June 30, 2026

VIA FEDERAL EXPRESS

Jay Bhattacharya, MD, PhD
Acting Director
Centers for Disease Control and Prevention
1600 Clifton Road NE
Atlanta, GA 30329-4027
[redacted]

Re: *Immediate Termination of all Immunization Safety Office Personnel and Full Reconstitution of the Office*

Dear Acting Director Bhattacharya:

We write on behalf of Informed Consent Action Network ("**ICAN**") to demand the immediate termination of all employees of Centers for Disease Control and Prevention's ("**CDC**") Immunization Safety Office ("**ISO**") and full reconstitution of the office with personnel who will genuinely prioritize the safety of Americans. As you are aware, the ISO is the primary federal office responsible for monitoring, evaluating, and researching vaccine safety in the United States. Despite these critically important functions, the ISO has failed in its mission.

ISO was established as part of CDC's Clinical Immunization Safety Assessment ("**CISA**") Network in 2001.[1] In the more than two decades since, it has failed to conduct the critical safety studies needed to support CDC's public assurances on vaccine safety. That failure is detailed in Chapter 11 of my book, *Vaccines, Amen: The Religion of Vaccines*, attached hereto. The chapter includes a detailed examination of the documented research gaps concerning vaccines. I respectfully submit that it will assist you in evaluating the failure of the ISO to date and the future direction of the ISO.

The ISO as currently constituted is not merely ineffective—it is an obstacle to genuine vaccine safety. For decades, the office has had the opportunity to perform even the most basic safety science, and it has deliberately declined to do so. It has aligned itself with pharmaceutical companies rather than with the public it is meant to protect. It has concealed data and manipulated the very surveillance systems designed to detect risk.

We therefore demand:

- **Immediate termination of all ISO personnel**. The institutional culture of ISO is irreparably compromised. No reform is possible without a complete change of personnel.

[1] https://archive.cdc.gov/www_cdc_gov/vaccinesafety/ensuringsafety/monitoring/cisa/history.html.

- **Full reconstitution of ISO** with scientists and officials who are committed to conducting genuine safety science and who will engage transparently with all stakeholders, including organizations that actually care about vaccine safety, and who will pledge to never work for any industry interests that profit from vaccines.
- Once reconstituted, **the immediate commencement of the long-demanded vaccinated vs. unvaccinated studies**, as IOM confirmed are possible.
- **Public release of all deidentified data** relied upon for any prior studies involving the ISO as well as release of such data for all future studies.

The American people—and especially the families of vaccine-injured children—have waited long enough. The ISO has failed—it is time to start over.

Very truly yours,

SIRI & GLIMSTAD LLP

/s/ Aaron Siri
Aaron Siri, Esq.
Elizabeth Brehm, Esq.
Marina Resciniti, Esq.
ebrehm@sirillp.com

Encl.

Chapter 11

"Vaccines Are Carefully Studied Post-Licensure!"

As we have just painstakingly reviewed, the dark cold reality is that each time a childhood vaccine has been unleashed for injection into millions of children, its safety profile was, at best, unknown. When I have confronted vaccinologists and other doctors in depositions and other forums with this undeniable evidence, and after that realization sinks in, there are two common retorts. The first is, "vaccines are carefully studied for safety after licensure! They are!" And the second is, "vaccines have made our children healthier!"

Childhood Health Has Declined with Increasing Vaccination

Let's just quickly dispel the notion that children have gotten healthier as we have increased the number of vaccines they are given.

In 1986, when the CDC schedule had 3 routine injections by age one, *under* 10% of children had a chronic health condition.[1] Fast forward to 2025: the CDC routine schedule now stands at 25 injections by age one, and now *well over* 40% of children have a chronic health condition (often multiple conditions), most of which result from some form of immune system dysregulation, including asthma, allergies, ADHD, autism spectrum disorder, atopic dermatitis, diabetes, epilepsy, and mental health disorders.[2]

Asthma, allergies, and atopic dermatitis, for example, are caused by a dysregulated immune system that overreacts to otherwise harmless substances.[3] ADHD and autism spectrum disorder are highly associated with immune dysregulation.[4] Epilepsy can be caused by the immune system attacking brain tissue as well as from neuroinflammation, which can be caused by vaccination.[5] Immune "system dysfunction represents a key mechanism in the onset and pathophysiology of mood disorders."[6]

The correlation between the increase in the CDC's childhood vaccine schedule and the increase in chronic childhood diseases doesn't mean that vaccines caused the entirety of this increase in illness and disability.[7] There are certainly other environmental insults that can harm children. But what it does mean is that it is a big fat lie that children have gotten "healthier" as the CDC vaccination schedule has expanded. The truth is precisely the opposite.

I know that for many, the idea that children have gotten healthier serves as proof that vaccines have improved health. They immediately believe that correlation means causation when someone claims vaccines resulted in a benefit. But point out that childhood health has declined as vaccinations increased and you will often hear, "correlation doesn't equal causation!" True. But what a correlation *should* do is make the medical community respond with something like, "hmmm, maybe we should rule out vaccines as the cause of widespread immune dysregulation, especially given the correlation, biological plausibility, and studies that indicate a causal relationship."

That would be a reasonable and scientific response. Especially when, as noted, most of the chronic illnesses that have risen sharply result from some form of immune system dysregulation. Instead, I am often met with hyperventilation at even the hypothesis that vaccines could be a contributing factor, instead of being met with calm agreement that a scientific inquiry to rule out vaccines as the cause is a good idea.

Has the needed inquiry by the medical establishment happened? Sadly, it has not. Not even close. And I intend to thoroughly prove that assertion.

Let's start with the claimed injury from vaccines that the public "health" community asserts it has studied more thoroughly than any claimed vaccine injury. The claimed vaccine harm they confidently and strenuously assert they have completely debunked with a mountain of studies. And not just a mountain of studies, but a mountain of studies that have painstakingly and thoroughly assessed this claimed harm, and have proven over and over again that this harm is never, ever, ever, caused by vaccines. Ever. That is right. Ever. It is the claim that, and stay calm if you are in the Vaccines Amen crowd, that … vaccines cause autism.

"Vaccines Do Not Cause Autism!!"

Here is what the CDC unequivocally states on its website:



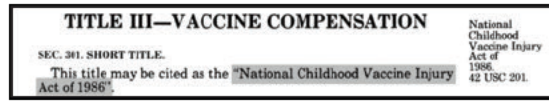
Now, let's see if the CDC has the studies to support its claim that "Vaccines Do Not Cause Autism." The point is not to prove vaccines can cause autism, but to see if this issue has in fact been properly studied. This is, after all, the harm the CDC and "health" authorities assert they have studied more thoroughly than *any* other claimed vaccine harm. Meaning, if vaccines and autism have not, in fact, been properly studied, imagine how well all the other serious claimed vaccine harms have been studied.

Before you close this book or flip out, seriously, stay with me.

1986 Congress Requires Study of Pertussis Vaccine & Autism

Let's start in 1986 when the rate of autism was around one in thousands of children and the CDC schedule included only one routine injected vaccine during the first year of life – a pertussis-containing vaccine injected three times by six months of age.

While autism was relatively uncommon in 1986, it was a serious enough concern that, in the 1986 Act, Congress required federal health authorities to review the scientific literature on whether pertussis vaccines can cause autism. Here is the relevant portion of the 1986 Act, highlighted in gray:

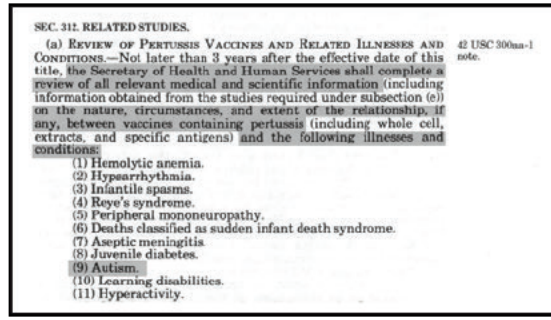


TITLE III—VACCINE COMPENSATION

National Childhood Vaccine Injury Act of 1986. 42 USC 201.

SEC. 301. SHORT TITLE.

This title may be cited as the "National Childhood Vaccine Injury Act of 1986".



SEC. 312. RELATED STUDIES.

(a) 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 (including information obtained from the studies required under subsection (e)) on the nature, circumstances, and extent of the relationship, if any, between vaccines containing pertussis (including whole cell, extracts, and specific antigens) and the following illnesses and conditions:

42 USC 300aa-1 note.

(1) Hemolytic anemia.
(2) Hypoarrhythmia.
(3) Infantile spasms.
(4) Reye's syndrome.
(5) Peripheral mononeuropathy.
(6) Deaths classified as sudden infant death syndrome.
(7) Aseptic meningitis.
(8) Juvenile diabetes.
(9) Autism.
(10) Learning disabilities.
(11) Hyperactivity.

Congress wasn't just requiring HHS to review pertussis vaccine and autism for fun. It listed autism because this was one of the harms claimed to be caused by the pertussis vaccine. This is why Congress, in the 1986 Act, required HHS to review the existing scientific literature regarding whether pertussis vaccines can cause autism.

1991 IOM Report on DTP/DTaP and Autism

HHS in turn commissioned the IOM to conduct this review. When that review was finally published in 1991, the IOM explained that it could not identify a single study to support the claim that pertussis vaccines do not cause autism. Not one study.[8]

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

> 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.[9]

You would assume that after the IOM could not find any studies assessing whether pertussis vaccine can cause autism, and the ominous warning above, that studies would have been conducted to answer this question.

2012 IOM Report on DTaP and Autism

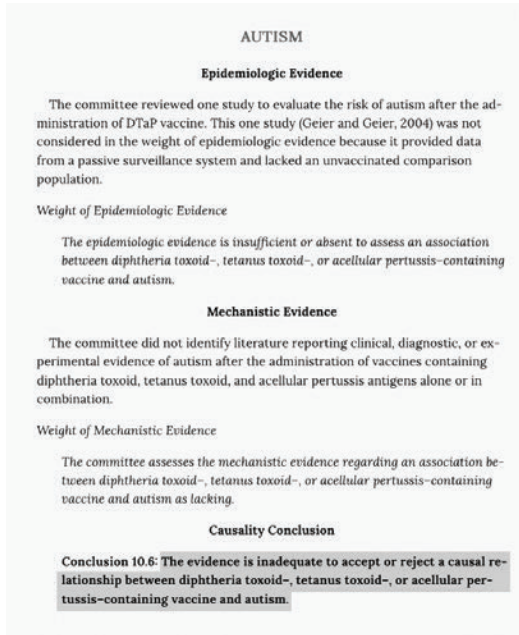
Well, let's fast forward two decades to 2012 when the IOM issued another report on vaccine safety, this time paid for by the CDC and HRSA, which we discussed in Chapter 1. The IOM was asked to assess the evidence bearing on whether pertussis vaccines, including DTaP, cause autism. They did so because this remained, according to HRSA, one of the most claimed injuries from this vaccine.[10] This time around, the request to the IOM also included reviewing whether tetanus and diphtheria vaccines can cause autism.

As in 1991, the IOM again convened a committee of experts to review all available epidemiological, clinical, and biological evidence. The committee was composed of individuals considered experts in pediatrics, internal medicine, neurology, immunology, immunotoxicology, neurobiology, rheumatology, epidemiology, and biostatistics.[11]

Despite the intervening decades between the 1991 and 2012 reports, the IOM's response to the CDC and HRSA in its 2012 report remained unchanged. The IOM could not locate a single study supporting the

claim that DTaP does not cause autism. As the IOM concluded: "The evidence is inadequate to accept or reject a causal relationship between diphtheria toxoid–, tetanus toxoid–, or acellular pertussis–containing vaccines and autism."[12]

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



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.

Ironically, the only study the IOM could locate (Geier and Geier, 2004) concluded that there *was* an association between DTaP and autism.[13] But the IOM gave this study no weight because it was based on the CDC and FDA's Vaccine Adverse Events Reporting System (**VAERS**) reports.

2014 AHRQ Report on DTaP and Hep B Vaccines and Autism

Two years later, in 2014, the Agency for Healthcare Research and Quality (**AHRQ**) again conducted a review searching for any studies regarding pertussis, tetanus, and diphtheria vaccines (including DTaP) and their possible link to autism.[14] HHS has explained 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."[15] As with the IOM reports from 1991 and 2012, the "comprehensive review" published by AHRQ in 2014 again concluded that it could not identify a single study to support the claim that DTaP (injected at 2, 4, and 6 months of age) does not cause autism. Not one.[16]

This review also had a section regarding Hep B vaccines (injected at 1 day, 1 month, and 6 months of age) and autism and did not identify a single study to support that Hep B vaccines do not cause autism.[17] Instead, the only study meeting AHRQ's strict 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 compared to those who did not get this vaccine. 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.[18]

An "OR 3.00" means an odds ratio of 3.00 which translates to a 200% increased risk. Meaning, the study found that infants receiving a Hep B vaccine had a 200% increased risk of autism compared to infants who did not receive this vaccine. And since the confidence interval for this finding was between 11% to 713% increased risk, the 200% increased risk was statistically significant.

So, AHRQ identified one study that found a statistically significant increased risk of autism from Hep B vaccine, and no studies to disprove this finding. With that, the review could not claim that the Hep B vaccine does not cause autism. Rather, in accordance with vaccine theology, AHRQ stated it could not conclude whether the Hep B vaccine does or does not cause autism.[19] So still not a single study to show DTaP or Hep B do not cause autism.

2017 NIH Meeting Regarding Autism

Moving on to 2017. 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."[20] In attendance at that meeting were approximately a dozen individuals, including RFK Jr. on one side of the table, where I was also seated, and on the other side of the table, Dr. Francis Collins (Director of the NIH), Dr. Anthony Fauci (Director of the National Institute of Allergy and Infectious Diseases), Dr. Joshua Gordon (Director of the National Institute of Mental Health and Chairman of the Interagency Autism Coordinating Committee), Dr. Diana Bianchi (Director of the Eunice Kennedy Shriver Institute of Child Health and Human Development), and Dr.

Linda Birnbaum (Director of the National Institute of Environmental Health Sciences).

