunity).")

[218] https://www.sirillp.com/wp-content/uploads/2024/06/FDA-Reply-aP-Petition-4b2b5a444605c16234394e0517a23efd.pdf.

[219] *See, e.g., https://www.youtube.com/watch?v=FBADJNTdeiQ&list=PLey4Qe-Uxcxa3152uA5wSC6XRsOK_-9_x&index=49* ("getting a booster is likely to help decrease the overall spread of Covid-19, it may also help your friends and neighbors as well."); https://www.youtube.com/watch?v=Ov94KWhLy-s&list=PLey4Qe-Uxcxa3152uA5wSC6XRsOK_-9_x&index=43 ("So getting vaccinated or receiving a booster ... is the best thing you can to do protect yourself and others."); https://www.youtube.com/watch?v=IJNc_DJ1DyE&list=PLey4Qe-Uxcxa3152uA5wSC6XRsOK_-9_x&index=42 ("Getting vaccinated and getting a booster shot can save your life and protect you and your family and friends from getting seriously ill and spreading infection.").

This occurred despite a CDC study, dated August 6, 2021, which found vaccinated individuals had a higher rate of infection and more viral carriage in their nasopharynx than the unvaccinated.[220] With the release of this study, the CDC Director stated on CNN that "what they [Covid-19 vaccines] can't do anymore is prevent transmission."[221] Then, on August 24, 2021, a study by the Wisconsin Health Department, reviewing swab specimens in 24 counties, found high viral loads in "158 of 232 unvaccinated (68%...) and 156 of 225 fully vaccinated (69%...) symptomatic individuals" and in "7 of 24 unvaccinated (29%...) and 9 of 11 fully vaccinated asymptomatic individuals (82%...)."[222] Our exchange with CDC in mid to late 2021 brought into focus the foregoing.[223]

Nonetheless, the implication these products could prevent infection and transmission persisted, including in a Pfizer report to the FDA on October 26, 2021, stating: "Maximizing the proportion of the population that is vaccinated is critically important to help reduce rates of infection, decrease transmission, prevent the emergence of new variants of concern, and hasten the end of the pandemic."[224] Despite the lack of clinical evidence to support these claims, FDA permitted Pfizer to continue to make them.

VI. IMPROPERLY ATTRIBUTING DECLINE IN MORTALITY TO VACCINES

Even before the pandemic and the Covid-19 vaccines, federal health agencies have historically attributed declines in mortality post-introduction of a vaccine to the vaccine even when it is unwarranted.

For example, the first measles vaccine was introduced in 1963, after there had been an over 98% reduction in measles mortality between 1900 and 1962.[225] Pursuant to official government mortality statistics, in 1900, the rate of mortality from measles was 13.3 per 100,000 individuals.[226] By 1960, it was 0.2 deaths per 100,000 individuals.[227] The same was the case in 1961 and 1962.[228] The first measles vaccine came on the market after that in 1963.[229]

This means there was an over 98% decline in measles mortality from 1900 to 1960, and this decline had nothing to do with the measles vaccine which did not yet exist.[230] The following government chart shows this decline in the measles death rate by over 98% from 1900 to 1960.[231]

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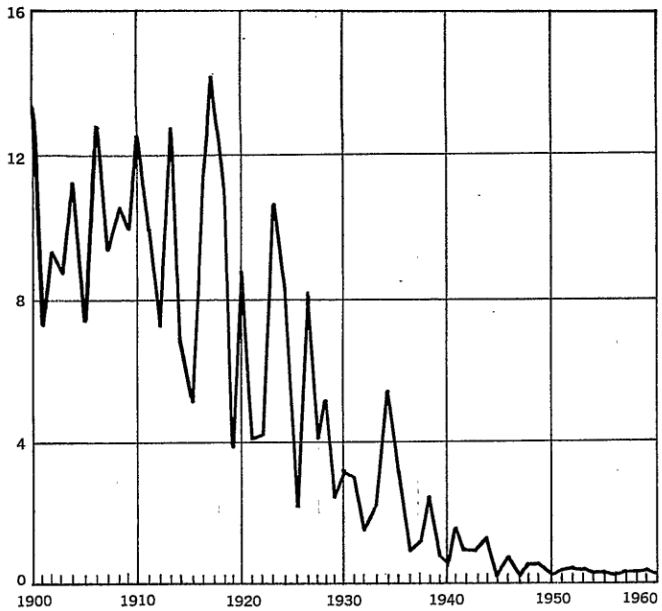
[220] https://pubmed.ncbi.nlm.nih.gov/34351882/ (In an outbreak in Barnstable County, MA, which data reflects had a 69% vaccination rate among eligible residents, CDC found 74% of those infected in the outbreak were fully vaccinated for Covid-19 and the vaccinated had on average more virus in their nasal cavity than the unvaccinated that were infected.)
[221] https://twitter.com/CNNSitRoom/status/1423422301882748929.
[222] https://www.medrxiv.org/content/10.1101/2021.07.31.21261387v4.full.pdf
[223] https://www.sirillp.com/wp-content/uploads/2024/06/CDC-Re-Natural-v-Vaccine-Immunity-58c0cb94d12325deb521f192f562551a.pdf.
[224] https://www.fda.gov/media/153409/download.
[225] https://www.cdc.gov/nchs/data/vsus/vsrates1940_60.pdf (https://perma.cc/ADA2-EALC).
[226] https://www.cdc.gov/nchs/data/vsus/vsrates1940_60.pdf (https://perma.cc/ADA2-EALC).
[227] https://www.cdc.gov/nchs/data/vsus/VSUS_1962_2A.pdf (https://perma.cc/C86V-77GM).
[228] https://www.cdc.gov/nchs/data/vsus/VSUS_1962_2A.pdf (https://perma.cc/C86V-77GM).
[229] https://www.cdc.gov/measles/about/history.html (https://perma.cc/53PN-TWJK).
[230] https://www.cdc.gov/nchs/data/vsus/vsrates1940_60.pdf (https://perma.cc/ADA2-EALC).
[231] https://www.cdc.gov/nchs/data/vsus/vsrates1940_60.pdf (https://perma.cc/ADA2-EALC).

