United States Institutes of Medicine (IOM) Reviews of Pediatric Vaccine Safety and Schedules Repeatedly Cite Lack of Scientific Basis for Positive Claims

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ABSTRACT: Advisory and mandatory vaccination programs and vaccination schedules are unsafe and unscientific and have been noted to be so for decades by Institute of Medicine (IOM), chartered by Congress in 1970 to serve as the leading independent (non-industry-funded) scientific and public policy agency of the United States government. Official government advice and pronouncements, research programs and mandates, however, are at odds with IOM's review of safety and scientific evidence (or lack thereof) and routinely contradict IOM's findings and cautions. Given the high regard with which US public policy and health recommendations are regarded, the impact of this disconnect is global and expensive in human and financial capital.

Introduction: The Institute of Medicine (IOM) serves as a Congressionally chartered science and medicine review body charged with providing advice and evaluation of medical and scientific matters pertaining to health.

The IOM website declares *"The mission of the Institute of Medicine is to advance and disseminate scientific knowledge to improve human health. The Institute provides objective, timely, authoritative information and advice concerning health and science policy to government, the corporate sector, the professions and the public."*[1]

In keeping with that mission, IOM has reviewed vaccine and vaccination schedules' safety repeatedly. A careful review of IOM findings over nearly 3 decades reveals that the oft-repeated claims that vaccine injuries are scarce and both vaccines and vaccine schedules are safe is neither evidence or science-based since they are strongly contradicted by the facts uncovered by IOM and should therefore not be relied upon for personal or public decision-making.[2]

Looking closely at the body reviewing these data and the implications of their findings gives us a picture devoid of the rosy assurances that vaccines are safe and effective and vaccine schedules well tested touted so often by both industry and government voices. Instead, we find a reason for deep concern, distrust of those assurances and an urgent need for additional, non-industry connected research.

IOM (known officially as the National Academy of Medicine since its name was changed in July, 2015), was created in 1970 under the congressional charter of the National Academy of

[1] http://www.ihi.org/resources/Pages/OtherWebsites/InstituteofMedicine.aspx
[2] See Laibow, RE, Regulations and Results http://www.inhere.org/wp-content/uploads/2018/08/Final-All-India-Medical-Congress-Paper.020415.pdf

Science, which was established in 1863. It is responsible for providing unbiased advice on issues concerning medicine, biomedicine and health.
As such, IOM acts under the responsibility given to the National Academy of Sciences to be an adviser to the federal government and, *upon its own initiative*, to identify issues of medical care, research, and education including vaccine safety and efficacy.

Under the Vaccine Act, 42 U.S.C. 300a-2 (c), The Institute of Medicine or other groups or associations conducting the [safety] study… (1) shall conduct such studies in consultation with the Advisory Commission on Childhood Vaccines (ACIP) established under section 2119 of the Public Health Service Act [42 U.S.C. 300aa–19].

Remarkably, the IOM has identified numerous vaccine dangers, indications, cautions, precautions and adverse events that are not being reported or acknowledged by ACIP or CDC, although required under the Vaccine Act.[3]

IOM's relevant reports include:[4]

- Childhood Immunization Schedule and Safety: Stakeholder Concerns, Scientific Evidence, and Future Studies -2013
- Adverse Effects of Vaccines: Evidence and Causality – 2011
- Immunization Safety Review: Vaccines and Autism – 2004
- Immunization Safety Review: Vaccinations and Sudden Unexpected Death in Infancy – 2003
- Immunization Safety Review: Influenza Vaccines and Neurological Complications – 2003
- Immunization Safety Review: Multiple Immunizations and Immune Dysfunction – 2002
- Immunization Safety Review: SV40 Contamination of Polio Vaccine and Cancer – 2002
- Immunization Safety Review: Hepatitis B Vaccine and Demyelinating Neurological Disorders – 2002
- Immunization Safety Review: Measles-Mumps-Rubella Vaccine and Autism – 2001
- Thimerosal – Containing Vaccines and Neurodevelopmental Disorders – 2001
- Adverse Events Associated with CHILDHOOD VACCINES
  Evidence Bearing on Causality – 1994
- Research Strategies for Assessing Adverse Events Associated with Vaccines: A Workshop Summary – 1994
- Adverse Effects of Pertussis and Rubella Vaccines – 1991

It should be noted that while IOM has no financial or organizational ties to the vaccine industry, both ACIP and CDC have very strong financial and organizational ties to that industry which appear to incentivize their vaccine recommendations.