During that meeting, Dr. Gordon (who, again, is the Director of the National Institute of Mental Health and the Chairman of the Interagency Autism Coordinating Committee), asserted that vaccines do not cause autism. I asked him for the study which compares vaccinated and unvaccinated children which supports this conclusion. In response, Dr. Gordon assured me such a study exists and emailed me, as we sat in the meeting, a published review titled: "Vaccines are not associated with autism: an evidence-based meta-analysis of case-control and cohort studies."[21]

While the title of this review makes it appear to include studies of all childhood vaccines, that is not the case. The review does not have a single study on whether the vaccines on the CDC schedule being injected into babies, three times each in the first six months of life – DTaP, Hep B, Hib, PCV13 and IPV – do not cause autism. Instead, the review only looked at whether MMR and a single ingredient, thimerosal, do not cause autism. Dr. Gordon had clearly not read this review beyond its title. I therefore emailed Dr. Gordon on July 10, 2017, as follows:

> Thank you for sending me the below abstract/review article and it was great meeting at NIH. Really appreciate the opportunity to dialogue on the issue of vaccines and autism.
>
> The abstract/review article you sent me below highlights the concern raised that there has never been a study assessing the relative risk of autism between vaccinated and unvaccinated child[ren]. To be sure, this review (and its abstract) leave the impression that the studies it relies upon compare "unvaccinated" children (no vaccines) with vaccinated children. Unfortunately, this is misleading since all 10 of the underlying studies relied upon for this review compared highly vaccinated children with highly vaccinated children. The only difference typically between the study and control groups was a single MMR vaccine or thimerosal vs. non-thimerosal vaccines. (I would be happy to provide you with a breakdown of each of the 10 studies reflecting same.) Meaning, what this review considers "unvaccinated" are vaccinated children typically only missing the MMR vaccine. Assuming the control children in these studies followed the current CDC recommended

vaccination schedule, they would each have received 21 vaccine injections during the first 12 months of life excluding the MMR vaccine. Hence, these studies tell us virtually nothing about the relationship of vaccines to autism because they are not comparing vaccinated and unvaccinated children.

For example, the IOM stated in 2011 that there isn't a single study that supports the assertion that DTaP (injected at 2 months, 4 months, 6 months, etc.) does not cause autism, concluding that "The evidence is inadequate to accept or reject a causal relationship between diphtheria toxoid-, tetanus toxoid-, or acellular pertussis-containing vaccine and autism." Attached is an excerpt of the discussion regarding autism and DTaP from the 2011 IOM report. … As another example, the only study regarding Hepatitis B vaccine and autism I have located found a three-fold increase in the odds of an autism diagnosis for neonates that received the hepatitis B vaccine at birth compared [to] those that did not. (Gallagher CM, Goodman MS. 2010) …

As we discussed at the meeting, I really am open to seeing the evidence that the vaccination schedule, and in particular the cumulative impact of the 31 vaccine doses the CDC recommends a child receive in the first year of life, are not casually [sic] related to autism. I would gladly share that support with the community concerned with this issue with my personal endorsement. On the other hand, if that proof doesn't exist, that does not mean that vaccines cause autism. It just means that we need to really do the science necessary to rule out that possibility. (Seeking to assess the health outcomes of those receiving vaccines and those not receiving vaccines really is asking for nothing more than how all drugs are safety tested prior to licensure.)

I respected what appeared to be your thoughtful rather than reflexive reaction to the spirited discussion at NIH. Conducting a true study of the health outcomes between actually unvaccinated and vaccinated children (at least an initial quick and easy retrospective study) that shows no connection with autism should be

> something that everyone should want. If it shows no connection, it will likely provide the greatest relief to the portion of the autism community that thinks there may be a connection. Parents who think that it was their actions, in vaccinating their children, that lead to their child's condition would feel freed from that guilt by knowing it wasn't the vaccines.
>
> I look forward to your response and being persuaded that the science on the question of whether vaccines cause autism really is settled.
>
> Thanks again in advance for your time and thoughtful consideration of this issue.[22]

On July 24, 2017, I sent Dr. Gordon a follow-up email with the peer-reviewed literature regarding aluminum adjuvants, immune activation, and related topics which according to certain scientists, when pieced together, could explain how vaccines can cause autism.

By August 14, 2017, Dr. Gordon had failed to provide any response to either of my emails, so I sent this follow-up email:

> I hope all is well.
>
> I have not received a response to the emails below of July 10 and July 24.
>
> The July 10 email was in response to a review you provided indicating it compared vaccinated and unvaccinated children (but which actually compares vaccinated children with vaccinated children who, at most, were missing MMR). As discussed at our meeting, I would like to see a study which supports the claim that the nearly two dozen doses of vaccines given in the first year of life (which would not include MMR and thimerosal) do not cause autism. I still await receipt of a study which supports same. Are you aware of any such study?
>
> The July 24 email elaborated on my prior email and also sought to facilitate a meeting … with various experts in the field of aluminum adjuvant that do believe there is a connection between aluminum

> adjuvant in vaccines and autism. Are you willing to have this meeting?[23]

On September 1, 2017, Dr. Gordon finally responded, and here was his response in full:

> Dear Aaron,
>
> I appreciate you following up with me, and apologize for the delay in my response. I think the information you are seeking would be best obtained from the CDC.
>
> Best,
> Josh[24]

Wow. And this was from the person heading up our nation's premier mental health institution and directing its autism research. So, this was my response sent on September 14, 2017:

> Thank you for your response. The information I seek is nothing more than a simple reference to one study which supports HHS's claim that the vaccines it recommends children receive in the first year of life do not cause autism. I gather from our exchange below that you are not aware of any such study. Let me know if that is incorrect.
>
> You are the Director of the Interagency Autism Coordinating Committee (IACC) which coordinates all efforts at HHS, including at the CDC, concerning autism. The IACC's members include the CDC itself, as well as the CDC's Chief Medical Officer & Associate Director for Science … Since you state below that the support I seek is best obtained from the CDC, I have cc'd the CDC members on your committee.
>
> I am just trying to get a copy of a study supporting HHS's claim that the vaccines it recommends in the first year of life do not cause autism. I assume you have the best intentions and I would really like to drop this issue – but, as you can appreciate, I like to rely on data/science. I am just asking for a citation to a single study supporting HHS's claim that the vaccines it

> recommends children receive in the first year of life do not cause autism. I would think you too, as the Director of IACC and NIMH, would be interested in seeing such a study and its underlying data.
>
> Also, can you kindly let me know one way or another if you are interested in meeting with the aluminum adjuvant experts whose letters and CVs were previously provided regarding the potential connection between aluminum adjuvants and autism. Again, I would think you would be interested in hearing them out. (Docs relevant to same reattached.)
>
> …Btw, your response below reminds of me of what former House representative, Dr. Dave Weldon, wrote in 2007: "When I first tasked my staff with investigating federal vaccine safety research we got a lot of confused responses and blank stares from federal officials. The FDA told us to check in with the CDC, telling us that CDC did most of the vaccine safety research. The CDC referred us over to the NIH. Then, the NIH referred us back to the CDC." Happy to send you his full statement.[25]

Then on October 25, 2017, I received the following email from the CDC's Executive Secretary, which merely directed me back to the CDC's page on autism which I had obviously already reviewed thoroughly:

> Dear Mr. Siri:
>
> Thank you for your inquiry. The Centers for Disease Control and Prevention (CDC) information on vaccines and autism can be found here, www.cdc.gov/vaccinesafety/concerns/autism.html.
>
> Please send any future correspondence to CDCExecSec@cdc.gov.
>
> Sincerely,
> Sandra Cashman, MS
> Executive Secretary
> Office of the Chief of Staff, CDC[26]

Truly incredible – especially after reviewing what is on this webpage. So, here was my response to Dr. Gordon:

> I received the attached email from HHS which I assume is your official response to the simple request to provide at least one study which supports that DTaP and the other vaccines HHS recommends during the first year of life do not cause autism.
>
> This response provides a link to the HHS webpage which claims "Vaccines Do Not Cause Autism" and lists a number of reviews/studies to support this assertion. Sadly, not a single one of these reviews/studies (which all related to either one vaccine, MMR, and/or one vaccine ingredient, thimerosal) provides a shred of support that the 29 doses of 9 different vaccines CDC recommends children receive by six months of age do not cause autism. Ironically, the very first study/review listed on this webpage is the 2011 IOM report, paid for by HHS, which looked at the most commonly claimed vaccine reactions, including that DTaP causes autism, and the IOM could not find a single study that supports the assertion that DTaP (injected at 2 months, 4 months, 6 months, etc.) does not cause autism. (See excerpt from the IOM report attached.) Your response therefore makes it clear you do not have a single study to share which supports that the vaccines given to children in the first year of life do not cause autism.
>
> It is understandable that you thought the study you sent me below actually contained unexposed controls (unvaccinated children) given its misleading title. But now that you know the reality that there is no study supporting the claim that vaccines given during the first year of life do not contribute to the incidence of autism, are you going to take action to conduct an appropriate study that would either support or reject this claim?
>
> I understand this is a difficult and controversial topic but I hope the National Institute of Mental Health and the IACC do not shy away from a scientific study because of fear of what it may show. There are a number of plausible reasons for how 29 doses of 9 different

vaccines given during pregnancy, 1 day, 2 months, 4 months, and 6 months can cause autism, including immune activation, aluminum adjuvant being carried to the brain by macrophages, MCP-1 signaling, molecular mimicry, etc. Vaccines are intended to create a permanent change in the body's immune system often using adjuvants intended to generate a sustained and significant immune event which modern science is not even close to fully understanding; there is also a growing understanding of the connections between the immune and nervous systems. But no need to make this complicated since all you need to do is … [c]ompare the rates of neurological and immune disorders between an exposed group (vaccinated) and unexposed group (unvaccinated) – this study can even be done retrospectively to avoid supposed ethical concerns.

You are in the unfortunate position of defending vaccine safety because, unlike drugs, most pediatric vaccines currently on the market have been approved based on studies with inadequate follow-up periods of only a few days or weeks (and no saline placebo control). You however are in the fortunate position to remedy this deficiency. In that regard, I have attempted as best as I can to engage with you in a constructive manner on this topic, giving you many months since our meeting to provide the support you were adamant existed during our meeting (a study of vaccinated versus unvaccinated children). Absent a response in the coming days with such support or firm plans to openly conduct such a study, I am left with the conclusion that you (directly or by order of your superiors) don't care to know the real answer to the question of whether giving 29 doses of 9 different vaccines by six months of life contributes to the incidence of autism (and other neurological and immune issues).

Dr. Collins asked during our meeting to consider the implications if Mr. Kennedy was wrong about his concerns regarding vaccine safety. Given your station, I ask you the same question. What if you are wrong about the safety profile of the first year vaccination schedule? What if it is a major contributor to the

> rising incidence of various neurological and immune (including immune mediated neurological) disorders that have risen in tandem with the increase in HHS's recommended vaccine schedule. If you conduct the desperately needed vaccine safety science noted above the worst that will have happened is that you will have the science to prove what you now can only assume. However, if you don't conduct this study and it eventually turns out your belief (and this email chain makes clear it is a belief) regarding vaccine safety is incorrect, I hope you can live with knowing you could have avoided these harms (and provided the basis to finally begin the desperately needed science of identifying the children susceptible to serious vaccine injury) but chose instead to sit on your hands…
>
> Very truly yours,
> Aaron[27]

Dr. Gordon never did provide a single study to support that any of the vaccines given in the first year of life do not cause autism. And remember, Dr. Gordon was literally the Director of the National Institute of Mental Health (NIMH) and Chairman of the Interagency Autism Coordinating Committee (IACC).

2017-2018 Exchange with HHS and Plotkin Deposition

The next stop on the hunt for the supposed mountain of studies that prove infant vaccines do not cause autism occurred on October 12, 2017. On that date, ICAN sent a letter to HHS regarding vaccine safety. The letter, endorsed by over 55 organizations representing more than 5 million Americans, asked in relevant part:

> Dear Secretary Hargan: …
>
> As the Secretary of HHS (the Secretary) … you shoulder virtually all responsibility for assuring the safety of vaccines administered to America's 78 million children.
>
> This notice respectfully requests confirmation that certain obligations regarding vaccine safety required under the 1986 Act have been fulfilled or will forthwith be fulfilled. …

…As with DTaP, there are also no published studies showing that autism is not caused by Hepatitis B, Rotavirus, Hib, Pneumococcal, Inactivated Poliovirus, Influenza, Varicella, or Hepatitis A vaccines. …[28]
Instead, [the CDC's] claim that "Vaccines Do Not Cause Autism" relies almost entirely upon studies exclusively studying only one vaccine, MMR (which is administered no earlier than one year of age), or only one vaccine ingredient, thimerosal, with regard to autism.[29] …

As for the MMR vaccine, the CDC's own Senior Scientist, Dr. William Thompson[30], recently provided a statement through his attorney that the CDC "omitted statistically significant information" showing an association between the MMR vaccine and autism in the first and only MMR-autism study ever conducted by the CDC with American children.[31] Dr. Thompson, in a recorded phone call, stated … :

I have great shame now when I meet families with kids with autism because I have been part of the problem … the CDC is so paralyzed right now by anything related to autism. They're not doing what they should be doing because they're afraid to look for things that might be associated. So anyway there's still a lot of shame with that. … I am completely ashamed of what I did.[32]

Hence, as for the only vaccine, MMR, actually studied by the CDC with regard to autism, it appears the CDC may have concealed an association between that vaccine and autism.[33]

When the former Director of the National Institute of Health, Dr. Bernadine Healy, was asked about whether public health authorities are correct to claim that vaccines do not cause autism, she answered: "You *can't* say that."[34] When asked again, Dr. Healy explained: "The more you delve into it – if you look at the basic science – if you look at the research that's been done, in animals – if you also look at some of these individual cases – *and*, if you look at the evidence that there *is* no

link - what I come away with is: *The question has not been answered."*[35]

Former NIH Director Dr. Healy goes on to explain:

This is the time when we do have the opportunity to understand whether or not there are susceptible children, perhaps genetically, perhaps they have a metabolic issue, mitochondrial disorder, immunological issue, that makes them more susceptible to vaccines plural, or to one particular vaccine, or to a component of vaccine... I haven't seen major studies that focus on - three hundred kids, who got autistic symptoms within a period of a few weeks of a vaccine. I think that the public health officials have been too quick to dismiss the hypothesis as irrational, without sufficient studies of causation. …

The reason why they didn't want to look for those susceptibility groups was because they're afraid if they found them—however big or small they were—that that would scare the public away. First of all, I think the public's smarter than that; the public values vaccines. But, more importantly, I don't think you should ever turn your back on any scientific hypothesis because you're afraid of what it might show![36]

The CDC has also failed to address the science supporting a link between vaccines and autism.[37] For example, the CDC has not addressed a study which found a [2]00% increased rate of autism among newborns receiving the hepatitis B vaccine at birth compared to those that did not.[38] Nor a recent and first ever vaccinated vs. unvaccinated pilot study which found vaccinated children had a 420% increased rate of autism and that vaccinated preterm babies had an even higher rate of autism.[39] There is also a persuasive body of science supporting a clear connection between aluminum adjuvants in vaccines and autism which the CDC, despite numerous requests, has failed to directly or substantively address.[40] Letters from three aluminum adjuvant experts on this point are attached as Appendix C.