Figure 19.—Death Rates for Measles: Death-registration States, 1900–32, and United States, 1933–60

(Rates per 100,000 population)



A similar decline of over 99% in measles deaths also occurred in England and Wales between 1900 and in 1968 where the measles vaccine was first introduced in 1968 (five years after it was introduced in the United States).[232]

Placing the pre-vaccine decline in measles deaths in context, there was a total of around 400 deaths from measles each year leading up to 1963. This amounted to one measles death for every 450,000 Americans which was at a time when nearly every American contracted measles.[233]

The same factors responsible for causing measles mortality to decline by over 98% from 1900 to 1962 likely continued to cause a reduction in measles mortality rate after 1962.

In countries or areas with poor nutrition, sanitation, and limited clean water, deaths from any pathogen, including measles, can occur at a higher rate. Those conditions still existed in some pockets of the United States in the early 1960s. As living conditions improved in those areas with the introduction of clean water, sanitation, acute medical care, etc., deaths from measles, as they do whenever these factors improve, declined.

Despite the fact vaccines had nothing to do with the over 98% reduction in mortality from measles since 1900, vaccines are typically given the credit for the entirety of this reduction in mortality.[234]

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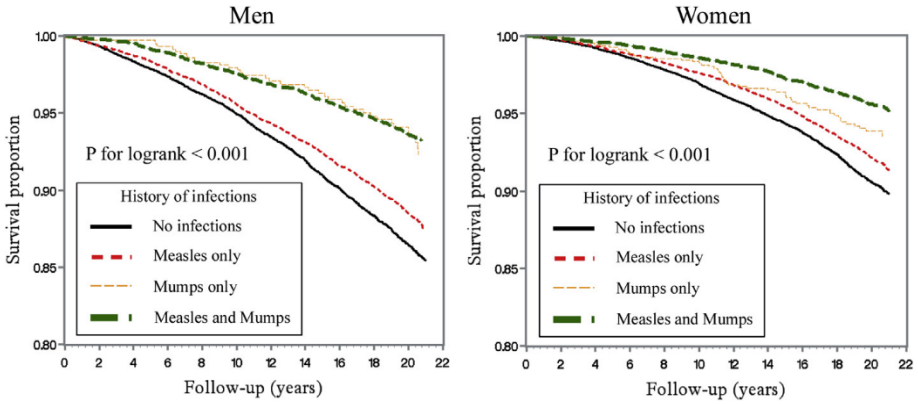
232 https://webarchive.nationalarchives.gov.uk/ukgwa/20160111174808/http://www.ons.gov.uk/ons/publications/re-reference-tables.html?edition=tcm%3A77-215593 (https://perma.cc/ZCV9-DHR4).

233 https://www.census.gov/library/publications/1962/compendia/statab/83ed.html (https://perma.cc/LH8X-EA4M).

234 *See, e.g.*, https://www.weforum.org/stories/2015/05/how-does-the-measles-vaccine-prevent-deaths-from-other-diseases/ ("Before vaccination, measles was responsible for millions of childhood deaths.… Where measles vaccines have been introduced, childhood deaths often plummet by as much as 50%.").

Moreover, studies reflect that while vaccination for measles, as well as mumps, rubella and chicken pox, prevent the infection and transmission of those viruses, the elimination of those pathogens have contributed to increases in various diseases, including cancer and heart disease. The studies supporting this claim were conducted and published after federal health authorities committed to the measles vaccine program.

In one of these studies, the nation of Japan tracked over 100,000 of its citizens for more than 22 years and it found, among other things, that having been infected with measles and mumps was "associated with lower risks of mortality from CVD [cardiovascular disease]."[235] After 22 years, only 7% of the men that had measles and mumps had died of cardiovascular disease while 14% of the men that never had measles or mumps died of cardiovascular disease.[236] This is reflected in the following table from the study:



Cardiovascular disease is the number one killer of Americans, taking the lives of approximately 700,000 Americans a year.[237] In contrast, as discussed above, according to the CDC, around 400 Americans died of measles annually pre-vaccine (this rate was declining without a vaccine), and around 40 Americans died annually of mumps in the years before the first mumps vaccine in 1967.[238]

Studies have also found an increased risk of cancer among those that have not had measles and other viruses for which children are vaccinated. For example, the International Agency for Research on Cancer found that those who never had measles had a 66% increased rate of Non-Hodgkin Lymphoma and a 233% increased rate of Hodgkin Lymphoma.[239] These two cancers

[235] https://pubmed.ncbi.nlm.nih.gov/26122188/ (https://perma.cc/6TJD-5FNZ).
[236] https://pubmed.ncbi.nlm.nih.gov/26122188/ (https://perma.cc/6TJD-5FNZ).
[237] https://www.cdc.gov/heartdisease/facts.htm.
[238] https://icandecide.org/wp-content/uploads/2023/10/cdc-reported-cases-and-deaths-m-vaccine-preventable-diseases-3.pdf. Note that in the pre-vaccine era, mothers provided passive immunity to their babies, which protected babies, and adults were protected because they almost always had measles as children. https://pubmed.ncbi.nlm.nih.gov/20483946/. This protected babies and adults who are more susceptible to harm from measles. The measles vaccine, however, does not afford the same protection as having had measles. *Id.* A mother who has only had the measles vaccine, as opposed to the natural infection, will confer only limited protection to her baby. *Id.* As for adults, 2% to 10% of them, depending on the study, will not develop immunity even after two doses of a measles vaccine. https://pmc.ncbi.nlm.nih.gov/articles/PMC4962729/. The measles vaccine thus reversed the declining lethality of measles by making vulnerable groups—babies and adults—who had generally been protected in the pre-vaccine era now potentially vulnerable to measles.
[239] https://pubmed.ncbi.nlm.nih.gov/16406019/ (https://perma.cc/RCY2-LXNW) (see Table 2 and in the Non-Hodgkin's Lymphoma (NHL) column divide the odds ratio 1 (never had measles) with .6 (had measles) which results in a 66% increased risk,

killed an estimated 21,170 Americans in 2022.[240] There are also studies documenting remission of Hodgkin's disease after having measles.[241]