ACIP, providing guidance to the US and, through its position of authority, the rest of the world, finds, in deep contradiction to scientific and clinical documentation that there are virtually no vaccine related adverse events and that the only contraindication for a medical exemption recognized by ACIP, with some limited exceptions, is a previous anaphylaxis reaction to a previous vaccination. They can accomplish this vanishing trick by redefining vaccine adverse

[3] See, for example, http://www.vaccinesafety.edu/IOM-Reports.htm
[4] https://vaxopedia.org/2016/10/09/iom-vaccine-reports/

events to exclude virtually everything except anaphylactic shock, including proximate death following vaccination.
The strongly industry-connected World Health Organization (WHO) joins ACIP and CDC in this scientific slight-of-hand. Issuing a new advisory on causal relationships between adverse events following immunization and vaccination itself[5], all adverse events in clinical applications of vaccines, including death, vanish since , so, as Drs. Pulayel and Naik observe, "*under WHO's revised manual on AEFI, only those adverse reactions observed during clinical trials of a vaccine, should be classified as vaccine related. All new serious adverse reactions including deaths seen during post-marketing of the vaccine should be considered as 'coincidental' or 'unclassifiable', and the vaccine should not be blamed.*"

By redefining vaccine-related adverse events out of existence, the scientific basis for any claims of safety are magically cancelled out and made to disappear. Reliance on any data which incorporates this skewed and anti-scientific guideline cannot be relied upon in any way.

Evidence of a previous anaphylaxis reaction to a previous vaccination, the only reason ACIP posits for a vaccine exemption, is of course an insurmountable issue for, for example, a child who has never been vaccinated. Such a person might well have serious medical or genetic conditions making them vulnerable to vaccine injury compared to peers. But this bar is one which, following the guidelines of WHO, totally obscures and eliminates any of the many well-known and well-characterized adverse responses to vaccination.

IOM focuses on those extensively while ACIP/CDC/WHO deny their existence.
ACIP/CDC/WHO all receive substantial income from the makers of vaccines and, in the case of ACIP and CDC, both personal and institutional revenue from those industrial sources.
IOM does not.

As authorized by Congress under its Charter and the Vaccine Act, the IOM has reported on numerous serious injuries from vaccinations that ACIP/WHO fail to include in their guidelines. IOM's careful reviews of the literature provide invaluable information which an ethical doctor or public policy-maker must rely upon in either making clinical decisions, giving a learned intermediary medical opinion or setting public policy with regard to vaccination and vaccine schedules.

ACIP Guidelines (conforming with WHO ones) routinely flout IOM findings: in 1991[6], for example, the IOM examined 22 commonly reported serious injuries following the Diphtheria, Tetanus and Pertussis (DTP) vaccine, a school-required vaccine in NYS. The IOM concluded

[5] https://www.who.int/vaccine_safety/initiative/detection/AEFI/en/
[6] file:///C:/Users/reley/AppData/Local/Packages/Microsoft.MicrosoftEdge_8wekyb3d8bbwe/TempState/Downloads/1815%20(1).pdf

that sufficient scientific evidence from the peer-reviewed literature supported a causal relationship between the DTP vaccine, and six (6) adverse health conditions not being reported by ACIP or CDC:

1. Acute encephalopathy
2. Chronic arthritis,
3. Acute arthritis,
4. Shock and unusual shock-like state,
5. Anaphylaxis
6. Protracted inconsolable crying.

The IOM reported that the scientific evidence was insufficient to determine whether the DTP vaccine was causing twelve (12) additional serious health outcomes that were also commonly observed following receipt of the school required vaccine:

1. Aseptic meningitis (serious inflammation of the brain);
2. Chronic neurologic damage;
3. Learning disabilities and attention-deficit disorder;
4. Hemolytic anemia;
5. Juvenile diabetes;
6. Guillain-Barre syndrome;
7. Erythema multiforme;
8. Autism;
9. Peripheral mononeuropathy (nerve damage);
10. Radiculoneuritis and other neuropathies;
11. Thrombocytopenia;
12. Thrombocytopenic purpura

It is important to note, that the IOM did not rule out these adverse health conditions as either "likely" or "possibly" caused by the DTP vaccine, nor did they find sufficient evidence to conclude there was a causal link, either way, because the evidence is insufficient to rule out possible harm or adverse reactions. They urge more careful surveillance and research into the matter.

Such surveillance and research has, to date, never been conducted.

In the report, the IOM underscored that they "encountered many gaps and limitations in knowledge bearing directly and indirectly on the safety of vaccines."

The IOM concluded that too few vaccine studies had been conducted, that the scientific record was inadequate, and that the few vaccine studies that had been completed suffered from poor study design, writing that "studies are too small or have inadequate length of follow-up to have a reasonable chance of detecting true adverse reactions."

In sum, the 1991 IOM report finding was that "If research capacity and accomplishment in this field are not improved, future reviews of vaccine safety will be similarly handicapped."[7]

In 1991, in addition to its report on the topic, in order to stimulate the required research on vaccine and vaccine schedule safety, the IOM published the results of a workshop on how to conduct the necessary research to establish the data that was so woefully lacking in vaccine safety and adverse events[8] second report, this time focusing on commonly reported serious health outcomes following vaccination against Diphtheria, Tetanus, measles, mumps, polio, Hepatitis B, and Hib.[9]

In the 1994 report, the IOM found that the scientific literature provided sufficient evidence to support a causal connection between these seven vaccines and twelve (12) serious adverse health outcomes, among them: Anaphylaxis, Thrombocytopenia, Guillain-Barre Syndrome and death. [10]