> The critical need for HHS to properly engage in vaccine safety science regarding autism is made even more vital by the fact that vaccine makers are immune from liability for vaccine injury and vaccines are not safety-tested prior to licensure to assess whether they cause autism. …
>
> Please confirm that HHS shall forthwith remove the claim that "Vaccines Do Not Cause Autism" from the CDC website, or alternatively, please identify the specific studies on which HHS bases its blanket claim that no vaccines cause autism?[41]

After sending the above letter, but before the Secretary responded, Dr. Stanley Plotkin made the incredible admission under oath regarding vaccines and autism discussed in Chapter 1. As a reminder, here is a truncated version of that exchange:

> **Q:** [W]as the IOM able to identify a single study supporting that DTaP and Tdap do not cause autism?
> **A:** No, they did not identify a study. …
> **Q:** [S]tudies are possible to determine whether or not a vaccine does or … does not cause autism, correct?
> **A:** They are possible, yes.
> **Q:** … If you don't know whether DTaP or Tdap cause autism, shouldn't you wait until you do know, until you have the science to support it to then say that vaccines do not cause autism?
> **A:** Do I wait? No, I do not wait because I have to take into account the health of the child.
> **Q:** And so for that reason, you're okay with telling the parent that DTaP/Tdap does not cause autism even though the science isn't there yet to support that claim?
> **A:** Absolutely.[42]

Let me sum up the High Priest's approach: just lie to parents in telling them that the science supports the finding that vaccines do not cause autism even if the science doesn't support that claim. And remember, as Dr. Paul Offit explained, Dr. Plotkin "trained a generation of scientists" involved in vaccine policy and advocacy "to think like he thinks."[43]

On January 18, 2018, the HHS Secretary responded to ICAN's demand regarding autism in a letter which stated in relevant part:

> Many studies have looked at whether there is a relationship between vaccines and autism spectrum disorder (ASD). These studies continue to show that vaccines do **not** cause ASD. For more information, please refer to the literature below:
>
> - https://www.cdc.gov/vaccinesafety/pdf/cdcstudiesonvaccinesandautism.pdf
> - http://nationalacademies.org/hmd/reports/2004/immunization-safety-review-vaccines-and-autism.aspx
> - http://www.jpeds.com/article/S0022-3476(13)00144-3/pdf?ext=.pdf
> - http://nationalacademies.org/HMD/Reports/2011/Adverse-Effects-of-Vaccines-Evidence-and-Causality.aspx
>
> While there is still a lot to learn about ASD, research from public and private organizations indicate that environmental and genetic factors may increase the risk of autism, not vaccines or vaccine ingredients. HHS continues to research this issue to search for answers to better understand the risk factors and causes of this disease. Recent efforts to coordinate autism research are reflected in the "Strategic Plan for Autism Spectrum Disorder Research" by the Interagency Autism Coordinating Committee at https://iacc.hhs.gov/publications/strategic-plan/2017/.[44]

After receiving the above response, I again read all the linked content. I say "again" because I had already read this basic material regarding vaccines and autism before the initial ICAN letter was sent because these were the obvious documents to review on this topic. On rereading them, it was again clear that *none* of these links contained a single study which supports the claim that the vaccines given to infants do not cause autism. Not one such study. As explained in ICAN's December 31, 2018 response to the HHS Secretary:

> Our opening letter … asserted that, like the DTaP vaccine, there are also no published studies showing that

autism is not caused by vaccines for Hepatitis B [and the other vaccines given by six months of age]...[45] HHS's response fails to provide a single study to rebut the foregoing [or] … address the science [ICAN cited] that does support a link between vaccines and autism. …

Instead, HHS's response merely provides five links in response to our request for the studies supporting that pediatric vaccines do not cause autism. The content of these five links all directly reinforce and confirm the very concerns raised in our opening letter.

The *first* link is to a document entitled "Science Summary: CDC Studies on Thimerosal in Vaccines."[46] The studies in this document are plainly insufficient to support the claim that "vaccines do not cause autism" as they at best only address whether thimerosal causes autism.

The *second* link is to an IOM report from 2004 entitled "Immunization Safety Review: Vaccines and Autism."[47] This report also cannot support the CDC's claim about all vaccines because it *only* addresses the MMR vaccine and thimerosal with regard to autism. …

The *third* link is a study which only looks at one vaccine component – antigens – comparing '*vaccinated* children' with '*vaccinated* children' with different antigen exposure.[48] This study again says nothing about whether any particular vaccine or HHS's childhood vaccine schedule causes autism. This study even concedes: "ASD with regression, in which children usually lose developmental skills during the second year of life, *could* be related to exposure in infancy, *including vaccines*."[49]

This antigen exposure study could have compared children receiving no-antigens, meaning no vaccines, with children receiving vaccine antigens. That would finally provide real data. Instead, the study engages in yet another nonsensical whitewash review in which it compares vaccinated children with vaccinated children, with the only real difference typically being that some children received DTaP while others received DTP.[50] … This study further ignores the fact that

> … since the late 1990s, the amount of aluminum adjuvant, a neuro-and-cyto-toxic immune stimulant, used in vaccines has significantly *increased* … [and] studiously ignores (as discussed below) the compelling body of science implicating this rising amount of aluminum adjuvant in vaccines with causing neurological dysfunction and autism.[51] …
>
> The *fourth* link HHS cites is the very IOM review … cited in our opening letter.[52] However, as we noted in our letter, the IOM could not identify a single study which supports the claim that DTaP does not cause autism.[53] Even more astonishing, a different part of HHS's response letter cites the 2014 "comprehensive review" which again could not identify a single study to support the claim that DTaP does not cause autism.[54] …
>
> The *fifth* (and final) link HHS cites in its letter is the "Strategic Plan for Autism Spectrum Disorder Research" by the Interagency Autism Coordinating Committee ….[55] Remarkably, this 196 page strategic plan outlines dozens of research priorities, but does not once mention closing the vaccine safety science gap regarding whether DTaP, Hepatitis B, and every other vaccine given by one year of age cause autism.[56]
>
> The strategy plan even explains that "neuroinflammation" may cause autism, but ignores the fact that neuroinflammation (a.k.a., encephalitis or encephalopathy) is a known reaction to numerous vaccines. … The strategic plan also recognizes "immune dysregulation" – which again can be caused by vaccines – may cause autism.[57] … This strategic plan even outlines numerous large-scale studies looking at a plethora of environmental exposures, but apparently none of these include looking at the exposure to vaccines.[58] … It would be simple to review vaccine exposures along with the hundreds of other exposures already being reviewed in these studies, but for apparently political reasons, HHS has chosen not to address this issue. …

ICAN's response to HHS then continues by explaining why HHS's failure to properly study vaccines and autism is troubling:

HHS has even remained silent and refused to seriously study the vaccine-autism connection despite the fact that HHS's leading autism expert, Dr. Andrew Zimmerman … has changed his expert opinion.[59]

Dr. Zimmerman is a former Director of Medical Research at the Center for Autism and Related Disorders at the Kennedy Krieger Institute and Johns Hopkins University School of Medicine, and is regarded as the leading national authority on autism...[60] Dr. Zimmerman testified on November 9, 2016 that vaccines can in fact cause autism and even answered "Yes" when asked under oath: "Do other people in your field, reputable physicians in your field, hold the opinion that vaccines can cause the type of inflammatory response that can lead to a regressive autism?"[61] Dr. Zimmerman further testified that once HHS understands and accepts the causal relationship between vaccines and autism, "it will prevent the development of autism in quite a few children."[62]

Dr. Zimmerman's similarly credentialed colleague, Dr. Richard Kelley, also provided the following very revealing testimony … under oath:

Lawyer: *Do you agree with the statement that vaccines do not cause autism?*
Dr. Kelley: No
Lawyer: *Is it generally accepted in the medical community that vaccines do not cause autism?*
Dr. Kelley: It is a common opinion.
Lawyer: *It is generally accepted in the medical field that vaccines do not cause autism?*
Dr. Kelley: I have no basis to judge that. It is most often when physicians are commenting on that they say there is no proven association.
Lawyer: *Do you know the position of the American Academy of Pediatrics about any link between vaccines and autism?*
Dr. Kelley: Yes. They also say there is no proven association.
Lawyer: *Do you agree with the position of the American Academy of Pediatrics?*

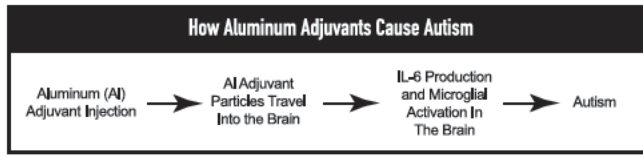
Dr. Kelley: I agree with their position as a public health measure. I don't agree with it scientifically.
Lawyer: *You are actually arguing for a link between vaccines and autism in this case, aren't you?*
Dr. Kelley: I am.
Lawyer: *And that is contrary to the medical literature, isn't it?*
Dr. Kelley: It's not contrary to the medical literature that I read. It is contrary to certain published articles by very authoritative groups who say there is no proven association in large cohort studies.
Lawyer: *Your opinion is contrary to, say, the opinion of the CDC, correct?*
Dr. Kelley: It is contrary to their conclusion. It is not contrary to their data.[63]

The view apparently held by HHS that "public health" demands hiding any relationship between vaccines and autism to assure high vaccine uptake, is troubling. …

Indeed, HHS appears frozen when confronted with replicated peer-reviewed studies, many of which were funded by HHS, regarding immune activation and aluminum adjuvants that support a causal relationship between the receipt of vaccines continuing [sic] aluminum adjuvants and the development of autism in children.[64]

Our opening letter attached letters to HHS from world-renowned experts on the toxicity of aluminum adjuvants, each of whom strongly supported the contention that aluminum adjuvants may have a role in the etiology of autism and cited the body of science that supports their assertion.[65]

This science reflects that: injected aluminum adjuvant is taken-up by immune cells (macrophages) at the injection site; these aluminum-adjuvant-loaded immune cells then travel through the lymph vessels to, among other places, the brain; the immune cells then unload their aluminum adjuvant cargo in the brain; and aluminum adjuvant in the brain causes a release of interleukin IL-6 and microglial activation, leading to autism.[66] Depicted in simple terms:



Despite years of vaccine safety advocacy demanding that HHS rebut, or at least address, the clear connection between aluminum adjuvant containing vaccines and autism, HHS appears unable to muster anything more than the public relations slogan – "Vaccines Do Not Cause Autism."

On May 24, 2014, Dr. Thompson explained that the CDC is "paralyzed right now by anything related to autism … because they're afraid to look for things that might be associated."[67] The reason for this fear may be that HHS has conceded or has been required by the Vaccine Court to pay financial compensation to at least a few dozen children where receipt of a vaccine on HHS's childhood vaccine schedule resulted in brain, neurological and/or immune dysfunction diagnosed as autism.[68] The damage awards in some of these cases were in the millions of dollars.[69] If a single study conducted by HHS shows that even 1 in 5 cases of autism are caused, directly or indirectly, by vaccines, it would result in approximately $1.3 trillion in liability.[70] Putting such potential liability into perspective, the entire federal budget in 2017 was $3.3 trillion.[71] This and the decimation of HHS's reputation if it were found that certain vaccines cause a significant fraction of autism cases, provide powerful incentives for HHS to *not* fund the basic scientific research needed to determine whether HHS's childhood vaccine schedule is a cause of autism.

It is hard to imagine that HHS has not already internally used the databases at its disposal, such as VSD, to compare the autism rate between vaccinated and unvaccinated children. If the results showed no difference in the autism rates between these two groups of children, no doubt this study would have been published. The fact that it has not been published is very concerning. …

> HHS's approach to this issue ignores the tens of thousands of families across this country that have attested – often in videos available online – that their best judgment based on the totality of their parental experience with their child is that vaccination caused their child's autism. Numerous peer-reviewed studies have found that, when surveyed, between 40% and 70% of autism parents squarely blame vaccines for their child's autism.[72] Many of these surveys explain how parents express a clear personal experience with vaccination affirming this conclusion.[73]
>
> … [B]ased on available data and information, as discussed above, HHS cannot scientifically claim that "Vaccines Do Not Cause Autism." HHS must therefore remove this claim from the CDC website until it can produce the studies to support the claim that vaccines do not cause autism. …
>
> We await your response to each of the points raised above and the questions listed … below.[74]

ICAN's response to the Secretary asked for an answer to the following question:

> 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.[75]

HHS never responded to the above despite follow-up by ICAN.[76]

2019-2020 Lawsuit Against CDC for Vaccine-Autism Studies

But we didn't give up on giving HHS and the CDC every possible chance to support their claim with actual studies. On June 21, 2019, we submitted a FOIA request to the CDC, on behalf of ICAN and the Institute for Autism Science, for copies of: "All studies relied upon by CDC to

claim that the DTaP vaccine does not cause autism." We made the same request for Hep B, Hib, PCV13 and IPV, as well as asking for the studies reflecting that, cumulatively, these vaccines do not cause autism. So, again, the CDC was being given yet another chance to simply produce the studies supporting its claim that vaccines do not cause autism.

Did the CDC produce such studies? Nope. Instead, it produced nothing and so, on behalf of ICAN and the Institute for Autism Science, we sued the CDC on December 31, 2019, to force it to produce the studies it relies upon to claim the vaccines given in the first year of life – DTaP, Hep B, Hib, PCV13, and IPV, individually and collectively – do not cause autism.[77]

As the date of the pretrial conference in this lawsuit approached, the CDC finally capitulated and provided a list of studies it claims it relies upon to assert that DTaP, Hep B, Hib, PCV13, and IPV, individually and cumulatively, do not cause autism.

This list included 16 studies and 4 reviews (*i.e.,* reviews of studies for a given research question). After reviewing this list, I vividly recall calling the DOJ attorney representing the CDC and asking him if he was certain his client, the CDC, had nothing to add to this list because none of the listed studies or reviews support the claim that the vaccines at issue do not cause autism. Meaning, I gave the CDC yet another chance. It declined to identify any further studies or reviews to add to its list.

With that, the list of 20 studies/reviews provided by the CDC is *the* definitive list of studies the CDC relies upon to claim—both to America and to the world—that vaccines given to infants do not cause autism. This list was memorialized in a signed stipulation entered into with the CDC on February 28, 2020, and then entered as an order of the Court on March 2, 2020. The substantive portion of this stipulation and order is reproduced in full below and available in the link in this endnote.[78]

> 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:
>
> - "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:

[See link in endnote 78 for list of the 20 studies cited by the CDC]

IT IS HEREBY STIPULATED AND AGREED, by and between the parties by and through their respective counsel that based on the foregoing, the above-captioned action is voluntarily dismissed...

As is clear from this Court order, the CDC was finally forced to identify specific studies to support its claim that infant vaccines do not cause autism, and not a single one of the 16 studies or 4 reviews it identified support the claim that vaccines injected into infants—DTaP, Hep B, Hib, PCV13, and IPV—do not cause autism. Instead, they included:

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

Meaning, of the 20 studies and reviews identified by the CDC, only one involved a vaccine on the CDC schedule given to infants: DTaP. This was the review that the IOM published in 2012, discussed above, which failed to identify a study to support that DTaP does not cause autism. Instead, as you already know, this IOM report found only one study regarding DTaP vaccine and autism, and that study found an association between this vaccine and autism.