Likewise, researchers at the Department of Health Care and Epidemiology at the University of British Columbia and the Department of Biology at the University of Victoria found that those who never had measles had a 50% increased rate of ovarian cancer, which killed an estimated 12,810 Americans in 2022.[242]

Other studies have reached similar conclusions that measles, as well as mumps, rubella, pertussis, and chickenpox, reduce the rate of various forms of other cancers, including a study from researchers at the University of Berne, Switzerland that specifically reviewed these fever-inducing (*i.e.*, febrile) infections and "consistently revealed a lower cancer risk for patients with a history of FICD [febrile infectious childhood diseases]."[243] And as an article in *The Quarterly Review of Biology* explained,

> [D]etailed retrospective and prospective clinical studies … support[] the conclusion that frequency of the infectious fever episodes and cancer diagnoses are inversely related (Abel et al. 1986; Mastrangelo et al. 1998; Kleef et al. 2001; Kleef and Hager 2006). For example, Grossarth-Maticek et al. (1987) performed a 10-year prospective cohort study of 1353 patients, concluding that episodes of high fever as a typical reaction to an acute illness during the entire life span are inversely related to later cancer incidence. Kölmel et al. (1992), based on 271 controls versus 139 melanoma patients, demonstrated an inverse relation between the number of febrile infections and the incidence of malignant melanoma. Similarly, Wrotek et al. (2009) have reported a lower frequency of fever in a population of 355 breast tumor patients, compared to 244 healthy women volunteers.[244]

This article also explained how a survey of studies of spontaneous cancer remissions found that "approximately 70% of documented cases were immediately preceded by an acute infection associated with high fever" and that this phenomenon has "been reported for centuries."[245]

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and in the Hodgkin's Lymphoma (HL) column divide the odds ratio 1 (never had measles) with .3 (had measles) which results in a 233% increased risk.).

[240] https://seer.cancer.gov/statfacts/html/hodg.html (https://perma.cc/6UWZ-257H); https://seer.cancer.gov/statfacts/html/nhl.html (https://perma.cc/7NE8-7E5X).

[241] https://pubmed.ncbi.nlm.nih.gov/4574047/ (https://perma.cc/4425-2ME4).

[242] https://pubmed.ncbi.nlm.nih.gov/16490323/ (https://perma.cc/B64P-YRV3); https://seer.cancer.gov/statfacts/html/ovary.html (https://perma.cc/HUE9-8SPJ).

[243] https://pubmed.ncbi.nlm.nih.gov/9824838/ (https://perma.cc/Y7BM-JK5W).

[244] https://www.journals.uchicago.edu/doi/10.1086/699409.

[245] https://www.journals.uchicago.edu/doi/10.1086/699409.

Studies have also found that children who have had measles have far less allergies and atopic diseases, such as asthma, and adults who have had measles have a reduced risk of Parkinson's Disease.[246]

When the measles vaccine was introduced, measles was considered a mild childhood infection, like chickenpox; the ecological relationship humans developed with measles through millennia did not eliminate measles as occurs with many other pathogens; and having had measles may confer benefits for survival that may exceed its negative effects.[247]

The negative impacts of introducing measles vaccine, the harms it causes, the fact it has made vulnerable populations (babies and adults) susceptible to measles (who would have been protected in the pre-vaccine era), are all ignored by public health agencies.

This same approach is what was seen with regard to Covid-19 vaccines. The policy was to create as much fear with regard to SARS-CoV-2 and Covid-19 and simultaneously create as much positive publicity regarding the Covid-19 vaccine, irrespective of the reality of the actual risks of the virus and the vaccine. Whenever things improved with Covid-19, they were attributed to the vaccine, and when deaths rose or injuries were reported, the typical response was that either excuses or denials were made for the vaccine or these claims were simply ignored.

Another Example

As another example, diphtheria is reported to have killed more children in 1900 than nearly any other infectious disease.[248] Between 1900 and 1926, when the first diphtheria vaccine was introduced, the death rate from this disease had already declined by 85%, from 40 deaths per 100,000 individuals to 6 per 100,000 individuals.[249] A vaccine did not contribute to this sharp decline since no vaccine of any kind for diphtheria existed until 1926. The further decline from 1926 to the mid-1940s also was likely mostly unrelated to vaccination since it was rarely used outside of certain demographics in major cities and the incidence of diphtheria mortality declined at a similar rate in areas with or without use of this vaccine.[250] What caused the decline in mortality from diphtheria was likely the same factors that caused the decline in mortality from almost all other childhood diseases during that period. The following is another official published by the

[246] https://pubmed.ncbi.nlm.nih.gov/19255001/ (https://perma.cc/FZ5Q-74MY); https://pubmed.ncbi.nlm.nih.gov/16854347/ (https://perma.cc/D9L7-NX5W) and https://pubmed.ncbi.nlm.nih.gov/4061437/ (https://perma.cc/J329-YLH8)/.