In the same 1994 IOM report, for many other serious adverse health outcomes being reported from vaccines, the IOM could not find sufficient published scientific studies with evidence one way or the other on causality, reporting that "the majority of vaccine-adverse event pairs the evidence was considered inadequate to accept or reject causality."[11]

The IOM could not find evidence *for, or against*, causality for 38 of the most commonly reported serious adverse health outcomes that were being reported following these seven vaccines, including:

> "*Demyelinating diseases of the central nervous system, Sterility, Arthritis, Neuropathy, Residual seizure disorder, Transverse myelitis, Sensorineural deafness, Optic neuritis, 3 Aseptic meningitis, Insulin-dependent diabetes mellitus, Sudden Infant Death Syndrome (SIDS).*"[12]

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[7] Ibid
[8] https://www.nap.edu/catalog/9269/research-strategies-for-assessing-adverse-events-associated-with-vaccines-a
[9] Institute of Medicine 1991. Adverse Effects of Pertussis and Rubella Vaccines. Washington, DC: The National Academies Press.
[10] Institute of Medicine 1994. Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality. Washington, DC: The National Academies Press.
[11] Ibid
[12] Ibid

In their 1994 Report, the IOM *reported "The lack of adequate data regarding many of the adverse events under study was of major concern to the committee. Presentations at public meeting indicated that many parents and physicians share this concern."* The report concluded that insufficient studies were available on the possible risks of combining vaccines (simultaneous administration):

"The committee was able to identify little information pertaining to the risk of serious adverse events following administration of multiple vaccines simultaneously."

In their 2011 report, *Adverse Effects of Vaccines: Evidence and Causality*,[13] IOM was forced to reiterate this theme: *"This is an issue of increasing concern as more vaccines and vaccine combinations are developed for routine use."*

As an example of the impact of the ACIP/WHO's unsafe and unscientific advisories, issued in the face of clear cries for deep concern and caution after careful review of the available data (and in consideration of the lack of available relevant safety data, under a law passed in New York State in one day without any public or legislative deliberation or testimony, students in New York State who are not vaccinated and were attending school with a religious exemption prior to the repeal of §2164 (9) of the PHL on June 13, 2019, are now required to "catch up" all 55 required doses of vaccinations before June 30, 2019. The Department of Health, pointing to ACIP's recommendations and advice that such a schedule has been "found" to be safe, will not permit "delaying the schedule." [14]

In 2011, IOM undertook a larger review and published a report entitled Adverse Effects of Vaccines: Evidence and Causality and reviewed 158 of the most common serious adverse health outcomes observed following vaccination against varicella, Hepatitis B, Tetanus, measles, mumps, and/or rubella.[15]

Remarkably, in that report, the IOM found studies with sufficient evidence that: "convincingly support(ed) a causal relationship" for fourteen (14) of these serious injuries, including pneumonia, meningitis, hepatitis, MIBE (deadly brain inflammation a year after vaccination), febrile seizures, and anaphylaxis."[16]

[13] Institute of Medicine 2012. Adverse Effects of Vaccines: Evidence and Causality. Washington, DC: The National Academies Press. https://doi.org/10.17226/13164.
[14] https://www.health.ny.gov/publications/2170/docs/vaccine_requirements_faq.pdf
[15] Institute of Medicine 2012. Adverse Effects of Vaccines: Evidence and Causality. Washington, DC: The National Academies Press. https://doi.org/10.17226/13164.
[16] Ibid

IOM concluded that there were studies providing sufficient evidence to support "acceptance of a causal relationship" for four (4) additional serious injuries[17]. Nowhere in the ACIP guidance tare these causal relationships accounted for or acknowledged.

The IOM found the scientific literature to be deficient in evidence to consider a causal role for those vaccines, and 135 other serious adverse health outcomes injuries that were being commonly reported, including:

> *'Encephalitis (brain inflammation), Encephalopathy (gradual degeneration of brain function, including memory, cognitive ability, concentration, lethargy, and eventually consciousness), Infantile Spasms, Afebrile Seizures, Seizures, Cerebellar Ataxia (inflammation of and/or damage to the cerebellum), Ataxia (the loss of full control of bodily movements), Acute Disseminated Encephalomyelitis (brief but widespread attack of inflammation in the brain and spinal cord that damages myelin – the protective covering of nerve fibers), Transverse Myelitis (neurological disorder caused by inflammation across both sides of one level, or segment, of the spinal cord that typically results in permanent impairments), Optic Neuritis (inflammation of the optic nerve and symptoms are usually unilateral, with eye pain and partial or complete vision loss), Neuromyelitis Optica (body's immune system over time repeatedly mistakenly attacks healthy cells and proteins in the body, most often those in the spinal cord and eyes resulting in permanent disability), Multiple Sclerosis, Guillain-Barre Syndrome (body's immune system attacks part of the peripheral nervous system), Chronic Inflammatory Demyelinating Polyneuropathy (auto-immune inflammatory disorder of the peripheral nervous system resulting in loss of nerve axons), Brachial Neuritis (auto-immune reaction against nerve fibers of the brachial plexus), Amyotrophic Lateral Sclerosis (rapidly progressive, invariably fatal neurological disease that attacks the nerve cells responsible for controlling voluntary muscles), Small Fiber Neuropathy (damage to the small unmyelinated peripheral nerve fibers), Chronic Urticaria (chronic hives), Erythema Nodosum (skin inflammation in the fatty layer of skin), Systemic Lupus Erythematosus (autoimmune disease in which the body's immune system mistakenly attacks healthy tissue), Polyarteritis Nodosa (inflammation resulting in injury to organ systems), Psoriatic Arthritis, Reactive Arthritis, Rheumatoid Arthritis, Juvenile Idiopathic Arthritis, Arthralgia (joint pain), Autoimmune Hepatitis, Stroke, Chronic Headache, Fibromyalgia, Sudden Infant Death Syndrome, Hearing Loss, Thrombocytopenia, Immune Thrombocytopenic Purpura."*[18]