Meaning, incredibly, 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.

Let me repeat this critical point: After a very public federal lawsuit demanding that the CDC identify the studies it claims support that the vaccines on its schedule given in the first six months of life (DTaP, Hep B, Hib, PCV13, and IPV) do not cause autism, the *only* study or review the CDC identified that involved one of these vaccines was an IOM review that canvassed the entire existing literature for any study regarding whether pertussis, diphtheria or tetanus vaccines do or do not cause autism, and could only find one such study, and that one study found an association between DTaP vaccine and autism.

Critically, when it had its back against the wall in a federal lawsuit, the CDC could not identify a single study that supported its claim that the vaccines given to infants (DTaP, Hep B, Hib, PCV13, and IPV) do not cause autism. Not one study.

2020 Giving the CDC More Chances and Edwards Deposition

Dumbfounded by the CDC's admission that it does not have a single study to support its claim that vaccines given to infants do not cause autism, on March 10, 2020, we, on behalf of ICAN and the Autism Science Foundation, sent another FOIA request to the CDC for "All studies supporting the claim that DTaP does not cause autism," in order to provide the CDC with yet another chance to provide the studies to support that vaccines given to babies do not cause autism. This new request asked the CDC for any studies that "support" the claim that DTaP does not cause autism – not just those it had previously "relied upon."

This gave the CDC a chance to point to any study in the world to support that these vaccines do not cause autism, even if the agency doesn't directly rely on the study to support its claim regarding autism. Instead of pointing to any additional studies, on March 23, 2020, the CDC responded by again directing us to the same list of twenty studies and reviews it previously listed in the stipulation and order of March 2, 2020.

If that were not enough, on March 27, 2020, we submitted yet another FOIA request on behalf of ICAN giving the CDC yet *another* opportunity to provide supportive studies by requesting: "Studies created or retained by CDC to support the claim that DTaP does not cause autism." The CDC again responded by pointing to the same list of 20 studies or reviews.

Nonetheless, the hunt for the illusory mountain of vaccine-autism studies continued. After all, vaccinologists and public "health" officials

roundly assure the public that they have carefully studied and debunked the claim that vaccines, and most critically those given to infants, do not cause autism.

So, on August 25, 2020, in a case specifically involving vaccines and autism, I was asked to take the deposition of Dr. Kathryn Edwards, the godmother of vaccines who we visited with earlier, and one of the world's leading vaccinologists. Dr. Edwards was brought in as an expert on the specific issues of vaccines and autism. Meaning, she knew months before being sworn in, that her deposition would specifically cover, in detail, vaccines and autism, and that she would be asked about infant vaccines and autism. Yet, here is what even she was forced to admit during that deposition when I asked her questions under oath:

Q: According 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: OK, so you're highly experienced at conducting clinical trials, correct?
A: I'm highly experienced conducting clinical trials.
Q: And you're familiar with many of the clinical trials relied upon to license many of the vaccines currently on the market, correct?
A: I am.
Q: 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. You've badgered me into answering the question the way you want me to, but I, I think that um, that I've, that's probably the answer.
Q: Is that your accurate and truthful testimony?
A: Yes. …
Q: In the expert disclosures for this case, it asserts that, among other things, you will testify that "the issue of whether vaccines cause autism has been thoroughly researched and rejected." …
Q: It's your testimony that MMR vaccine cannot cause autism?
A: That's correct.
Q: It's your testimony the Hep B 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 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? Let me just finish. Are there any studies, one way or another, that's for whether it does or doesn't cause autism?
A: As part 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: OK, 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 see whether I agree with it.[79]

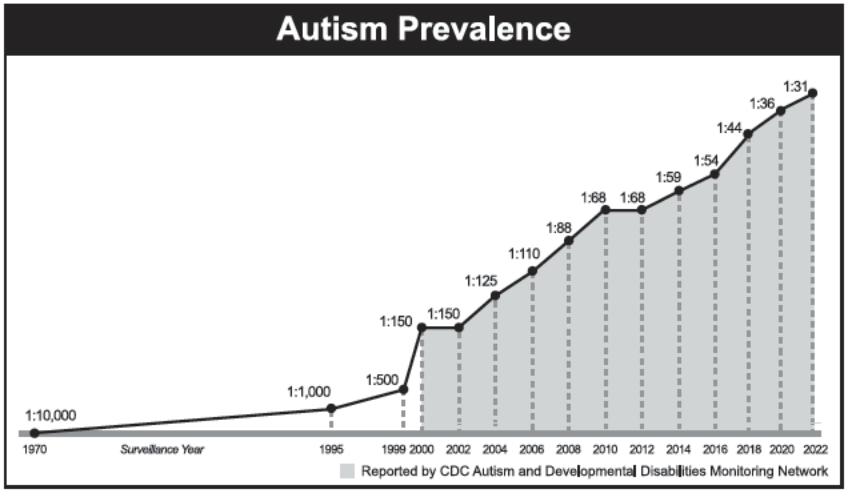
After years of asking, requesting, demanding, deposing, and suing the pivotal entities and figures in the world of vaccinology and federal "health" agencies, there is literally nobody left to ask, request, demand, depose, or sue to find the supposed mountain of studies that supposedly support that infant vaccines do not cause autism.

A mountain they claim is beyond belief in its volume and thoroughness of studies. Yet the "health" officials claiming this mountain exists are incapable of identifying a single study to support that infant vaccines do not cause autism. Literally not one study. What is clear, and requires no leap of faith, is that the claim "vaccines do not cause autism" is not science. It is an ideological belief.

The Importance of Studying Vaccines and Autism

The belief is so strong that some "health" professionals have even claimed that there is no reason to study infant vaccines and autism at all. Putting aside the fact that this concedes there was never a "mountain of studies" in the first place, this argument requires incredible religious conviction for a few reasons.

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.[80]



Given this steep rise, it is plain that the cause of autism is a change that has occurred throughout the United States since the 1980s. A study published in *Environmental Health* from the University of Colorado reviewed the correlations between numerous factors suspected of potentially causing autism and the change in the level of their exposure during childhood since the 1980s.[81] The 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 represent the rate of autism:

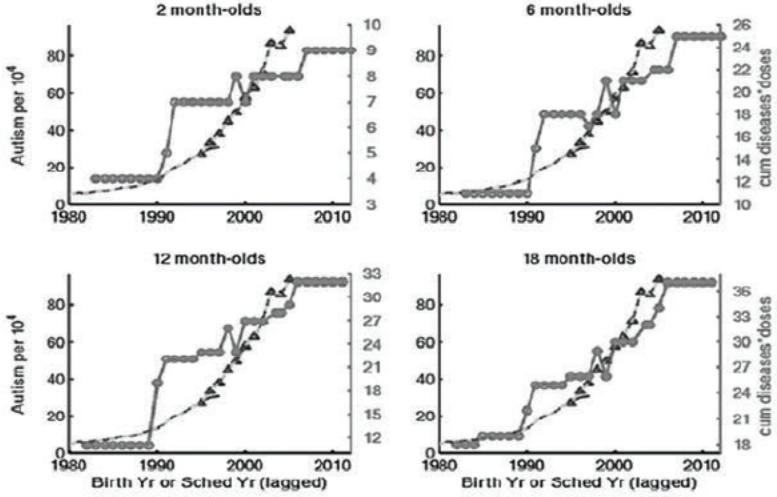


Figure S8. Temporal trend in autism compared to temporal trend in cumulative number of immunizations administered to U.S. infants and toddlers by 2, 6, 12 and 18 months via immunization according to the CDC recommended schedule.

Correlation does not equal causation, but it does, in this instance, provide a blaring safety signal that merits investigation, including because of parental claims that vaccines caused their child's autism as well as the science reflecting that autism is caused by immune system dysregulation and vaccines can cause immune system dysregulation.[82]

Even setting aside correlation and biological plausibility, parental claims that vaccines caused their child's autism should have been sufficient to warrant proper study of this issue. Numerous peer-reviewed studies have found that, when surveyed, between 40% and 70% of parents with a child with autism blame vaccines for their child's autism, often pointing to the vaccines given in the first six months of life.[83] Many of these surveys report that parents express a clear personal experience with vaccination affirming this conclusion.[84] There are also thousands of

parents who have provided video and/or written testimony sharing that they witnessed their child fall ill immediately after vaccination, regress, and then receive an autism diagnosis.

The response from "health" authorities has, sadly, not been a serious and respectful effort to investigate. Instead, when a parent – whose experience is that their child developed autism from vaccination – tries to share their experience with a medical professional, the media, or others, they are often immediately labeled "anti-science," "anti-vaxxer," "quack," and/or "conspiracy theorist." In more recent times, these parents are censored or cancelled from social media. The calls by this community for the study of infant vaccines and autism have not been heeded. The response has been ad hominem rather than scientific. It has been driven by the religious beliefs regarding vaccines of vaccinologists and the broader medical community.

The consequences of this belief may be dire and almost beyond measure in terms of suffering and harm. Autism, as common as it has become, is not a diagnosis to be taken lightly. Among the children who meet the criteria for an autism diagnosis, which include persistent deficits in social communication and interaction and repetitive behaviors, an estimated 68% demonstrate aggression toward a caregiver; 52% demonstrate self-injurious behavior; 49% bolt from safe places, creating risk of drowning, traffic injuries, etc.; and 40% are nonverbal.[85]

The following is the text from a heartbreaking meme I have often seen in parent groups for children with autism:

> Every parent plans to raise their child for about 18 years, set them free for 30 years and then hope they come back to help them face the final years of their own life. A SPECIAL NEEDS parent plans to raise their child for 65 years and while doing so also has to prepare for the other 20 or so after they themselves are long gone. … Let that sink in for just a moment and you will begin to understand the drive and determination that many of us have while we are here on Earth.

Beyond the immeasurable suffering autism causes, it is also a national crisis because it literally threatens to bankrupt the United States. In 2010, a total of 72,449 adults with autism received Social Security Income from the U.S. government (accounting for 0.6% of beneficiaries), and as of 2023, that number has risen to 319,130 adults (accounting for 3% of beneficiaries).[86] And this is just the tip of the iceberg. There are an estimated 3.9 million individuals in the United States

with autism who cannot yet legally drink, and the number of children diagnosed with autism annually is growing exponentially.[87]

As these children enter adulthood, they will add a crushing burden on the Social Security system, through no fault of their own, and many will begin receiving lifelong benefits. By 2040, it is estimated that the total societal cost of autism will exceed one trillion dollars, and by 2060, five trillion dollars.[88] Not only could these costs cause a fatal strain on the Social Security system, but the infrastructure to handle the surge in adults with autism, especially those with profound autism (who often need 24/7 supervision) is nonexistent today. Identifying the environmental cause of autism is a national emergency and ruling out vaccines as a cause is beyond urgent.

Unfortunately, instead of scientifically investigating whether vaccines given to babies cause autism, vaccinologists and "health" authorities have squandered billions of dollars to promote their religious beliefs about these products, rather than conducting the desperately needed studies. If just one penny were contributed to a fund to study vaccines and autism every time a vaccinologist or "health" professional said, "vaccines do not cause autism," we could have conducted hundreds of studies on infant vaccines and autism.

So long as the CDC and "health" authorities claim that vaccines do not cause autism, despite not having the science to support that claim, the necessary scientific inquiries are unlikely to receive the funding and attention they deserve. This is because the CDC's pronouncements regarding vaccines impact policy, research, and funding priorities across government agencies as well as research institutions in the U.S. and around the world.

Consider that the CDC and "health" authorities have conducted a decades-long media campaign seeking to assure parents that vaccines do not cause autism. Parents of autistic children have also been gaslit, attacked, and berated by the media, public "health" authorities, the medical establishment, almost everyone. Yet these parents stubbornly refuse to change their conclusion regarding what caused their child's autism.

The reason, in my experience, is that parents of children with autism cannot unlive what they have experienced with their children. Hence, no number of metaphorical beatings can change their reality. They know their children, and their lived experience will not change no matter what you do or say to them.

But because the cult of vaccines does not bend to reason, logic, or compassion when it comes to claiming vaccines are "safe," public "health" officials continue to ignore and disparage these families and just keep repeating louder and louder and louder "vaccines do not cause autism!" Not *like* a religious mantra, but because it *is* a religious mantra.

IOM Reports Reveal Other Claimed Harms Studied Even Less Than Autism

Since autism is the claimed vaccine harm health authorities assert they have most thoroughly studied, just imagine the state of the "science" regarding the numerous other serious harms parents claim are caused by vaccines. Think about it. Really let that sink in. That said, you don't need to spend too much time imagining because the IOM reviews conducted over the years on vaccine safety – paid for by HHS, the CDC, and other federal "health" agencies – make this deficiency painfully clear.

In 1991, at HHS's request per the 1986 Act, the IOM issued a report that evaluated 22 commonly reported serious injuries linked to pertussis and rubella vaccines.[89] The IOM located sufficient studies to support that 6 serious injuries *are* causally related to these vaccines, including acute encephalopathy (brain damage) and chronic arthritis. It located sufficient studies to rule out 4 injuries as not related to these vaccines. The IOM, however, found that the studies had *not* been conducted for it to conclude whether or not these vaccines caused 12 other commonly reported serious injuries, including:

> autism, aseptic meningitis, chronic neurological damage, Guillain-Barré syndrome, juvenile diabetes, learning disabilities, attention-deficit disorder, thrombocytopenia[90]

In 1994, again at HHS's request per the 1986 Act, the IOM evaluated 54 commonly reported serious injuries from vaccination for diphtheria, tetanus, measles, mumps, polio, hep B, and Hib.[91] The IOM located sufficient science to support that 12 serious injuries *are* causally related to these vaccines, including death, thrombocytopenia, and Guillain-Barré syndrome.[92] It located sufficient studies to rule out 4 injuries as not related to these vaccines. The IOM, however, found that the studies had *not* been conducted 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, sudden infant death syndrome, sterility, transverse optic neuritis[93]

Given the lack of studies needed to reach a conclusion regarding whether these vaccines cause 38 of the 54 commonly reported serious injuries

from these vaccines, the IOM lamented that: "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."[94]

As we discussed in Chapter 1, fifteen years later, in 2012, the CDC and HRSA paid the IOM to review what they said were the 158 most common injuries claimed to occur from various childhood vaccines.[95] The IOM located science to support that 18 serious injuries were causally related to these vaccines, including pneumonia, meningitis, measles inclusion body encephalitis, and febrile seizures.[96] It located sufficient studies to rule out 5 as not related to these vaccines. The IOM, however, found that the studies had *not* been conducted 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[97]

Meaning, out of the 158 most common serious injuries claimed to have been caused by one or more of these vaccines per the CDC and HRSA, the IOM found the needed studies had not been conducted for more than 86% of these injuries to determine whether there is a causal relationship between the vaccine and the injury.[98]

What makes this finding even more incredible is that this report, commissioned and paid for by the CDC and HRSA, was plainly intended to be used to defend against vaccine injury claims. The CDC and HRSA were basically bribing the IOM to reach a finding that none of these harms are caused by vaccines. But even bending over backwards, which the IOM did well beyond the point of breaking if you read the report, it still could not reach the CDC and HRSA's desperately desired conclusion that none of these were related to vaccination.