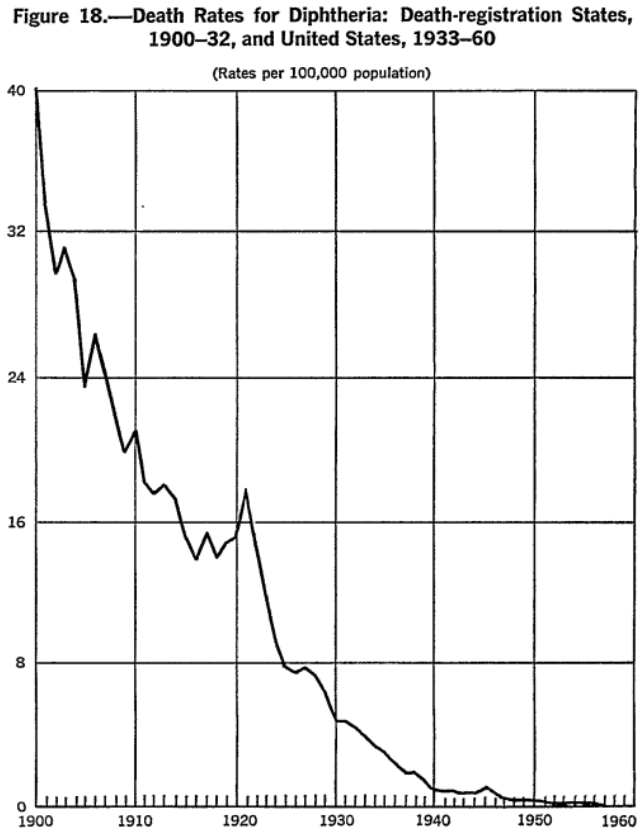
[247] Langmuir AD, Henderson DA, Serfling RE, Sherman IL. The importance of measles as a health problem. Am J Public Health Nations Health. 1962 Feb;52(2) Suppl:1-4. https://pmc.ncbi.nlm.nih.gov/articles/PMC1522578/

[248] https://www.cdc.gov/nchs/data/vsus/vsrates1940_60.pdf

[249] The death rate per 100,000 individuals in the United States in 1900, 1940, and 1948 for diphtheria was 40.3, 1.1, and 0.4, respectively. https://stacks.cdc.gov/view/cdc/6200 (https://perma.cc/KED8-WH64).

[250] https://pmc.ncbi.nlm.nih.gov/articles/PMC1997101/pdf/pubhealthreporig01174-0001.pdf (https://perma.cc/2879-BZ3U) ("The simultaneous decline in diphtheria morbidity and mortality rates in all age groups of individual States located in different sections of the country, which began after a cyclic increase in incidence between 1915 and 1925, suggests the operation or influence of other factors besides, or in addition to, artificially induced immunity. Studies such as that included in the 1930 White House Conference on Child Health and Protection indicated that immunization programs were reaching a relatively large proportion of children in some areas or cities and a very low proportion in others as late as 1930. In spite of this wide variation, both morbidity and mortality began to decline rapidly after 1925 in all States simultaneously."); https://www.cdc.gov/vaccines/pubs/pinkbook/dip.html ("[D]iphtheria toxoid-containing vaccines became available in the 1940s" and "universal childhood vaccination program which included diphtheria toxoid-containing vaccines beginning in the late 1940s.").

former United States Department of Health, Education, and Welfare (now HHS) showing the decline in the diphtheria death rate starting in 1900.[251]



While diphtheria bacteria are still present in the United States, there have only been two clinical cases of diphtheria in the past 15 years in the United States. This is despite the fact that most adults do not receive diphtheria boosters as recommended by the CDC every ten years. [252] This likely reflects the literature which supports that harmful effects from the diphtheria toxin are counteracted not by up-to-date vaccinations but by iron, vitamin C, and vitamin B3, and deficiencies of these vitamins and minerals have mostly been eliminated in developed countries.[253]

Many pathogens that were deadly to children in the United States have mostly disappeared without a vaccine. For many of these diseases, researchers sought to develop a vaccine but failed. For example, scarlet fever was one of the deadliest infectious diseases for children in 1900, with a death rate of 9.6 deaths per 100,000 children, with an even higher death rates in many years during the early 1900s. Researchers sought to develop a vaccine but repeatedly failed. By the 1950s, deaths from scarlet fever had significantly declined and by the late 1900s, deaths from scarlet fever were essentially non-existent.[254]

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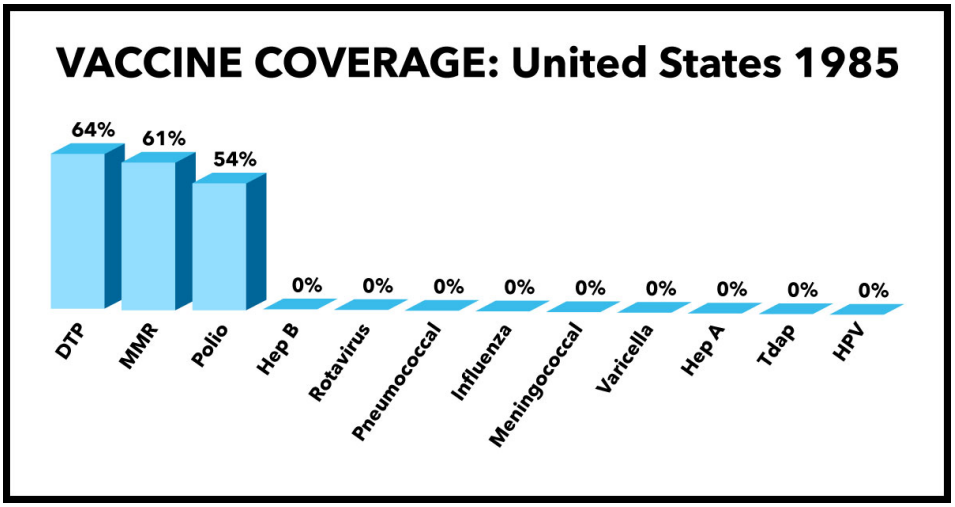
[251] https://www.cdc.gov/nchs/data/vsus/vsrates1940_60.pdf (https://perma.cc/A6W8-LNB2).
[252] https://www.cdc.gov/vaccines/imz-managers/coverage/adultvaxview/pubs-resources/vaccination-coverage-adults-2019-2020.html.
[253] https://www.ncbi.nlm.nih.gov/pubmed/2151460 (https://perma.cc/U6QS-KBYZ); https://www.ncbi.nlm.nih.gov/pubmed/7830565 (https://perma.cc/Z6RV-ZU3Z); https://www.ncbi.nlm.nih.gov/pubmed/4326212 (https://perma.cc/4GUC-UNA5); https://www.ncbi.nlm.nih.gov/pubmed/189004 (https://perma.cc/HPF8-4AGA).
[254] https://www.statnews.com/2017/11/27/scarlet-fever-cases/ (https://perma.cc/MR4X-G5A7).