It is important to note that, writing 20 years after their initial report and call for rigorous research, frighteningly for those responsible for decision-making about vaccines at any level, of

[17] Ibid
[18] Ibid

the 158 most common serious adverse health outcomes, the **IOM could only find sufficient evidence to reject causality in 5 of them while for 135 vaccine-injury pairs, the IOM concluded - and reported - that the studies had not been conducted**.[19]

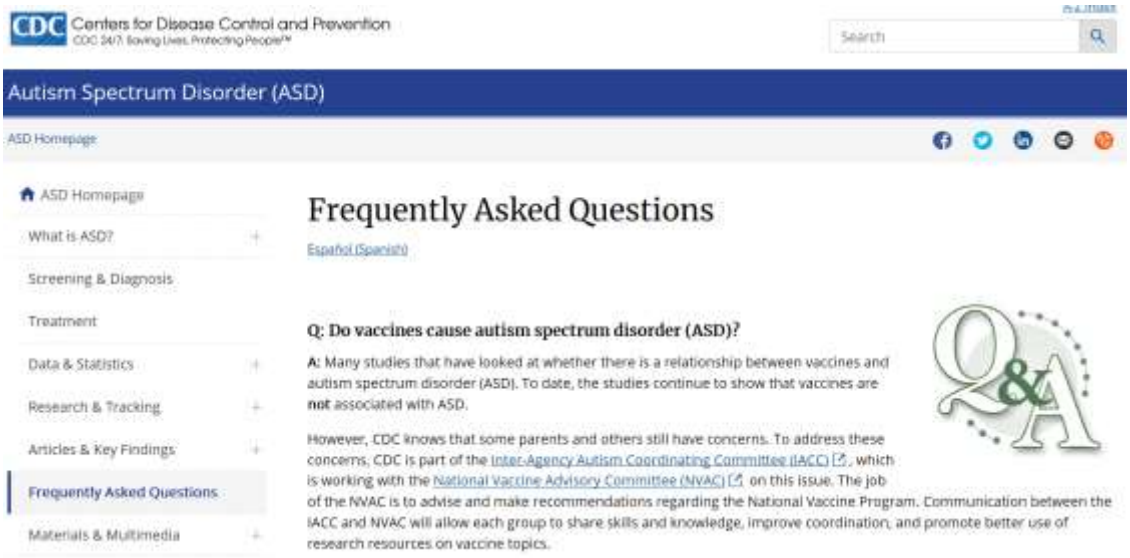
Wading directly into the autism controversy, IOM also considered the causal relationship between autism and the DTaP vaccine administered to children at two, four, six, and fifteen months of age. The IOM reported that they could not locate a single study supporting that DTaP does or does not cause autism.

"The evidence is inadequate to accept or reject a causal relationship between diphtheria toxoid–, tetanus toxoid–, or acellular pertussis–containing vaccine and autism."[20]

Consider the following, taken directly from the CDC website on the question of whether vaccines cause autism:

The IOM also failed to find any studies ruling out autism as a result of vaccination against Hepatitis A, Hepatitis B, Hib, Inactivated Poliovirus, Influenza, Rotavirus, Pneumococcal, or Varicella.

Yet, untruthfully and deeply troublingly, the CDC website reports that "Vaccines Do Not Cause Autism." [21]



The 2011 IOM Report also noted that insufficient research has been conducted to develop ways to predict individual susceptibility to serious vaccine injuries making the doctor's role as the learned intermediary even more important and compelling public health policy makers to

[19] Ibid Emphasis added by authors.
[20] Ibid
[21] https://www.cdc.gov/ncbddd/autism/topics.html

consider these vitally important issues. ACIP/WHO guidance are diametrically opposed to the ongoing concerns which continue to beset personal and community vaccine decisions.[22]

The IOM has elsewhere reported that such research on individual or group susceptibility must consider child's personal genome, behaviors, microbiome, intercurrent illness, and present and past environmental exposure. The IOM found *"The committee was able to identify little information pertaining to why some individuals react adversely to vaccines when most do not."*[23]