Keep in mind these 158 serious injuries are only those that the CDC and HRSA stated were the most claimed injuries. What the CDC and HRSA would have said, if they were honest, is: "while there are many other claimed harms, these are the 158 serious injuries that are hard for us to ignore because they typically occur rapidly after vaccination, there is a basis to believe they are causally related to vaccination, and we cannot find another explanation; and so we need you, IOM, to affirm our religious belief that these harms are not caused by vaccines." Even the IOM, however, could not oblige because hiding from reality becomes difficult when you are required to issue a report identifying specific data and studies, not just repeat a mantra.

These three IOM reports collectively reflect that even for the most commonly claimed serious vaccines harms, per our federal "health" authorities, the studies needed to rule out vaccines as a cause were not conducted – just like the studies needed to rule out vaccines as a cause of autism were not conducted.

AHRQ Report Reveals Childhood Vaccine Safety Literature Is Vacuous

When the damning reality regarding vaccine clinical trials and the IOM reports was brought to HHS's attention by ICAN's notice in 2017, HHS responded by pointing to what it claimed was "the most comprehensive review" of the literature on vaccine safety ever conducted—the report we discussed earlier by the Agency for Health Research and Quality (**AHRQ**), an agency within HHS.[99]

HHS pointed to the AHRQ report to claim that vaccines have been shown to be "safe." Great. That called for yet another reading of the report. I delved back into this 740-page report again carefully. And after having read it again, I came to the same conclusion again, and one I think most would: if this is "the most comprehensive review" of the published literature on vaccine safety, it is petrifying. I mean, truly terrifying.

This 2014 report begins by identifying 20,478 studies as related or potentially related to vaccine safety, but excludes 20,312 of them for various reasons including that they did not address vaccine safety, or had an unacceptable design.[100] After this weeding out process, AHRQ was left with only 166 studies it deemed relevant and potentially reliable for assessing vaccine safety, and only 97 of those involved children. That's it, just 97 studies.

Let me make sure I really drive this point home. AHRQ, in what HHS said is "the most comprehensive review" of the literature on vaccine safety, found there were only 97 studies ever conducted, at *any* point in history, that it deemed in some way potentially reliable to assess

the safety of childhood vaccines given to babies and children in the United States. So much for the mountain of studies they publicly claim assess vaccine safety. And keep in mind, that does *not* mean these 97 studies supported that one or more vaccines were safe, that was just the initial universe of studies AHRQ said it identified to *potentially* answer that question.

It gets worse. These 97 studies were virtually all funded and/or authored (usually both) by a pharma company reviewing its own vaccine.[101] AHRQ, no doubt, would have known that using the inclusion criteria it chose to use would result in primarily including studies conducted by pharma or federal "health" agencies.

For example, AHRQ excluded all individual case reports (usually instances of immediate and obvious vaccine injuries) despite the fact that practitioners can typically afford to publish only in this form.[102] It excluded all experimental studies which could actually explain the biological mechanisms of how vaccines can cause injury or death, such as studies on how vaccines or aluminum adjuvants can cause immune system dysregulation.[103] It even excluded animal studies which – because of ethical restrictions applicable to human research – often provide the best available scientific evidence of how vaccines can harm immune function, the brain, and other body systems.[104]

The result is that this "comprehensive review" included only 97 studies that are applicable to children,[105] 77 of which were directly funded and/or authored (typically both) by the very pharma company whose vaccine(s) the study reviews.[106] 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 pharma company whose vaccine(s) the study reviews.[107]

But it gets worse. AHRQ then further cut down these 97 studies, explaining that comparing vaccinated (exposed) and unvaccinated (unexposed) children is critical for evaluating vaccine safety and asserts that only 59 of these studies compared "vaccinated versus unvaccinated children or adolescents."[108] It is great to see a federal "health" agency actually recognize this obvious point – that you need to compare "vaccinated versus unvaccinated" children to assess safety – but as we will discuss below, even these studies did *not* involve unvaccinated children.

But for now, we are down to 59 studies that AHRQ claims compared "vaccinated versus unvaccinated children or adolescents," and here is a breakdown of these 59 studies by vaccine type: rotavirus (34 studies), HPV (13 studies), influenza (6 studies), Hib (3 studies), meningococcal (2 studies), and varicella (1 study). [109] (Note that only 20 of these 59 studies even involve an injected vaccine, as the remainder involve

rotavirus which is given orally and two of the influenza studies involve inhaled strains.[110])

Looking at this list, you will note that among these 59 studies, there isn't even one study identified for any of the following seven vaccines: Hep B, DTaP, PCV, IPV, MMR, Hep A, or Tdap. Not one study. And these seven vaccines constitute a majority of the routine childhood vaccines, including four vaccines injected three times each in the first six months of life—Hep B, DTaP, PCV, and IPV.

So, again, to be clear, the "most comprehensive review" of the literature on vaccine safety, according to HHS, did not identify a single study meeting its own criteria of reliability for a majority of the routine vaccines on the CDC's childhood schedule, and none of the routine vaccines given to infants. Not one study. None. Literally, zero.

And it gets even worse. As for the 59 studies AHRQ *did* identify for six different vaccines, AHRQ's claim that they each had an unvaccinated group is not true. This is because in almost all the studies involving an injected vaccine, the control group was vaccinated or injected with one or more active vaccine ingredients.

For example, in the three Hib studies that AHRQ labeled as "vaccinated versus unvaccinated children or adolescents," the "control group" were all vaccinated. By way of example, one of these studies reviewed the Hib-PHiD vaccine made by GSK in a study funded by GSK and authored by GSK employees which, incidentally, is not even a U.S. vaccine. It compared 199 infants who received Hib-PHiD, DTPa, HBV, IPV, and Hib (the experimental group) with 101 infants who received DTPa, HBV, IPV, and Hib (the control group which AHRQ labeled "unvaccinated").[111] Labeling this a "vaccinated versus unvaccinated" study is patently ridiculous. But it does, as plainly intended, let GSK get away with any harm this product causes because while approximately 5% of infants in each group reported a serious adverse event, since the rates were similar in each group, the vaccine was deemed "safe" by the GSK employees studying a GSK vaccine in a GSK funded study.[112]

Using one final example, in all 13 studies involving HPV vaccine that AHRQ labels "vaccinated versus unvaccinated adolescents," the "unvaccinated" group either received a vaccine *or* an injection of the active ingredient in the HPV vaccine, AAHS (save one study in which 17 girls apparently received nothing).[113] Reviewing the results of these 13 studies should have made heads spin with concern. This is because HPV vaccines were studied in adolescent and older women who, unlike children or babies, can articulate if they are experiencing a serious adverse reaction, such as neurological issues. And in most of these studies, the rate of serious adverse event reports in both groups (the vaccinated group and the fake "unvaccinated" group) were often

shockingly high, frequently in the double digits. Yet, the vaccine was deemed "safe" in these GSK- or Merck-funded studies using their own employees reviewing their own vaccine because the rate of harm was similar in both groups.[114]

ICAN's lengthy written response to HHS does an excellent job of going through each of these studies, setting forth what the "unvaccinated" group actually received, the harms reported in each group, and the conflicts of interest related to each study.[115] It is a terrifying read.

I can't stress this enough. The belief system that drives vaccinologists blinds them to the dangerous practice of ignoring high rates of serious adverse events in two groups that were both vaccinated. It requires suspending reason, logic, and reality to label a vaccinated child, or one receiving an injection of active vaccine ingredients, as "unvaccinated." It is, at best, delusional. But, sadly, it also obfuscates harms caused by these products.

But twisting reality should not be surprising since the real goal of AHRQ's "comprehensive review" was *not* about providing good scientific evidence to reassure the public that the vaccines on the CDC's childhood schedule are safe. It was about ensuring high vaccine uptake by producing a report that provides the superficial appearance of vaccine safety for the public.[116] Indeed, the review begins by focusing upon and bemoaning that "vaccination rates remain well below established Healthy People 2020 targets for many vaccines" and that "[i]ncreasing vaccination rates remains critically important."[117] It even laments that "public concerns about vaccine safety continue to persist" despite "the rigorous processes new vaccines must undergo before receiving approval" and that they meet "stringent criteria for safety."[118]

The individuals writing this review clearly never actually looked at the clinical trials relied upon to license childhood vaccines. They are just repeating their dogmatic beliefs relayed to them by vaccinologists, including those on the technical expert panel that participated in developing the report, including Dr. Kathryn Edwards.

Ironically, despite starting with the assumption of safety, throwing out almost all non-biased studies, and the other limitations described above, this review still found that vaccines can cause babies and children to develop numerous serious adverse reactions, such as febrile seizures, arthralgia (pain in the joints), thrombocytopenic purpura (the immune system attacking the body's own platelets), meningitis (inflammation of the membranes surrounding the brain and spinal cord), and encephalitis (inflammation of the brain).[119]

This report reflects that even when HHS and its subagencies give it their absolute "best", it is painfully clear they have, at best, never properly studied vaccine safety. Worse, when studies are conducted outside

the church of vaccinology (meaning not by pharma, the CDC, etc.) or when pharma must disclose harms per federal law, the reality of vaccine harm becomes even more painful. We turn to that next.

Harms Pharma Has Basis to Conclude Are Caused by Vaccines

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

For drug products, it is often pharma's internal safety data, obtained during a lawsuit alleging a drug injured someone, that results in pharma being held accountable. Those internal records not only become the basis for holding pharma financially accountable for the drug injury, but their content also becomes the substance of news stories that put a spotlight on the issues with the drug product. This forces pharma to develop safer and more effective drugs.

But as you know, that will virtually never happen with injuries claimed from vaccine products. No matter how many children it injures or kills, a pharma company will never have to face a lawsuit claiming that it could have made its vaccine products safer. Hence, the internal safety data held by pharma companies will likely never have to be disclosed in a lawsuit and, without accountability in the courts or by the media, pharma companies will have no incentive to address safety issues.

But while pharma does not need to disclose their internal safety data and safety analyses, federal law *does* require each pharma company to publicly disclose each harm it has evidence to support is caused by its product. How? It must list them in Section 6.2 of the package insert for each vaccine.

The federal law on this is clear. It provides that pharma companies are 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."[120]

This means a pharma company *cannot* list injuries it merely believes may be correlated with the vaccine. Nor can it list injuries it suspects, but has no basis to support, are causally related. It is *only* permitted to list harms it has a basis to conclude are causally related to the vaccine.

With access to safety data that is unavailable to the public or health authorities, pharma companies can identify injuries caused by vaccines that committees within HHS, IOM, CDC, and AHRQ are unable to identify, as they don't have access to such data.

These adverse events identified by pharma companies are typically listed in Section 6.2 of each vaccine's package insert. And again, 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. If there was only a correlation between the vaccine and a claimed harm, without evidence of a causal relationship between the vaccine and the claimed harm, the adverse event would not meet the criteria under federal law for being listed.

As for the harms included in Section 6.2 of the package insert for childhood vaccines, you may ask whether pharma has disclosed many. Sadly, yes, they have, many of which are very serious, often involving immune, neurological, and other chronic disorders. What is most concerning about these disclosed harms is that many of them are the same ones that have risen sharply since the 1980s. You can look at 6.2 of each package insert to see these harms or review a four-page partial list compiled by ICAN in the document linked in this endnote.[121]

Sadly, virtually none of these numerous serious harms have been studied to confirm or rule out the vaccine as the cause. Even worse, whatever internal evidence pharma companies relied upon to disclose these harms remains hidden from the public.

Let me put it this way. While the publicly available data and scientific literature on vaccine safety are extremely limited, Section 6.2 of each vaccine package insert provides a window through which we can see what harms pharma companies have a basis to conclude are caused by vaccines. And the view through that window is frightening. Just look for yourself in the sources linked in the last endnote.

The Studies Can Be Done

I can already hear the retort: "but, but, but we can't do studies to prove a negative! We can't prove a vaccine does not cause a certain injury." That belief, and it is a belief, is nonsense.

The IOM did rule out MMR causing autism, stating: "The evidence favors rejection of a causal relationship between MMR vaccine and autism."[122] It ruled out that influenza vaccine can cause Bell's palsy, stating: "The evidence favors rejection of a causal relationship between inactivated influenza vaccine and Bell's palsy."[123] So the studies clearly can be done to actually rule out an injury, even using the ridiculous, tainted, biased approach IOM used to rule out these injuries.

Let me make it even simpler. The way to study these harms is to engage the basic scientific method used all the time to assess if a product causes an injury: compare those receiving the product with those who have not received the product. That is just basic science. Meaning,

you compare one group getting the weight loss pill with another group that doesn't receive any weight loss pill, track them for a few years, and compare all health outcomes. Boom – now you can get some real safety and efficacy data.

But with vaccines that does *not* happen before or after licensure. Yet it can. There is certainly no ethical issue with doing it before licensure, but that virtually never happens. After licensure, even under existing ethics rules, existing databases can be used to compare the health outcomes between exposed (vaccinated) and unexposed (no vaccines) groups.

Parents, organizations, etc., have been demanding this study for decades. Do you think it hasn't been done? Or do you think it has been done but hasn't been published? Let's add some meat to the bones of these questions.

Vaccinated v. Unvaccinated Studies

Plenty of the studies—even those conducted by pharma and federal agencies, if you read between the lines—reflect that vaccines can cause serious harm. But the real way to assess vaccine safety is to start by comparing vaccinated and unvaccinated children, which can be easily and ethically accomplished using existing databases that already have this health data.

The issue isn't whether it can be done, but whether those with the resources will do it—and then actually publish the results.

Nothing brings the imbalance in resources between the Vaccines Amen crowd and those outside this religious order into sharper relief than published studies comparing vaccinated and unvaccinated children. There are a handful of such studies, but none of them are funded by pharma or the public "health" apparatus. They have been conducted by researchers using a shoestring budget because there *is* no deep pocket willing to fund these studies.

What do the few such studies show? The findings are incredibly concerning which is why pharma and "health" agencies use their multi-billion-dollar machine to wage war against these few brave scientists and the articles they have dared to publish. Before we discuss these few studies, let's start with a bit of background on conducting a vaccinated versus unvaccinated study.

Over a decade ago, HHS commissioned the IOM 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."[124] This is not an IOM report we

have previously discussed, as it did not focus on individual vaccines but rather on the safety of the CDC childhood vaccine schedule as a whole.