Had a vaccine for scarlet fever been developed in the 1940s, for example, it may very well still be on the childhood schedule today and considered essential for controlling scarlet fever. Scarlet fever and diphtheria are similar in that each is a bacterium that releases a potentially harmful toxin when they have been "infected" by a certain virus. Both cause sore throats and, without a lab test, doctors may confuse a case of diphtheria with scarlet fever, and vice versa. These two diseases also have something else in common: they both declined at a similar rate since 1900. The pivotal difference between them is that a vaccine was developed for diphtheria, but there is no vaccine for scarlet fever.

Placing the impact of vaccination on mortality into further context, note that the vaccination rate in the 1980s was 0% for 11 of the 14 current routine childhood vaccines and hence these vaccines' contribution to the reduction of mortality prior to their use was also 0%. In other words, these vaccines did not (and could not) have any contribution to the reduction in infectious disease mortality until their introduction, which in most cases did not occurred well after the 1980s. This chart reflects the vaccine uptake in 1985.[255]



Moreover, based on the CDC's mortality data, for most diseases for which vaccines were introduced, deaths in the United States were rare in the year prior to these vaccines' introduction, typically ranging from a few dozen to a few hundred deaths, and the rate of decline in mortality post vaccine introduction often remained the same or slowed compared to the period prior to the vaccine's introduction.[256]

The common lore that millions would die in the United States without a vaccine is not supported by the data, but our public health authorities welcome this misrepresentation. Just as they do the fears raised by SARS-CoV-2 that were clearly misplaced and/or untrue.

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[255] https://web.archive.org/web/20190618125412/https:/www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/e/coverage-levels.pdf (https://perma.cc/GZ2F-E2AC).

[256] https://www.cdc.gov/nchs/data/vsus/vsrates1940_60.pdf; https://web.archive.org/web/20190615081539/https:/www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/e/reported-cases.pdf.

Most Commonly Used Vaccine in the World and Mortality

A final example of vaccines' impact on mortality is the DTP vaccine. Although the DTP vaccine remains the most widely used vaccine in the world, it was not licensed based on a placebo-controlled trial and studies conducted in recent decades have found that DTP increases mortality. Meaning it causes more children to die when it is used. A landmark study on this issue was funded by the Ministry of Foreign Affairs of Denmark and the European Union and published in 2017.[257] After comparing children vaccinated with DTP to children that received no vaccines, it found that that DTP-vaccinated children were 10 times more likely to die in the first 6 months of life. The study therefore concluded:

> All currently available evidence suggests that DTP vaccine *may kill more children* from other causes than it saves from diphtheria, tetanus or pertussis."[258]

This study, and others, found that children vaccinated with DTP were dying from causes never associated with the vaccine, such as respiratory infections, diarrhea, and malaria.[259] This indicated that, while DTP reduced the incidence of diphtheria, tetanus, and pertussis, it increased susceptibility to other infections.[260]

A 2014 review of DTP and mortality by an advisory group to the WHO, called the Strategic Advisory Group of Experts (SAGE), identified 16 studies that compared death rates between children receiving DTP and children not receiving DTP, and found that a majority of the 16 studies indicated that DTP increases mortality.[261] SAGE discounted the studies showing DTP increases mortality on the basis that: (i) these studies were not "randomized" (*i.e.*, children were not randomly assigned to either receive or not receive DTP, potentially introducing bias); (ii) "OPV [Oral Polio Vaccine] was administered concomitantly with DTP in most included studies" and hence it "was not possible to separate any possible effects of DTP from OPV in the available studies"; and (iii) these studies were often conducted in communities with existing so-called "herd immunity" that could have introduced further bias.[262]

The 2017 study was designed to avoid these limitations stated by SAGE. It addressed the "randomized" issue by using data whereby vaccines were administered based on birthdates, an accepted form of randomization.[263] It addressed the "OPV with DTP" issue by comparing children receiving no vaccines with those receiving only DTP.[264] It addressed the "herd immunity" issue by looking at death rates at the time of the introduction of DTP in that region.[265] The result was the

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[257] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5360569/ (https://perma.cc/6R29-ZSHK).
[258] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5360569/ (https://perma.cc/6R29-ZSHK).
[259] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5360569/ (https://perma.cc/6R29-ZSHK).
[260] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5360569/ (https://perma.cc/6R29-ZSHK).
[261] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5360569/ (https://perma.cc/6R29-ZSHK).
[262] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5360569/ (https://perma.cc/6R29-ZSHK). As an example of the necessity for utilizing randomization to avoid bias, unvaccinated children often do not receive vaccines because they are very frail, malnourished, or sick, and hence more likely to die irrespective of vaccination. Thus, the unvaccinated group is often sicker than the vaccinated group, making the vaccine appear safer. By randomly picking which children receive or do not receive the DTP vaccine, a researcher can avoid this type of bias.
[263] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5360569/ (https://perma.cc/6R29-ZSHK).
[264] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5360569/ (https://perma.cc/6R29-ZSHK).
[265] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5360569/ (https://perma.cc/6R29-ZSHK).