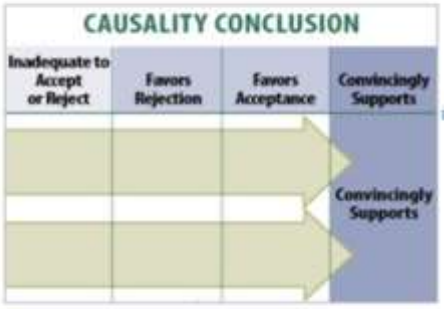
Further, the IOM recommended that *"research should be encouraged to elucidate the factors that put certain people at risk."*[24]

Despite these recommendations by the organization tasked and funded by the US Government with guiding research and policy, in 2011, seventeen (17) years later, the IOM reported that such research had still not been conducted: *"Both epidemiologic and mechanistic research suggest that most individuals who experience an adverse reaction to vaccines have a preexisting susceptibility. These predispositions can exist for a number of reasons—genetic variants (in human or microbiome DNA), environmental exposures, behaviors, intervening illness, or developmental stage, to name just a few…Some of these adverse reactions are specific to the particular vaccine, while others may not be. Some of these predispositions may be detectable prior to the administration of vaccine... [M]uch work remains to be done to elucidate and to develop strategies to document the immunologic mechanisms that lead to adverse effects in individual patients."*[25]

In the official summary of that report, the official website of the National Academy of Sciences notes:[26]

Using epidemiologic and mechanistic evidence, the committee developed 158 causality conclusions and assigned each relationship between a vaccine and an adverse health problem to one of four categories of causation:

- Evidence convincingly supports a causal relationship
- Evidence favors acceptance of a causal relationship
- Evidence favors rejection of a causal relationship
- Evidence is inadequate to accept or reject a causal relationship



The committee finds that evidence convincingly supports a causal relationship between some vaccines and some adverse events—such as MMR, varicella zoster, influenza, hepatitis B, meningococcal, and tetanus-containing vaccines linked to anaphylaxis. Additionally, evidence favors rejection of five vaccine-adverse event relationships, including MMR vaccine and autism and inactivated influenza vaccine and asthma episodes. However, for the majority of cases (135 vaccine-adverse event pairs), the evidence was inadequate to accept or reject a causal relationship. Overall, the committee concludes that few health problems are caused by or clearly associated with vaccines.

[22] Adverse Effects of Vaccines: Evidence and Causality, 2011, Loc cit.
[23] https://www.nap.edu/read/2138/chapter/2#12
[24] Ibid
[25] Adverse Effects of Vaccines: Evidence and Causality, 2011, Loc cit.
[26] http://nationalacademies.org/hmd/reports/2011/adverse-effects-of-vaccines-evidence-and-causality.aspx

Since the evidence for causal relationships are lacking, the report is forced to conclude, because of a striking lack of research and data, that ***"few health problems are caused by or clearly associated with vaccines."*** [27],[28]

The objectively minded must wonder what the concluding statement might be in the presence of such urgently required, but consistently not-conducted, research.

In 2013 IOM reviewed the safety of the CDC's pediatric vaccination schedule and reported, yet again. *"most children who experience an adverse reaction to immunization have preexisting susceptibility,"* and they *"found that evidence assessing outcomes in subpopulations of children who may be potentially susceptible to adverse reactions to vaccines (such as children with a family history of autoimmune disease or allergies or children born prematurely) was limited and is characterized by uncertainty about the definition of populations of interest and definitions of exposures and outcomes."* [29]

Nor do ACIP-derived guidelines and policies make any provision whatsoever for "pre-existing susceptibility" or considerations other than anaphylaxis.
Although it is a life threatening condition, in the context of the necessary, but un-done research on vaccine reactions and safety issues, it is not surprising that an article called *WHAT IS THE RISK OF ANAPHYLAXIS AFTER VACCINATION IN CHILDREN AND ADULTS?* in the journal of the American Academy of Asthma, Allergy and Immunology states: "*Anaphylaxis is a potentially life-threatening allergic reaction, which can occur after many different exposures, e.g., food, venom, drugs, or vaccines. For context, each year in the United States, more than 100 million people receive influenza or other vaccines. Virtually all vaccines have the potential to trigger anaphylaxis. However, the magnitude of the risk of anaphylaxis after vaccination has not been well described."*[30] Nor, it should be pointed out, have the standards and procedures for reporting such events through the entirely voluntary Vaccine Adverse Events Reporting System, (VAERS) been either studied or established.