After the IOM conducted its review, instead of providing answers, its report revealed that no studies had ever been conducted which compared the health outcomes of children receiving the CDC's childhood vaccine schedule with children who did not receive any vaccines. As the IOM explained:

> [N]o 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.[125]

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."[126]

Due to the lack of science 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."[127] Left unsaid, but equally true: **there is no evidence that the schedule is safe**.

Equally troubling is that despite acute adverse events such as inconsolable crying or extreme lethargy in recently vaccinated babies that can last for days, the IOM acknowledges that science does not yet even know "if there is a relationship between short-term adverse events following vaccination and long-term health issues."[128]

I can already hear screams from the Vaccines Amen crowd that it would be unethical to conduct a vaccinated versus unvaccinated study. But this claim is without merit. Putting aside that it is unethical for the CDC to continue promoting its childhood vaccine schedule as proven safe without the data to support this claim, there are simple ways to ethically conduct studies comparing vaccinated and unvaccinated children. For example, use *existing* health databases that already have data for unvaccinated children. Simple. Even the IOM's report from 2013 asserts 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]."[129]

To date, neither the CDC nor any other agency within HHS has published such a study. It's hard to imagine they would not have published this study *if* it showed vaccinated children were healthier. I would imagine they would be overjoyed to publish a study that finds vaccines do not cause serious harm and, in the process, rebuts the vaccinated versus unvaccinated studies, some of which we will review shortly, that show significant harm from vaccines.

Instead of using the VSD to publish a relatively simple study comparing health outcomes between vaccinated and unvaccinated children, which the IOM said could be conducted, what did the CDC do? It expended a ton of resources and taxpayer dollars to publish a 64-page white paper regarding how to conduct such studies using the VSD.[130]

Incredibly, this CDC white paper acknowledges that many chronic disorders children are experiencing today in epidemic numbers are biologically plausible outcomes from the CDC's childhood vaccine schedule, but have not yet been properly studied.[131] Yet the CDC has still not published a vaccinated versus unvaccinated study despite passage of over a decade since the IOM called for it, and the CDC white paper that resulted from that call to action. Think about it: if they wanted to show the "anti-vaxxers" are wrong, why not just publish this study?

Let me put it this way. No such study has been *published*. But has it been *conducted*? Maybe it was conducted, but not published, because it produced results that do not fit the beliefs about vaccines? I will let others speculate. In the meantime, let's review studies and other data that are publicly available, comparing health outcomes between vaccinated and unvaccinated children.

We start with a pilot study from the School of Public Health at Jackson State University which found that 32% of vaccinated preterm babies had a neurodevelopmental disorder while 0% of the unvaccinated preterm babies had a neurodevelopmental disorder.[132] A startling and disturbing finding.

Another study by the same group at the School of Public Health at Jackson State University found that vaccinated children, compared to unvaccinated children (receiving no vaccines), had a statistically significant 74% *decreased* risk of being diagnosed with a case of chickenpox and a 70% *decreased* risk of being diagnosed with a case of pertussis.[133] I trust vaccinologists would agree with this finding as it fits their beliefs. But this same study also found that vaccinated children had a statistically significant *increased* risk of 290% for allergies, 320% for ADHD, 320% for autism, 190% for eczema, 420% for learning disabilities, and 270% for any neurodevelopmental disorder. Overall,

vaccinated children had a 140% increased risk of any chronic condition.[134] I trust vaccinologists would *not* agree with this finding as it does not fit their beliefs.

Let's look at one other study. In this study, published in Sage Open Medicine, researchers aggregated data from three U.S. medical practices. The health outcomes of the vaccinated and unvaccinated children born between 2005 and 2015 in these three medical practices were compared. The study found that vaccinated children, compared to unvaccinated children, had a statistically significant increased rate of 118% for developmental delay, 349% for asthma, and 113% for ear infections.[135] These concerning findings matched the findings from the School of Public Health at Jackson State University.

Let me also share two examples from outside the medical literature. The first was a project in which the NYS School Health Examination Form, completed by a doctor for each child, was collected for every unvaccinated child within four contiguous school districts in Ulster County, NY.[136] By including all of the unvaccinated children in these districts, it sought to avoid selection bias and cherry-picking. To ensure accuracy an MD also interviewed each family to confirm the information on the medical forms. The health of these unvaccinated children was then compared to the background health of all children, obviously most of whom are vaccinated.

These results were provided to our firm, and we sent a letter that included the following table, to the New York State Department of Health (**NYS DOH**):

Condition	Rate in Unvaccinated Ulster Children	Background Rate
Allergy – Food	2%	8%
Allergy – Environmental	2%	8.4%
Asthma	1%	7.5%
Seizures	0%	0.6%
Diabetes	0%	Type 1: 22.3 per 100,000 Type 2: 13.8 per 100,000
Autism Spectrum Disorder	0%	1 in 54 children
Attention Deficit Hyperactivity Disorder	2%	9.4%
Eczema	1%	12%

Our letter concluded by stating: "The Ulster Children are the living proof that unvaccinated children have far better health outcomes than vaccinated children" and requested that if the department "contest[s] these results, [that it] please provide the scientific support that reflects that vaccinated children have better long-term health outcomes than the

unvaccinated."[137] The NYS DOH's response never provided any such support, nor addressed or contested the findings regarding the Ulster children, and hence our follow-up letter to the department stated:

> The New York State Department of Health has an annual budget of approximately $88.5 billion and a specific focus on promoting vaccines. In fact, a significant portion of your agency's efforts are geared toward promoting vaccines, encouraging the public they are safe, and otherwise increasing vaccination rates. It would therefore be within your interest to share studies which, in fact, support the safety of the childhood vaccine schedule. The fact that you have not done so to date appears a clear and plain admission that you have no such studies.
>
> As public servants, you should be reticent to continue to mandate a liability-free product to children without proper safety studies. Your assumptions regarding these products are akin to beliefs; you believe the assumptions are true without evidence, even in the face of evidence to the contrary. Parents should not have to participate in your beliefs about these products. They prefer to rely on the data, the studies, and their family's experiences regarding these products, which show that their children are healthier than those that participate in your mandated schedule of dozens of injections of these products per child.[138]

The NYS DOH never provided any supporting data or studies to contest the findings shared with it. Instead of contravening data or studies, the department plainly relied upon its beliefs and ideology to guide it.

Bringing this into sharp focus, the NYS DOH decided to wage war on the Amish community, seeking to levy financially ruinous fines on them unless they vaccinate their children. My firm has the privilege of representing the three Amish schools that received these violations. The sworn court papers in this case evidenced to the Court that the families with children in these three Amish schools have a total of 168 unvaccinated children (no vaccines) and that none of these children have any of the chronic health issues that plague children in the United States.

We also provided sworn expert evidence to the Court attesting that among a random sample of 168 U.S. children, one would expect to find (based on the background rate of chronic disease among U.S.

children) 31 cases of environmental allergies, 15 cases of ADHD, 10 cases of asthma, 9 cases of food allergies, and 4 cases of ASD. Yet, the 168 unvaccinated Amish children whose families New York wants to persecute are free from the chronic health conditions—all related to some form of immune system dysregulation[139]—that plague the vaccinated communities in New York.[140]

Since vaccination is supposedly about improving health, and the Amish who do not vaccinate are clearly healthier, one would expect the NYS DOH to leave them alone. But that is not how this religion works. The vaccine zealots in the NYS DOH cannot stand that the Amish refuse to abandon their beliefs in favor of the religious beliefs held by the NYS DOH officials regarding vaccines. The "health" officials are willing to sacrifice the way of life and belief system of these Amish children and their community, that has kept them far healthier, if they refuse to bend the knee to adopt cult-like vaccine beliefs.

These "health" officials also apparently cannot stand that the Amish children are healthier and are even willing to wage war against them until they submit and receive every vaccine New York demands—so they can be just as "healthy" as all the children outside the Amish community.

The Amish earnestly seek to avoid conflict but because violating their sincerely held religious beliefs is not an option, they have been placed in the impossible position of being required to leave New York to simply send their healthy children to Amish schools on Amish land. As of this writing, my firm, along with co-counsel, continues to litigate on behalf of the Amish to defend their freedom to practice their religion in peace.

There is one more large-scale vaccinated versus unvaccinated study that will be discussed in the next chapter, which, until the release of this book has not been made public. But before that, I need to address one final retort I can already hear the Vaccines Amen crowd screaming.

"But We Have Vaccine Safety Surveillance Systems in the CDC!"

The last argument I will often hear, after it becomes plain that pre- and post-licensure clinical trials and studies do not affirm vaccine safety is that "we know vaccines are safe because we have vaccine safety systems in the CDC that monitor and assure safety." Sadly, these systems, if anything, raise the concern level regarding vaccine safety to a fever pitch.

VAERS

The first system we will discuss is the Vaccine Adverse Event Reporting System (**VAERS**). It 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 come from pharma companies, health care providers, and state immunization programs.[141]

The CDC is emphatic that VAERS can never be used to establish causation between a vaccine and an injury and, at best, can be used for signal detection. So, let me repeat, the CDC states VAERS can never be used to claim a vaccine causes a harm. Yet, while it cannot be used to claim a vaccine causes a harm, the CDC and other "health" officials routinely use VAERS data to claim vaccines are safe. It makes sense when you understand it is a religion.

Taking a look at a period of time 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.[142] Those numbers alone are concerning but they become even more concerning when, as explained by a Harvard study, you understand that "fewer than 1% of vaccine adverse events are reported."[143]

Let's take a closer look at that Harvard study. In 2006, AHRQ provided a one million dollar grant to create a software program at Harvard Pilgrim Health Care that would automate reporting injuries after vaccination to VAERS.[144] The reason to automate VAERS reporting is that health care professionals are extremely busy, and completing a VAERS report, even if they had plenty of free time, is extremely burdensome and time consuming. This is just one of the reasons for massive underreporting.

Turning back to the AHRQ-funded study, the result was the successful creation of a system at Harvard Pilgrim which automatically created adverse vaccine event reports. Great. And here is what they found during the three years they were automatically capturing potential adverse vaccine reactions:

> 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.[145]

Meaning, once they automated capturing injuries after vaccination, they found 35,570 reportable reactions in just 376,452 vaccine recipients.[146] That is a concerning figure.

Even more concerning is that the CDC refused to cooperate with integrating this new program with VAERS. After creating the software

program that automatically created VAERS reports, its Harvard 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.[147] You would hope the CDC would rush to take this final step to help improve vaccine safety, but as you already know, that is not how this religion works. Instead, the CDC refused to cooperate. 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.[148]

Basically, the CDC said, "hey, your results don't match our beliefs, so we are just going to ignore you!" And with that, the CDC refused to even communicate with the Harvard Medical School researchers being funded by AHRQ.

The reason the CDC says that VAERS cannot be used to determine whether a vaccine causes a harm is that, while you have the numerator of people harmed, you don't know the denominator to use to get a rate of harm. Automating VAERS reports from a fixed pool of people would have resolved this issue. This is precisely what the CDC was plainly intent on preventing: the ability to actually be able to assess causation between a harm and a vaccine, using VAERS. This is not just speculation. Read the exchange between HHS and ICAN on this point and I trust you will agree—see endnote to this sentence for that exchange.[149]

One thing that is clear from the CDC's refusal to automate VAERS is that its focus is to protect its holy grail, vaccines, from any criticism, not to guard childhood health. Consider that the CDC long ago developed and championed electronic systems that track the movement of every vaccine from pharma companies to the point of injection, and systems that track the vaccination status of every child in each state.[150] Yet it cannot automate VAERS—even though a system to do precisely that was developed almost two decades ago? The reality is that VAERS is like a holy vessel, never to be changed, and its purpose is to be trotted out by the CDC and the FDA to claim a vaccine does not cause a harm, when needed, but almost never to claim a vaccine does cause a harm.

To leave no doubt whatsoever on this point, let me show you what the CDC did when its own analysis of the VAERS data revealed massive safety signals for numerous harms from Covid-19 vaccines. On December 4, 2020, before the first Covid-19 vaccine was rolled out in

the United States on December 10, 2020, the CDC released the VAERS Standard Operating Procedures for Covid-19 (**VAERS SOP**), which explained how it would analyze VAERS data to detect potential safety signals for the Covid-19 vaccines. The VAERS SOP stated in relevant part as follows:

> The analyses for COVID-19 vaccine safety signals will focus on … Proportional Reporting Ratios [PRR] and Empirical Bayesian [EB] 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.[151]

Meaning, the CDC planned to conduct safety signal monitoring using Proportional Reporting Ratios (**PRR**), and the FDA planned to conduct safety signal monitoring using Empirical Bayesian (**EB**) data mining.

Our firm requested the PRR signal detection data from the CDC through FOIA on June 30, 2022.[152] The CDC responded on July 29, 2022, that it had *not* conducted PRR analyses and only performed EB analysis. The response stated, in relevant part:

> [I]t was determined that the Proportional Reporting Ratio (PRR) analyses would not be performed. Instead, the … FDA performs Empirical Bayesian (EB) data mining with VAERS data. EB … is considered the "gold standard" … [and despite] no written communications regarding the use of EB over PRR … [it] was assumed to be the preferred method of detecting safety signals among COVID-19 vaccines. PRR is included in the SOP [reviewed above] as a potential alternative … but EB was always understood to be the superior method.[153]

The issue with this response is that the CDC's claim it did not perform PRR was false.

How do I know? Because on September 2, 2022, after pressure from Senator Ron Johnson on this issue, the CDC Director finally admitted to Senator Johnson that PRR had in fact been performed, stating: "CDC performed PRR analysis between March 25, 2022, through July 31, 2022."[154] Our firm then sued the CDC based on this admission and ultimately received 51 Excel files containing PRR data.[155]

These files showed that the CDC's own threshold for triggering a safety signal was blown away for numerous serious adverse events. The

CDC's own VAERS SOP, which we reviewed above, defined a safety signal as a PRR of 2 or above. Here is just a small sample of PRR results related to adults for various conditions from the CDC's own analysis (up to March 18, 2022) that it tried to hide from us by falsely claiming it never did this analysis (keeping in mind, again, any PRR of 2 or above reflects a safety signal, according to the CDC):[156]

Condition	PRR
Intermenstrual Bleeding	73.72
Heavy Menstrual Bleeding	63.05
Postmenopausal Haemorrhage	57.63
Pulmonary Thrombosis (blood clots in pulmonary artery)	52.40
Thrombectomy (medical procedure to remove blood clot)	28.94
Menstrual Disorder	24.99
Left Ventricular Failure (left-side heart failure)	14.91
Bell's Palsy (weakness or paralysis on one side of face)	12.37
Electric Shock Sensation	10.96
Cardiac Failure Acute	8.58
Death	6.25
Tinnitus	4.52

The PRR results the CDC tried to hide from us related to children are equally disturbing. Here is a small sample of a few findings it sought to hide for children ages 5 to 11 years, again noting that a PRR of 2 or above reflected a safety signal (at least when truth was original to the CDC):

Condition	PRR
Multisystem Inflammatory Syndrome	177.62
Bell's Palsy	80.74
Left Ventricular Dysfunction	48.44
Pericardial Effusion (excess fluid surrounding heart)	32.29
Pericarditis (inflammation around the heart)	32.29
Menstrual Disorder	21.53
Menstruation Irregular	17.94
Ventricular Extrasystoles (extra heartbeats)	8.97

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.[157]

Given that the CDC decided to abandon the PRR data and rely upon the EB data, our firm requested the EB data mining results from the FDA through FOIA and was denied. Hence, we sued the FDA in federal court, and in response, the agency filed a motion requesting that the litigation be stayed for at least 18 months due to supposed resource constraints, crying in large part about how our firm sues the FDA too much, which we explained would be unnecessary if they were just transparent with the public.[158] As of this writing, that federal lawsuit has been going on for over two and a half years with no end in sight as the FDA is fighting like hell to keep that data hidden.