2017 study discussed above. And because placebo-controlled trials of DTP are considered unethical, even though a placebo-controlled trial was never conducted to license this product, the 2017 study on DTP and morality is likely the best available evidence that will exist regarding whether DTP kills more children than it saves.

DTP policy has not, however, changed globally, even after another study published in 2018, which again did not have the limitations identified by SAGE in 2014, again found DTP increases mortality.[266] This time the study looked at children between 6 and 35 months of age. The 2018 study compared children receiving DTP, who were generally healthier and had better nutritional status, with children who did not receive DTP and who generally were unhealthier and had worse nutritional status. There, the children who did not receive DTP should have had worse health outcomes because they were generally unhealthier and had worse nutrition. The result:

> Although having better nutritional status and being protected against three infections, 6-35 months old DTP-vaccinated children tended to have higher mortality than DTP-unvaccinated children. All studies of the introduction of DTP have found increased overall mortality.[267]

A non-profit group contacted UNICEF, a primary distributor of DTP vaccine, regarding these studies, asking it to provide proof that the studies showing DTP increased mortality were incorrect. UNICEF asked CDC to help it respond to this request but when CDC sent a proposed response to UNICEF, UNICEF asked CDC, "why we cannot prove or disprove this claim despite the fact that this issue has been followed since 2001."[268] The email exchange between CDC and UNICEF does not appear to seriously consider the data or studies but, rather, appeared to view them as a public relations issue.

Covid-19 Vaccines and Mortality

The foregoing should help put the public health agency bias into perspective with regard to how it approached Covid-19 vaccines and the claim that the vaccines reduced overall mortality. This is reflected by a CNN headline in 2022 that "Covid-19 vaccines have saved more than 3 million lives in US, study says."[269]

Public health agencies took no issue with this plainly unsupportable claim and, in fact, encouraged claims just like this.

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[266] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5868131/pdf/fpubh-06-00079.pdf (https://perma.cc/7F7U-ZZWJ).
[267] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5868131/pdf/fpubh-06-00079.pdf (https://perma.cc/7F7U-ZZWJ).
[268] https://icandecide.org/UNICEF-Emails.
[269] https://www.cnn.com/2022/12/13/health/covid-19-vaccines-study/index.html (https://perma.cc/F5FN-3A8J).

Putting this claim in context in 2019, according to the CDC, the total number deaths in the United States was 2,845,819.[270] That is similar to the total deaths in the United States in 2018 and 2017.[271] But, in 2020 the total deaths in the United States was 3,433,986.[272] That means 588,167 more people died in 2020 than died in 2019. "Health" authorities attributed this increase in deaths to Covid-19. This means that if the Covid-19 vaccine reduced deaths from Covid-19, we should have seen the total deaths in the United States begin to revert closer to the 2019 total death figure, or at least drop below the total deaths seen in 2020 when there was a pandemic but no vaccine.

What actually occurred? The total deaths in the United States did not decline after introducing the Covid-19 vaccine. Indeed, in 2021, there were a total of 3,449,536 deaths which exceeded the total deaths from 2020 of 3,433,986. [273] And keep in mind that Covid-19 had presumably killed many of the most vulnerable in 2020 such that less people should have died in 2021 even without a vaccine.

The fact that total deaths increased in 2021, as compared to 2020, is the best available data point on whether Covid-19 vaccines reduced deaths. This is because it avoids the controversy regarding whether someone died with or from Covid-19. It also avoids the controversy of whether someone died after or because of a Covid-19 vaccine. Simply put, if Covid-19 vaccines reduced mortality, then all-cause mortality should have declined and started to approach the total deaths seen in 2019. That didn't happen.

This increase in mortality, however, does match what occurred in the clinical trial for Pfizer's Covid-19 vaccine. As discussed above, in that trial, there were far more deaths in the vaccinated group than the placebo group—precisely 21 deaths in the vaccinated group and 17 deaths in the placebo group.[274]

Also, when Covid-19 deaths were decreasing during the first half of 2021, legacy media outlets credited Covid-19 vaccines with this decline, publishing headlines such as "Vaccines may have prevented a quarter-million Covid-19 cases and 39,000 deaths."[275] But then, when deaths started going up in the latter half of 2021 and start of 2022, headlines turned to "Covid vaccines not linked to deaths."[276]

Similarly, health agencies around the world that had, with great fanfare, been publishing data showing that the unvaccinated were dying at a greater rate than the vaccinated, quickly removed these dashboards and ceased public data sharing once the data started showing that the vaccinated were dying at a greater rate. This data was standardized to be a rate, not an absolute number; so if Covid-19 vaccines reduced mortality, the rate of death for the vaccinated should have remained lower no matter how many people got vaccinated. For example, here was the data published by Scotland at the end of 2021 which started to consistently show that the vaccinated had a higher

[270] https://www.cdc.gov/flu/weekly/weeklyarchives2022-2023/data/NCHSData07.csv (https://perma.cc/S2Q2-5XHN).
[271] https://www.cdc.gov/flu/weekly/weeklyarchives2022-2023/data/NCHSData07.csv (https://perma.cc/S2Q2-5XHN).
[272] https://www.cdc.gov/flu/weekly/weeklyarchives2022-2023/data/NCHSData07.csv (https://perma.cc/S2Q2-5XHN).
[273] https://www.cdc.gov/flu/weekly/weeklyarchives2022-2023/data/NCHSData07.csv (https://perma.cc/S2Q2-5XHN).
[274] https://www.fda.gov/media/151733/download.
[275] https://www.cnn.com/2021/10/05/health/covid-vaccines-reduce-senior-deaths/index.html (https://perma.cc/2QPX-WNS5).
[276] https://www.bbc.com/news/health-60653946 (https://perma.cc/2PAK-7BTQ).