In its 2013 report entitled "The Childhood Immunization Schedule and Safety: Stakeholder Concerns, Scientific Evidence and Future Studies (2013)"[31] the same concerns initially raised in 1991 were repeated and reiterated. Despite repeated IOM direction to do so, Health and Human Services (HHS) the parent organization of FDA, CDC and ACXIP, has consistently failed to

[27] Ibid
[28] Emphasis added by authors
[29] http://nationalacademies.org/hmd/reports/2013/the-childhood-immunization-schedule-and-safety.aspx
[30] https://www.aaaai.org/global/latest-research-summaries/Current-JACI-Research/What-is-the-risk-of-anaphylaxis-after-vaccination
[31] Institute of Medicine 2013. The Childhood Immunization Schedule and Safety: Stakeholder Concerns, Scientific Evidence, and Future Studies. Washington, DC: The National Academies Press.

even begin to frame out studies designed to identify susceptible subpopulations. IOM reported that that HHS should: *"develop a framework that clarifies and standardizes definitions of … populations that are potentially susceptible to adverse events."*. [32]

IOM stated: *"Given the widespread use of vaccines; State mandates requiring vaccination of children for entry into school, college, or day care; and the importance of ensuring that trust in immunization programs is justified, it is essential that safety concerns receive assiduous attention."*[33]

Such "assiduous attention" is still not forthcoming.

In 2012, IOM rejected the majority of studies on MMR and Autism as flawed.[34] And reported that **most of the studies available at the time on the question of the MMR vaccine and autism connection were too flawed to be considered for the report on vaccines/autism link**.[35] In fact, the IOM soundly rejected 17 out of 22 studies:

> *"The committee reviewed 22 studies to evaluate the risk of autism after the administration of MMR vaccine. Twelve studies (Chen et al., 2004; Dales et al., 2001; Fombonne and Chakrabarti, 2001; Fombonne et al., 2006; Geier and Geier, 2004; Honda et al., 2005; Kaye et al., 2001; Makela et al., 2002; Mrozek-Budzyn and Kieltyka, 2008; Steffenburg et al., 2003; Takahashi et al., 2001, 2003) were not considered in the weight of epidemiologic evidence because they provided data from a passive surveillance system lacking an unvaccinated comparison population or an ecological comparison study lacking individual-level data. Five controlled studies (DeStefano et al.,2004; Richler et al., 2006; Schultz et al., 2008; Taylor et al., 2002; Uchiyama et al., 2007) had very serious methodological limitations that precluded their inclusion in this assessment. Taylor et al. (2002) inadequately described the data analysis used to compare autism compounded by serious bowel problems or regression (cases) with autism free of such problems (controls). DeStefano et al. (2004) and Uchiyama et al. (2007) did not provide sufficient data on whether autism onset or diagnosis preceded or followed MMR vaccination.*
>
> *The study by Richler et al. (2006) had the potential for recall bias since the age at autism onset was determined using parental interviews, and their data analysis appeared to ignore pair-matching of cases and controls, which could have biased their findings toward the null. Schultz et al. (2008) conducted an Internet-based case-control study and*

[32] Ibid
[33] Ibid
[34] Institute of Medicine 2012. Adverse Effects of Vaccines: Evidence and Causality. Washington, DC: The National Academies Press..
[35] Emphasis added by authors

excluded many participants due to missing survey data, which increased the potential for selection and information bias.

The five remaining controlled studies (Farrington et al., 2001; Madsen et al., 2002; Mrozek-Budzyn et al., 2010; Smeeth et al., 2004; Taylor et al., 1999) contributed to the weight of epidemiologic evidence and are described below." (References therein)[36]

In that document, IOM reported, based on their conclusion and review of the medical literature, that vaccines do not cause autism on five studies, two of which were the same data analyzed twice, four of which were too small to be considered reliable, and one of which appears to have been fraudulently manipulated. Thus, the conclusion was reached on a data set which IOM noted to not reach the standards of scientific reliability, rendering the conclusion meaningless.[37],[38]

Shockingly, but perhaps not surprisingly, subsequent studies, including a meta-analysis, and an updated IOM report has ignored the flaws in the 17 studies rejected, and totally overlooked the flaws in the remaining 5 studies.[39]

While the schedule of vaccinations has increased dramatically over the decades of its repeated reviews and reports, the positive findings have not: IOM's repeated conclusion is that there is neither scientific basis nor safety assurance available for either the vaccines themselves or the vaccination schedule s for children of different ages.

IOM concludes its reports calling for additional science upon which to base any further recommendations and pronouncements about safety or lack thereof. In spite of that recurring concern and call for documentation, public and private stakeholders continue to reassure the public at large and the medical and policy communities in particular that concerns about vaccine safety and administration schedules are completely unwarranted and are, in fact, anti-scientific and, increasingly, anti-social.

Since IOM is the only significant independent body conducting these schedules, there appears to be rigorous science on the caution end of the policy "see-saw" and little, if anything, of substance on the vaccination support end. Whether their long-preserved independence can still be relied upon remains to be seen, however.

Whether they can or not at this point, the specifics of these detailed reports and their areas of concern must be considered in depth to allow the reader a more balanced, rigorous and science-

[36] Ibid
[37] Ibid
[38] Emphasis added by authors
[39] Childhood Immunization Schedule and Safety: Stakeholder Concerns, Scientific Evidence, and Future Studies, op cit.

based view than that generally available even in professional sources rather than relying on blanket assurances that are not now, and have not been in the past, based on rigor or, indeed, based on data.