This example should provide another window into how the CDC uses VAERS. To be sure, for the very few adverse reactions the CDC is willing to recognize, it touts VAERS with regard to those reactions. But outside the very few harms the CDC is willing to recognize, which it does to claim it cares about safety, when the reality is it doesn't, it uses VAERS to affirm to the public its *a priori* belief that vaccines are safe.

VSD

The next system that vaccine apologists point to is the Vaccine Safety Datalink (**VSD**) which is a database that contains the vaccination history and medical diagnostic codes (which would reflect what medical conditions a person may have) for over 10 million Americans. While this system could be helpful in assessing vaccine safety, it currently is not. Instead of being used to improve safety, it is used as a tool to silence vaccine critics and expand vaccine recommendations, even for unlicensed off-label uses.

Until around 2001, the VSD was maintained at the CDC. Until that time, independent scientists who are not devout vaccine zealots were able to obtain access to the VSD at the request of members of Congress and through other legal means. The issue for the CDC is that those scientists' studies found that vaccines cause various harms. The CDC could not have that. So, the CDC moved the VSD to a health industry trade association in 2001 to avoid having the VSD data subject

to FOIA, and to assure that only the scientists and studies it approves, and whose results conform with CDC's policy that vaccines are safe and effective, meaning fit its beliefs, utilize the VSD and get published.[159]

This means any study published using the VSD cannot be relied upon due to selection bias, since only studies matching the CDC's beliefs are published. If ten other studies using VSD on the same issue did not match its beliefs, they simply would not have been published. This selection bias renders any study published using the VSD unreliable because there may be a dozen other similar studies that reached the opposite result that simply were not published.

If that were not reason enough to discount any study using the VSD, every study published using the VSD violates the most basic scientific standards and process because the underlying data are almost never available for inspection by the public and other scientists.[160] Refusal to make these data available is another reason to not rely on any VSD study, as they cannot be reproduced by independent scientists. The lack of transparency and reproducibility violates core features of the scientific method.

Consider that HHS regulations provide severe penalties if researchers, using HHS funding, refuse to share data underlying their studies, but yet the CDC does not apply this same standard to its own VSD studies.[161] That is because vaccine science is not science. It is religion.

It gets worse because the secret studies that the CDC performs using the VSD with secret data are virtually all squarely aimed at increasing vaccine uptake, even for uses and in populations not approved by the FDA.[162]

What the VSD should be used for is to assess the actual safety of vaccines, including the long-term impact of vaccination. As the CDC has even acknowledged, public stakeholders "have expressed more concerns about long-term than short-term health outcomes" and "long-term health outcomes have been less well-studied in the context of vaccine safety," but VSD is currently 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.[163]

And when these studies are finally conducted, they should not be conducted by the CDC's Immunization Safety Office which, as discussed, works to increase vaccine uptake, communicates about setting policy with pharma companies, and has even been accused by a Senior Scientist at the CDC of fraudulently modifying results of prior vaccine studies, including for the purpose of avoiding liability for HHS in Vaccine Court.[164]

Nor should the studies be conducted by any organization that would suffer any financial and/or reputational harm from a finding that vaccines can cause certain harms. Which would, of course, disqualify HHS or its subagencies from conducting these studies. This is because any finding that vaccines cause, for example, 1 in 5 cases of either allergic rhinitis, ADHD, learning disabilities, or neurodevelopmental delay, all of which studies have found to be related to vaccination, would result in trillions of dollars of liability and a loss of public confidence in HHS and its subagencies.[165]

Of course, if HHS and the CDC were confident in the safety of childhood vaccines (and cared at all about preventing harm to children from vaccine products), they would simply make the deidentified data in the VSD available to the public. After all, it is paid for by taxpayers. This way, independent scientists could conduct vaccine safety studies. But that is not how the religion of vaccines works.[166]

V-SAFE

Next up is V-safe. With the spotlight on Covid-19 vaccines, the CDC plainly realized VAERS and VSD, and the way the CDC uses them, would not survive public scrutiny. So, it rolled out a new vaccine safety monitoring system, called V-safe. With that, the CDC assured the public, "COVID-19 vaccines are being administered under **the most intensive vaccine safety monitoring effort in U.S. history**."[167] The details in this section are a bit thick, but once you understand V-safe, it provides a great big picture example of how the religion of vaccines works.

As explained by the CDC, "V-safe is a smartphone-based tool that uses text messaging and web surveys to give personalized health check-ins after you receive a COVID-19 vaccine" and "quickly tell CDC if you have any side effects after getting a COVID-19 vaccine" which "information helps CDC monitor the safety of COVID-19 vaccines in near real time."[168] The CDC also represents that: "This information helps us communicate timely and transparent information about the safety of vaccines to public health officials, healthcare providers, and the public."[169]

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**).[170] The V-Safe Protocol explains that: "The 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."[171]

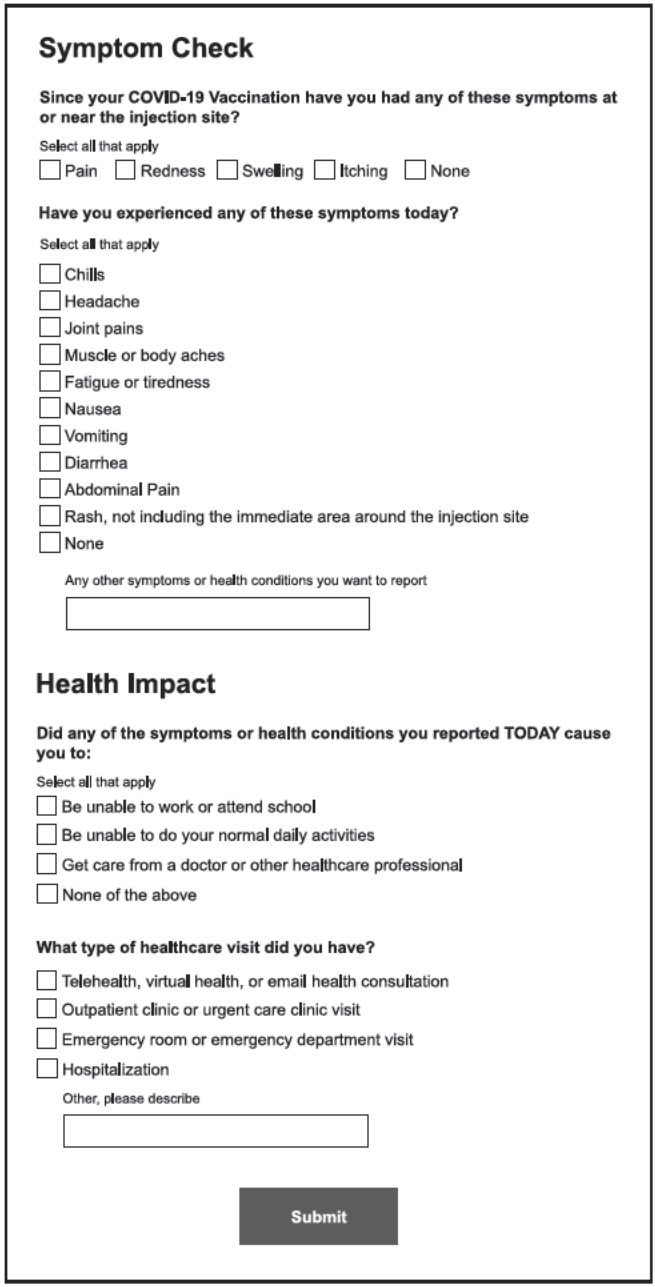
That all sounds great. Now let's look at the reality. In terms of users, V-safe was launched simultaneously with the release of the first Covid-19 vaccine in December 2020. Nine million of the approximately 10 million V-safe users registered between December 2020 and April 2021.[172]

This period from December 2020 to April 2021 was when many were excited to get this vaccine, and there were no mandates. Most V-safe users were likely vaccine enthusiasts and signed up to participate in its roll-out, not report issues. The data submitted by 10 million V-safe users, therefore, 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. The 10 million V-safe users, if anything, may have been prone to *under*report health impacts, not overreport, since most were likely vaccine enthusiasts.

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 allowed users to enter information in free-text fields, up to a certain character limit.

For the 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 says 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."[173] Meaning, the check-the-box symptoms data collected by V-safe was effectively useless for 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 any concerns for the CDC as seen from the numerous studies the CDC published with very high rates of symptoms.[174]

Here is a recreated image of a survey sent to V-safe users during the first week after injection:



Symptom Check

Since your COVID-19 Vaccination have you had any of these symptoms at or near the injection site?

Select all that apply

☐ Pain ☐ Redness ☐ Swelling ☐ Itching ☐ None

Have you experienced any of these symptoms today?

Select all that apply

☐ Chills
☐ Headache
☐ Joint pains
☐ Muscle or body aches
☐ Fatigue or tiredness
☐ Nausea
☐ Vomiting
☐ Diarrhea
☐ Abdominal Pain
☐ Rash, not including the immediate area around the injection site
☐ None

Any other symptoms or health conditions you want to report

Health Impact

Did any of the symptoms or health conditions you reported TODAY cause you to:

Select all that apply

☐ Be unable to work or attend school
☐ Be unable to do your normal daily activities
☐ Get care from a doctor or other healthcare professional
☐ None of the above

What type of healthcare visit did you have?

☐ Telehealth, virtual health, or email health consultation
☐ Outpatient clinic or urgent care clinic visit
☐ Emergency room or emergency department visit
☐ Hospitalization

Other, please describe

Submit

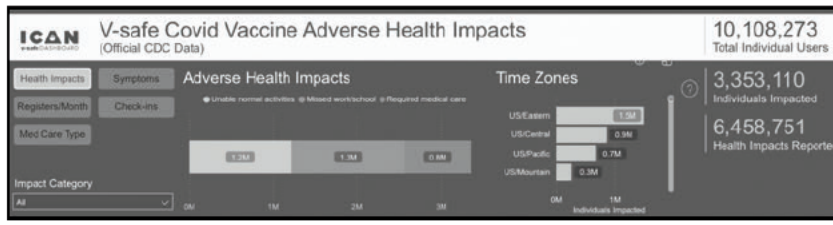
Other than the list of 10 symptoms, the only other check-the-box safety information collected was whether users reported needing medical care, missed school or work, or could not perform normal daily activities (**health impact data**). If a user selected that he or she needed medical care, the user was asked to select whether he or she sought

telehealth, urgent care, emergency care, or was hospitalized (as seen in the image above).

The health impact data was collected weekly for the first six weeks after injection and then at 3, 6, and 12 months. 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, it *must be* the health impact data that it planned to use to rapidly detect any safety issues.[175]

Since 2021, the CDC has published over 40 studies to support its claim that Covid-19 vaccines are safe. The main data used in these studies are V-safe's health impact data, with a focus on the rate of people who reported needing medical care after the vaccine. The studies formed the core of the CDC's support for the safety of Covid-19 vaccines. However, the CDC in all these studies only reports the *first week* of health impact data after injection. That's it—just one week after injection. Reporting to the public only the first week of health impact data is, at best, highly misleading because the CDC is well aware that injuries from Covid-19 vaccines can occur long after the first week.[176]

When we finally obtained the check-the-box data from the CDC, after over two years of legal demands and federal litigation by my firm on behalf of ICAN, it was clear why the CDC wanted to hide this data from the public. The hidden data showed 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 do normal activities after the injection.[177]



That finding was jaw dropping. It showed that even among the vaccine enthusiasts, nearly 1 in 13 people sought medical care after a Covid-19 vaccine. And it gets worse because, on average, each person seeking medical care sought it 2 to 3 times, and approximately 75% of medical care visits were reported as urgent care, emergency room, or hospitalization.

Since V-safe was supposed to assess safety and the only metric that really assessed safety was seeking medical care, if 1 in 13 V-safe users seeking medical care an average of 2 to 3 times each was not enough to declare a safety issue, it is plain V-safe was not created or designed to *ever* find a safety issue. It was created, as is the CDC's practice, to publicly

claim it is assessing safety but in reality it is just another system designed to affirm the CDC's *a priori* belief and policy that these vaccines are safe.

The CDC could have made V-safe a rapid and robust safety system by simply 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 at least for chest pain. And here is where this religion truly acts like a cult: the first version of the V-Safe Protocol, issued November 19, 2020, reflecting the intended design of V-safe, specifically identified "Adverse Events of Special Interest" in a chart titled "Prespecified Medical Conditions," but the CDC never included any of these conditions or their symptoms as check-the-box options in V-safe: [178]

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 of prespecified adverse events of special interest identified for V-safe included, among other conditions, acute myocardial infarction (heart attack), coagulopathy (bleeding disorder), death, GBS, Kawasaki disease, multisystem inflammatory syndrome, myocarditis/pericarditis, narcolepsy/cataplexy, seizures/convulsions, stroke, and transverse myelitis.

A month before issuing the V-safe Protocol, the CDC also identified all but two of these adverse events of special interest in an October 22, 2020 presentation titled "CDC post-authorization/post-licensure safety monitoring of COVID-19 vaccines."[179] Many of these adverse events of special interest were also identified in a July 2020 NEJM article,[180] an October 16, 2020 JAMA article,[181] and a different CDC presentation on October 30.[182] And keep in mind the first Covid-19 vaccine was not released until the end of December 2020.

Yet, despite the CDC itself directly identifying these harms of special interest months before the launch of V-safe, including in the protocol for designing V-safe itself, the CDC did *not* include check-the-box options for these conditions *or* for common symptoms of these conditions.

The CDC could have easily taken advantage of this incredible opportunity to make V-safe, with over 10 million users, useful for actually assessing safety by including these events of special interest as check-the-box options for V-safe users. This would have enabled the CDC and the scientific community to easily calculate a rate for which V-safe users developed myocarditis, or other adverse events that had been pre-specified by the CDC as potential problems (*e.g.*, strokes, seizures, etc.) following Covid vaccination.