rate of hospitalizations and deaths, and so it was soon thereafter pulled down by health authorities, which also occurred in countries around the world:[277]

Table 15 – Hospitalizations

	Unvaccinated		
Week	No. hospitalised	Population	Age-standardised hospitalisation rate per 100,000 (95% confidence intervals)
18 December - 24 December 2021	133	1,111,023	**34.39** (24.69 - 44.09)
25 December - 31 December 2021	164	1,105,601	**54.05** (40.55 - 67.55)
01 January - 07 January 2022	174	1,099,417	**43.75** (33.00 - 54.51)
08 January - 14 January 2022	130	1,093,639	**32.46** (23.48 - 41.44)
	2 Doses		
Week	No. hospitalised	Population	Age-standardised hospitalisation rate per 100,000 (95% confidence intervals)
18 December - 24 December 2021	170	1,864,017	**25.89** (20.42 - 31.36)
25 December - 31 December 2021	228	1,518,996	**41.01** (33.36 - 48.66)
01 January - 07 January 2022	247	1,116,431	**61.14** (50.52 - 71.76)
08 January - 14 January 2022	191	989,345	**45.18** (36.00 - 54.35)

Table 16 – Deaths

	Unvaccinated		
Week	No. of deaths	Population	Age Standardised Mortality Rate per 100,000 with 95% confidence intervals
11 December - 17 December 2021	18	1,567,709	**7.21** (2.67 - 11.74)
18 December - 24 December 2021	6	1,559,729	**1.70** (0.23 - 3.16)
25 December - 31 December 2021	8	1,549,716	**4.93** (0.55 - 9.30)
01 January – 07 January 2022	12	1,541,298	**7.62** (2.38 - 12.85)
	2 Doses		
Week	No. of deaths	Population	Age Standardised Mortality Rate per 100,000 with 95% confidence intervals
11 December - 17 December 2021	36	1,866,427	**7.68** (5.04 - 10.31)
18 December - 24 December 2021	24	1,522,561	**6.54** (3.79 - 9.28)
25 December - 31 December 2021	21	1,121,214	**7.11** (3.85 - 10.38)
01 January – 07 January 2022	26	995,855	**11.89** (7.14 - 16.64)

There are also studies which reflect the foregoing – that Covid-19 vaccines increased mortality. On the other side, there are also studies that indicate that those who did not receive a Covid-19 vaccine died at a higher rate than those using this product. These latter studies, conducted by vaccine promoters, typically suffer from the same two flaws: first, vaccinated individuals are simply far less likely to be tested or be coded as dying from Covid-19, and second, if the vaccine is itself causing mortality, those studies will not reflect same.

[277] https://publichealthscotland.scot/MEDIA/11223/22-01-19-COVID19-WINTER_PUBLICATION_REPORT.PDF; https://x.com/AaronSiriSG/status/1486432700969807873 (https://perma.cc/7PPB-WDXZ).

The all-cause mortality figure cuts through these flaws, also known as confounders. It avoids these confounders by taking human judgment and bias out of the equation; it provides a natural experiment. In 2018 and 2019, there was no Covid-19 and no vaccine. In 2020, there was Covid-19 but no vaccine. And in 2021 and 2022, there were both. Given the claims by health authorities, we should see a rise in all-cause mortality in 2020 from Covid and then a decline in 2021 as a large majority of Americans received the Covid-19 vaccine. That is, unless the vaccine does not actually reduce mortality. U.S. all cause deaths in 2020 were 3,383,729 and that number *increased* in 2021 to 3,464,231.[278]

It is also worth noting that the number of deaths claimed to be caused by Covid-19 is truly unprecedented as compared to all other diseases for which Americans vaccinate. CDC data reflects that there were a few dozen to a few hundred deaths per year from most diseases prior to introduction of vaccination for any given disease. And these deaths typically occurred at a time preceding advances in medical care, abundant clean water, universal sanitation, etc. in this country. In contrast, CDC claims Covid-19 killed hundreds of thousands of people annually. This raises questions about the origin of Covid-19 and whether it was natural.

Consider that even with a disease that they claimed killed hundreds of thousands (not dozens or hundreds), with presumably far more advanced technology to create effective vaccines, and billions of taxpayer dollars to design and develop the most effective vaccines, after vaccinating nearly everyone in America, they cannot even show they reduced overall mortality. But, yet, that is precisely what the CDC and the mainstream media will claim because when deaths goes down, correlation equals causation, but when deaths go up, correlation does not equal causation. Such is the dangerous bias our public health agencies have for the Covid-19 and all other vaccines.

Individuals Susceptible to Vaccine Injury

Whether it is for childhood vaccines or Covid-19 vaccines, studies needed to identify individuals who are susceptible to serious adverse reactions or chronic disease from one or more vaccines have not been conducted. In 1994, the IOM asserted it "was able to identify little information pertaining to why some individuals react adversely to vaccines when most do not" and hence urged that "research should be encouraged to elucidate the factors that put certain people at risk."[279] In 2013, the IOM acknowledged this research still had not been conducted, stating it "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."[280] That remains the current state of affairs.

The net health benefit or harm of vaccination should be properly quantified for each child prior to vaccination. Political and other factors should not drive the decision. In particular, increasing vaccination rates above a certain percentage should not drive a medical decision to vaccinate a child. Instead, it should be driven only by the question of what is in the best interest of a particular child.