The concerns that IOM has repeatedly raised over decades are of grave concern to the individual child exposed to unsafe and unscientific medical interventions on the basis of professional and policy misinformation and public institutions

Although IOM is a US institution, the vaccine-related, unscientific recommendations and practices are a matter of grave concern not only in the US but around the world because US health and policy findings and practices are looked upon with great respect and trust. Indeed, the US has carefully synchronized its policies and recommendations with WHO.

It would appear, at least in the matter of pediatric vaccination, that respect and trust might well be placed on the lesser-known IOM reports rather than on the recommendations and practices of the Advisory Committee for Immunization Practices (ACIP) which routinely and without, to our knowledge, reference to these reports makes its ever burgeoning recommendations for more new shots and more booster shots. By age 18, a US child can receive as many as 54 shots containing 70 antigens against 16 diseases. In 1989, a US child could receive 12 shots containing 25 antigens against 8 diseases.[40],[41]

[40] https://childrenshealthdefense.org/child-health-topics/known-culprit/vaccines-culprit/cdc-recommended-vaccine-schedule-1986-vs-2019/
[41] https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html

Physicians and health officials at every level around the world rely on the US science-based reputation so completely that they often routinely implement, or use as a guideline for implementation, the ACIP recommendations, resulting in widespread unsound and dangerous practices.

IOM, the official government body tasked with vaccine safety reviews, has repeatedly warned of vaccine and vaccine schedule dangers in the face of an absence of scientific validation of either and serious questions raised by trustworthy observers about both.

ACIP, on the other hand, unscientifically recognizes only one danger related to vaccination which might stand as a reason to not receive vaccinations: anaphylactic reaction to a previous vaccination.
There is not the remotest shred of scientific evidence for this official position which is also illogical in that unvaccinated persons have no way in which they can qualify for vaccine avoidance. Those with, for example, a proven genetic mutation making their vaccination a grave danger for them, would not qualify under the CDC/ACIP guidance.

As IOM points out, such restrictions have no basis in science and, further, ignore the science that does exist about vaccine dangers and cautions.

Official CDC/ACIP pronouncements incorrectly, although robustly and repeatedly, advise that the vaccine schedules, including the very rapid and aggressive "catch-up" schedule involve multiple vaccinations are well-studied and their safety is supported by science.[42]

Different childhood vaccines can be given at the same time.

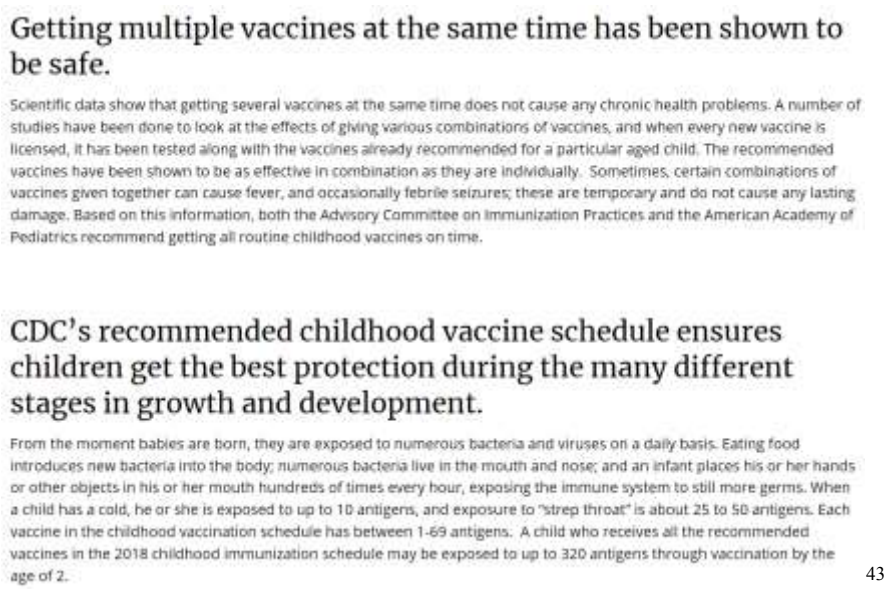
Many vaccines are recommended early in life to protect young children from dangerous infectious diseases. In order to reduce the number of shots a child receives in a doctor's visit, some vaccines are offered as combination vaccines. A combination vaccine is two or more different vaccines that have been combined into a single shot. Combination vaccines have been in use in the United States since the mid-1940s. Examples of combination vaccines are: DTap (diphtheria-tetanus-pertussis), trivalent IPV (three strains of inactivated polio vaccine), MMR (measles-mumps-rubella), DTap-Hib, and Hib-Hep B.

Often, more than one shot will be given during the same doctor's visit, usually in separate limbs (e.g. one in each arm). For example, a baby might get DTaP in one arm or leg and IPV in another arm or leg during the same visit.

Giving a child several vaccines during the same visit offers two advantages.

First, children should be given their vaccines as quickly as possible to give them protection during the vulnerable early months of their lives. Second, giving several shots at the same time means fewer office visits. This saves parents time and money, and can be less traumatic for the child.