Instead, the CDC purposely chose to not include any of these adverse events of special interests, or their symptoms, as check-the-box options. Instead, it relegated any potential reporting of these harms to the free-text fields, knowing full well that, among other issues, fewer people would report issues in a free-text field (versus a check-the-box option) and this free-text data would be more difficult to standardize. The CDC also later argued that the free-text data should not be released because it contained protected personal information.

The CDC clearly did not design V-safe with the interests of the public in mind, but rather to collect extremely limited check-the-box data that was most likely to affirm its religious beliefs and publicly-announced policy claim that these products are "safe."

Let me put it this way, the CDC did not design V-safe with the interest of the public in mind – it designed V-safe to ensure that it would affirm its policy that Covid-19 vaccines are safe. Not to actually assess if these products are safe. Let's recap why. The CDC only included check-the-box options for symptoms that the CDC says are normal and good to have as they reflect the vaccine is creating immunity. This is also why it only tracked those symptoms for one week after injection—they were irrelevant to assessing safety. It didn't matter what percentage of people reported them. In fact, the higher the percentage, the more the CDC would say the vaccine was working and creating immunity. Showing its worship of vaccines, and its willingness to sacrifice health to protect its holy vaccines, the CDC purposely left off the check-the-box list of symptoms actual conditions or symptoms that it knew could be caused by Covid-19 vaccines. It then only collected health impact data, which itself was limited, and when even that showed concern, tried to hide it from the public, publishing over 40 studies that only revealed the first week of health impact data. That is until ICAN forced the CDC, after we filed and aggressively litigated two federal lawsuits, to release these data. The CDC's dangerous ideological beliefs should have no place in

public health and its design of V-safe and how it used its data should make that crystal clear.

Post-Licensure Safety Wrap-Up

I just threw a mountain of information at you, so let me also do a very quick recap of this chapter before going to the next. Autism—the issue claimed to have been most thoroughly studied—has not been studied for infant vaccines. The IOM has made plain that, like autism, most of the commonly reported injuries have not been properly studied. HHS's so-called "comprehensive review" also confirms vaccine safety has not been properly studied. Even the injuries pharma companies have a basis to conclude are caused by their vaccines have barely been studied. The CDC's supposed vaccine safety systems do little more than raise serious concerns about vaccine safety. And the few studies that *have* looked at health outcomes between children exposed to vaccines and those not exposed have found the vaccinated had far higher rates of various chronic health conditions. And that is where we turn next.

approximately 150 nanograms cells substrate double-strand DNA and single-strand DNA per dose purposefully fragmented to approximately 215 base pairs in length?" Dr. Plotkin answered: "Yeah, that's probably correct, yes." https://icandecide.org/plotkintranscript/ at p. 328 (https://perma.cc/7WCZ-G2TC). See also https://soundchoice.org/wp-content/uploads/2021/01/epidemiologic-molecular-relationship-vaccine-manufacture-autism-prevalence.pdf (https://perma.cc/2E38-QEYA); https://pubmed.ncbi.nlm.nih.gov/26103708/ (https://perma.cc/E6TH-2LK8) (See Table 3, reflecting an average of 142 nanograms of single-stranded DNA and 35 nanograms of double-stranded DNA in the rubella vaccine component of each dose of MMR-II; and an average of 276 nanograms of single-stranded DNA and 35.74 nanograms of double-stranded DNA in each dose of Havrix). For DNA remaining in the final formulation, assuming pharma companies follow FDA's guidance, they would fragment "the DNA size to below approximately 200 base pairs." https://www.fda.gov/media/113760/download at pp.29-30. Doing the math, supposing only 100 nanograms of double-stranded DNA remain, and are broken down into 200 base pair fragments, this equals approximately 463 billion pieces of human DNA from an aborted fetal cell line in each vaccine dose; double that number for single-stranded DNA. https://www.technologynetworks.com/tn/tools/copynumbercalculator (https://perma.cc/RBL9-QSJW). In addition to the human DNA, there is also an unspecified amount of human cellular debris in each vaccine dose. See also https://thehighwire.com/ark-videos/aborted-fetal-tissue-in-vaccines/.

140 https://www.fda.gov/media/151733/download.

141 https://www.fda.gov/media/151733/download; https://blogs.bmj.com/bmj/2021/01/04/peter-doshi-pfizer-and-modernas-95-effective-vaccines-we-need-more-details-and-the-raw-data/ (https://perma.cc/CX8Y-SNMV).

142 https://www.fda.gov/media/151733/download.

143 http://bioethics.hms.harvard.edu/person/faculty-members/marcia-angell (https://perma.cc/5K-VA-4YZV).

144 https://www.nybooks.com/articles/2009/01/15/drug-companies-doctorsa-story-of-corruption/; https://link.springer.com/article/10.1007/s12262-019-01939-8; https://pmc.ncbi.nlm.nih.gov/articles/PMC521592/ (https://perma.cc/794G-APTN).

145 https://www.nybooks.com/articles/2009/01/15/drug-companies-doctorsa-story-of-corruption/.

146 https://investors.pfizer.com/financials/annual-reports/default.aspx; https://investors.merck.com/financials/sec-filings/default.aspx (https://perma.cc/9WJA-EX3G) ; https://www.gsk.com/media/4751/annual-report.pdf (https://perma.cc/C5NG-6E5Z) ; https://www.sanofi.com/en/investors/reports-and-publications/ (https://perma.cc/XDL8-VMKS).

147 https://web.archive.org/web/20170501174817/https://www.hhs.gov/sites/default/files/fy2017-budget-in-brief.pdf?language=es.

148 This is in fact what the *Nuremberg Code* demands. https://research.unc.edu/human-research-ethics/resources/ccm3_019064/ (https://perma.cc/PQD9-VDQ8) ("The voluntary consent of the human subject is absolutely essential. This means that the person … should have sufficient knowledge and comprehension of the elements of the subject matter involved, as to enable him to make an understanding and enlightened decision.").

149 https://www.nap.edu/read/13563/chapter/4.

Chapter 11

1 https://pubmed.ncbi.nlm.nih.gov/3944229/ (https://perma.cc/NGA9-93KW) ("According to data from the National Health Interview Survey (NHIS) [1979-1981] over two million children under 17 years (3.8%) are afflicted by chronic conditions that cause some limitation of activity."); https://pmc.ncbi.nlm.nih.gov/articles/PMC1646496/ (https://perma.cc/KN4A-94TV) ("Data from the National Health Interview Survey indicate that the prevalence of activity-limiting chronic conditions among children under age 17 years doubled between 1960 and 1981, from 1.8 to 3.8 per cent."); https://pubmed.ncbi.nlm.nih.gov/9551003/ (https://perma.cc/JTZ5-JBNK) (Among "children younger than 18 years who were included in the 1992-1994 National Health Interview Survey … [a] significant proportion of children, estimated at 6.5%

of all US children, experienced some degree of disability."); https://www.cdc.gov/chronic-disease/about/index.html (https://perma.cc/N4GT-38L2) ("Chronic diseases are defined broadly as conditions that last 1 year or more and require ongoing medical attention or limit activities of daily living or both.").

2 https://pubmed.ncbi.nlm.nih.gov/21570014/ (https://perma.cc/62JZ-SRY4) (The 2007 National Survey of Children's Health found that: "An estimated 43% of US children (32 million) currently have at least 1 of 20 chronic health conditions assessed, increasing to 54.1% when overweight, obesity, or being at risk for developmental delays are included."); https://pubmed.ncbi.nlm.nih.gov/40058728/ (https://perma.cc/3VHC-L7H2) (Only considering a "condition that is typically pediatric-onset and expected to be persistent or severe" or a "functional/ activity limitation related to a condition that is typically pediatric-onset and expected to be persistent or severe" from the National Health Interview Survey data it found that children falling into this category "has risen from 22.57% in 1999/2000 to 30.21% in 2017/2018"); https://www.cdc.gov/school-health-conditions/chronic-conditions/index.html (https://perma.cc/298V-C59B) ("In the United States, more than 40% of school-aged children and adolescents have at least one chronic health condition"); Unpublished Henry Ford Health study, reviewing actual health codes and medical records, found that 57% of vaccinated children had a chronic health condition by 10 years of age as of 2016, see Chapter 12.

3 https://pubmed.ncbi.nlm.nih.gov/30741719/ (https://perma.cc/P4L2-9KPZ).

4 https://pubmed.ncbi.nlm.nih.gov/28849096/ (https://perma.cc/HZ8E-ETE5); https://pubmed.ncbi.nlm.nih.gov/39426507/ (https://perma.cc/BTM6-HFF8); https://pmc.ncbi.nlm.nih. gov/articles/PMC5373490/ (https://perma.cc/KZS3-5ERS); https://pubmed.ncbi.nlm.nih.gov/39481220/ (https://perma.cc/H9QN-U2E7).

5 https://pmc.ncbi.nlm.nih.gov/articles/PMC10906461/ (https://perma.cc/LV9U-GQKE).

6 https://pubmed.ncbi.nlm.nih.gov/39681901/ (https://perma.cc/LN7W-ZAX8).

7 See endnotes above for references regarding the rise in chronic health issues; https://www.cdc.gov/vaccines/hcp/imz-schedules/resources.html (https://perma.cc/25CK-BEU8) (CDC's vaccine schedules for 1983, 1989, and 1994-2025); http://www.cdc.gov/mmwr/preview/mmwrhtml/00041753.htm (https://perma.cc/L6B4-YM88) (1990, MMR changes from 1 to 2 does, with first dose at 12 months); https://www.cdc.gov/mmwr/preview/mmwrhtml/00023705.htm (https://perma.cc/QUG2-JKCA) (1991, routine Hib conjugate added); https://www.cdc.gov/mmwr/preview/mmwrhtml/00033405.htm (https://perma.cc/4HCR-FC7Z) (1991, routine Hep B added); https://www.cdc.gov/mmwr/preview/mmwrhtml/00047346.htm (https://perma.cc/WWJ6-FQUX) (1997, routine influenza during pregnancy added); https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6207a4.htm (https://perma.cc/E3FL-D994) (2011, routine Tdap during pregnancy added); https://www.cdc.gov/mmwr/volumes/72/wr/mm7241e1.htm (https://perma.cc/NC4S-XJ6J) (2023, routine RSV during pregnancy added).

8 https://www.nap.edu/read/1815/chapter/1#v.

9 https://www.nap.edu/read/1815/chapter/9.

10 https://www.nap.edu/read/13164/chapter/2#2.

11 https://www.nap.edu/read/13164/chapter/1#v.

12 https://www.nap.edu/read/13164/chapter/12#545.

13 Id.

14 https://www.ncbi.nlm.nih.gov/books/NBK230053/pdf/Bookshelf_NBK230053.pdf (https://perma.cc/6KHR-F2RK).

15 https://icandecide.org/wp-content/uploads/2019/09/HHS-Response-1.pdf (https://perma.cc/54DC-2E7Q).

16 https://www.ncbi.nlm.nih.gov/books/NBK230053/pdf/Bookshelf_NBK230053.pdf (https://perma.cc/6KHR-F2RK).

17 Id.

18 Id.

19 Id.

20 http://sirillp.com/NIH-Meeting-2017 (https://perma.cc/9QWA-YDXC).

21 http://sirillp.com/emailmetastudy (https://perma.cc/LNF5-5JQN).

22 http://sirillp.com/Gordon-emails (https://perma.cc/MT9H-FRPY).

23 Id.

24 Id.
25 Id.
26 http://sirillp.com/cdcautismemail (https://perma.cc/3N6P-H3B8).
27 http://sirillp.com/Gordon-emails (https://perma.cc/MT9H-FRPY).
28 https://nap.nationalacademies.org/read/13164/chapter/12#545.
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30 Dr. Thompson has been a scientist at the CDC for over 25 years and a senior scientist on over a dozen CDC publications at the core of many of the CDC's vaccine safety claims. https://www.ncbi.nlm.nih.gov/pubmed; https://www.researchgate.net/profile/William-Thompson-38.
31 https://web.archive.org/web/20250401004753/https://www.rescuepost.com/files/william-thompson-statement-27-august-2014-3.pdf (https://perma.cc/KM26-ZJTW).
32 https://icandecide.org/article/whistleblower-william-thompson-reveals-mmr-vaccines-association-with-autism/ (https://perma.cc/58WB-NLXA).
33 Studies of MMR and autism are also confounded due to "healthy user bias" which arises when parents of infants injured by one or more vaccines stop vaccinating and, hence, do not then give their child the MMR vaccine *because* of an earlier vaccine injury. This bias results in healthier children in the group vaccinated with MMR. https://pubmed.ncbi.nlm.nih.gov/1415136/ (https://perma.cc/DWR9-AAEE); https://www.cdc.gov/pcd/issues/2015/15_0187a.htm (https://perma.cc/BAG6-UGNC).
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35 Id.
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48 https://www.ncbi.nlm.nih.gov/pubmed/23545349 (https://perma.cc/XU7R-FQ55).
49 Id. (emphasis added).
50 Id.
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69 Id.
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100 Id.
101 Id.
102 Id.
103 Id.
104 Id. (AHRQ also excluded studies using VAERS, one of the few resources available to study vaccine safety without pharma type funding).
105 Excluding two studies it double counted.
106 https://www.ncbi.nlm.nih.gov/books/NBK230053/.
107 Id.
108 Id.
109 Id.
110 The 34 rotavirus studies that AHRQ claims compare "vaccinated with unvaccinated children" compared children receiving oral drops of rotavirus with children receiving oral drops of the following vaccine ingredients: Polysorbate 80, Citrate, Phosphate, Dextran, Sorbitol, Amino acids, Dulbecco's Modified Eagle Medium, Calcium Carbonate, and/or Xanthan. See Chapter 10. The two studies involving LAIV, an inhaled influenza vaccine, involved a pharma company reviewing its own product: one involved 20 immunocompromised children with cancer in which 10 received LAIV and 10 received a placebo, https://pubmed.ncbi.nlm.nih.gov/21496468/ (https://perma.cc/8MP9-EHHT), and the other compared 261 children who received LAIV with 65 children who first received placebo and were then offered LAIV after 28 days, https://pubmed.ncbi.nlm.nih.gov/21060780/ (https://perma.cc/7L2Y-PW9V).
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131 Id.
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175 https://web.archive.org/web/20220101081450/https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html (V-safe "information helps CDC monitor the safety of COVID-19 vaccines in near real time."); https://web.archive.org/web/20230125013322/https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/v-safe/index.html ("This information [from V-safe] helps us [CDC] communicate timely and transparent information about the safety of vaccines to public health officials, healthcare providers, and the public.").
176 For example, myocarditis can arise at least 42 days after vaccination. https://pubmed.ncbi.nlm.nih.gov/34614329/ at Figure 1 (https://perma.cc/JW7L-J5PF). Thrombosis with thrombocytopenia syndrome (TTS), which can also be caused by the COVID-19 vaccine, can arise up to 18 days after vaccination. https://web.archive.org/web/20211216171853/https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-12-16/02-COVID-See-508.pdf at slide 16.
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