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[278] https://www.cdc.gov/mmwr/volumes/71/wr/mm7117e1.htm; https://www.cdc.gov/mmwr/volumes/72/wr/mm7218a3.htm.
[279] https://www.nap.edu/read/2138/chapter/12#307. *See also* https://www.nap.edu/read/1815/chapter/9.
[280] https://www.nap.edu/read/13563/chapter/9#130. *See also* https://www.nap.edu/read/13164/chapter/5#82.

In any event, as discussed, even most mandated vaccines do not prevent infection and transmission of the target pathogen, including inactivated polio vaccine,[281] acellular pertussis vaccine,[282] tetanus vaccine,[283] and meningococcal vaccine.[284] In fact, children vaccinated against some of these pathogens are potentially more likely to transmit them than non-vaccinated children.

Take, for example, the inactivated polio vaccine (**IPV**), which is the only polio vaccine that has been used in the United States for over 25 years. IPV was phased in and oral polio vaccine (**OPV**), which had been used starting in the 1960s, was phased out due to safety issues. Polio is transmitted from fecal to oral contamination. IPV does not prevent transmission because it is injected into the arm and primarily creates antibodies to polio virus in the blood (IGG antibodies) but not the intestinal tract (IGA antibodies) where the polio virus proliferates. As CDC explains, "IPV does not prevent intestinal infection and therefore does not prevent poliovirus transmission."[285] This means that children not vaccinated for polio and children vaccinated with IPV can both become infected with and transmit polio. The only difference is that the IPV-vaccinated children are supposed to have less symptoms if they become infected. This means that if an IPV-vaccinated child and an unvaccinated child both become infected with polio, the IPV-vaccinated child is more likely to continue to socialize, as he or she should have less symptoms, whereas the unvaccinated child is more likely to have symptoms and remain home in bed.

Another example is the pertussis vaccine. In the 1990s, acellular pertussis vaccine, the "aP" in DTaP, was phased into use in the United States and the DTP was phased out due to safety concerns. Despite there being six doses of pertussis vaccine on the routine childhood schedule, the amount of circulating pertussis bacterium appears to have remained the same or increased.[286] After decades of assuming pertussis vaccine could eliminate pertussis, certain studies resulted in the unexpected conclusion that "aPV pertussis vaccines do not prevent colonization," "do not exert any herd immunity effect," and the lack "of mucosal immune responses after aPV administration favor infection, persistent colonization, and transmission of the pathogen."[287] Ultimately, since the pertussis vaccine can reduce symptoms and studies reflect vaccinated and non-vaccinated individuals carry the same amount of pertussis bacteria in their nasopharynx upon infection, being

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[281] https://www.cdc.gov/vaccines/vpd/polio/index.html ("Inactivated polio vaccine (IPV) is the only polio vaccine that has been given in the United States since 2000."); https://www.cdc.gov/orr/polioviruscontainment/diseaseandvirus.htm ("IPV… protects people from polio disease but does not stop transmission of the virus.") *linking to* CDC, *et al.*, Polio Global Eradication Initiative webpage https://polioeradication.org/polio-today/polio-prevention/the-vaccines/ipv/ ("IPV induces very low levels of immunity in the intestine. As a result, when a person immunized with IPV is infected with wild poliovirus, the virus can still multiply inside the intestines and be shed in the feces … IPV does not stop transmission of the virus.").

[282] https://www.cdc.gov/mmwr/preview/mmwrhtml/mm4902a4.htm (In 1999, CDC provided for "exclusive use of acellular pertussis vaccines for all doses of the pertussis vaccine series."); https://pubmed.ncbi.nlm.nih.gov/24277828/; https://pubmed.ncbi.nlm.nih.gov/31333640/ ("Mucosal immunity is essential to prevent colonization and transmission of B. pertussis organisms. … [P]reventive measures such as aPVs [acellular pertussis vaccine] that do not induce a valid mucosal response can prevent disease but cannot avoid infection and transmission. … aPV pertussis vaccines do not prevent colonization. Consequently, they do not reduce the circulation of *B. pertussis* and do not exert any herd immunity effect.").

[283] https://www.cdc.gov/tetanus/about/index.html ("Tetanus … does not spread from person to person.").

[284] https://www.cdc.gov/vaccines/vpd/mening/public/index.html ("Rates of meningococcal disease have declined in the United States since the 1990s and remain low today. Much of the decline occurred before the routine use of MenACWY vaccines. … [D]ata suggest MenACWY vaccines have provided protection to those vaccinated, but probably not to the larger, unvaccinated community (population or herd immunity)."

[285] https://www.cdc.gov/poliovirus-containment/diseaseandvirus/; https://www.cdc.gov/mmwr/volumes/71/wr/mm7133e2.htm.

[286] https://pubmed.ncbi.nlm.nih.gov/29180031/ ("That vaccination does not prevent B. pertussis infection in humans, nor the circulation of the organism in human populations in any important manner, comes from the observation that the inter-epidemic intervals have not changed in a major way since the implementation of mass vaccination.").

[287] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6616129/.

vaccinated actually makes individuals more likely to spread pertussis because those experiencing symptoms typically are aware they are sick and stay away from others.

VII. CONCLUSION

Given that public health authorities (due in large part to conflicts) and pharmaceutical companies (due in large part to immunity to liability) have not carefully and transparently studied childhood vaccines, it should not come as a surprise how Covid-19 vaccines were handled. The entire vaccine framework in this country, as explained herein, needs to be dismantled and rebuilt with the goals of full transparency, data sharing, ending of conflicts, accountability, and informed consent.

The foregoing report was prepared in a limited period of time and the undersigned reserves the right to edit any items herein for clarity, accuracy or otherwise. Thank you for the opportunity to provide this submission to the committee.

/s/ *Aaron Siri*
Aaron Siri, Esq.
SIRI & GLIMSTAD LLP
745 Fifth Ave, Suite 500
New York, NY 10151
Tel: (212) 532-1091
Fax: (646) 417-5967
aaron@sirillp.com

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