[42] https://www.cdc.gov/vaccinesafety/concerns/multiple-vaccines-immunity.html



Getting multiple vaccines at the same time has been shown to be safe.

Scientific data show that getting several vaccines at the same time does not cause any chronic health problems. A number of studies have been done to look at the effects of giving various combinations of vaccines, and when every new vaccine is licensed, it has been tested along with the vaccines already recommended for a particular aged child. The recommended vaccines have been shown to be as effective in combination as they are individually. Sometimes, certain combinations of vaccines given together can cause fever, and occasionally febrile seizures; these are temporary and do not cause any lasting damage. Based on this information, both the Advisory Committee on Immunization Practices and the American Academy of Pediatrics recommend getting all routine childhood vaccines on time.

CDC's recommended childhood vaccine schedule ensures children get the best protection during the many different stages in growth and development.

From the moment babies are born, they are exposed to numerous bacteria and viruses on a daily basis. Eating food introduces new bacteria into the body; numerous bacteria live in the mouth and nose; and an infant places his or her hands or other objects in his or her mouth hundreds of times every hour, exposing the immune system to still more germs. When a child has a cold, he or she is exposed to up to 10 antigens, and exposure to "strep throat" is about 25 to 50 antigens. Each vaccine in the childhood vaccination schedule has between 1-69 antigens. A child who receives all the recommended vaccines in the 2018 childhood immunization schedule may be exposed to up to 320 antigens through vaccination by the age of 2.

43

Neither is the case, as IOM repeatedly documents, making this important category of guidance illogical, dangerous and disingenuous.

The reviewed IOM Reports further show that the Centers for Disease Control (CDC)'s Advisory Committee on Immunization Practices (ACIP) has failed to recognize nearly all proven adverse reactions to vaccines. It is worthy of note that the courts of the United States, including the Supreme Court,[44] have opined on several occasions that vaccines are *"unavoidably unsafe"* and the industry is uninsurable in the United States.

The only other uninsurable industry, for comparison, is civilian production of nuclear power.[45]

As the global push for higher and higher levels of vaccination in populations, regardless of the safety or lack thereof, the propaganda intensity increases while the level of science supporting either vaccination or the schedules proposed by CDC/ACIP remain the same: close to nil.

To add to the problem, in the US at least, various governmental agencies and private institutions will only recognized ACIP listed adverse reactions as the basis for physician-issued medical exemptions from vaccination, not realizing that ACIP has a strongly a-scientific position NOT based in anything remotely like sound science.

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[43] https://www.cdc.gov/vaccinesafety/concerns/multiple-vaccines-immunity.html

[44] Bruesewitz et al vs Wyeth LLC https://www.supremecourt.gov/opinions/10pdf/09-152.pdf

[45] The **Price-Anderson Nuclear Industries** Indemnity **Act** of 1957, last renewed in 2005) (e. g, "**Price-Anderson Act"**) provides liability backed by the US Congress against claims stemming from nuclear incidents since private underwriters decline to take on the risk of nuclear incidents. The current renewal expires in 2025.

Relying on that source, therefore, decision makers are missing the vast majority of adverse reactions and interfering with the role of the physician as the licensed learned intermediary for purposes of Informed Consent.

The truth about the dangerous, even cataclysmic lack of vaccine safety has been clearly represented in the public record for decades. IOM, a Federal agency tasked with reviewing vaccine safety, has been diligently sorting, sifting and separating the strong science from the weak science or the absence of science in publicly available reports.

Much of this distortion in favor of unsupported proclamations of vaccine "safety" can be traced directly to the difference between the definition of "Conflict of Interest" for employees of the US Government and advisors to it.

18 U.S.C. § 208 is a criminal conflict of interest statute which requires an employee to be disqualified ("recused") from a particular matter if it would have a direct and predictable effect on the employee's own financial interests or on certain financial interests that are treated as the employee's own, such as those of the employee's spouse or a prospective employer.

Special Government Employees, SGEs, however, have a very special, and highly profitable exemption from these restrictions which allows them to profit directly from their advisory work, as the members of ACIP regularly do.[46],[47]

Paul Offit, MD, for example, a member of ACIP, acted on his own behalf when he voted to approve RotaTeq™, a rotavirus vaccine for infants developed by him for Merck, on which he is a patent holder. Conservative estimates put his RotaTeq-related income at approximately $46 Million US. RotaTeq has been found to be contaminated with DNA from two procin3e circoviruses:PCV1 and PCV2. Merck, its manufacturer, has not commented on when, or if, these serious contaminants will be removed.

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[46] 18 U.S.C. § 208 prohibits all employees, including SGEs, from participating personally and substantially in any particular matter that has a direct and predictable effect on their own financial interests or the financial interests of others with whom they have certain relationships. In addition to an employee's own personal financial interests, the financial interests of the following persons or organizations are also disqualifying: spouse; minor child; general partner; organization which the individual serves as officer, director, trustee, general partner or employee; person or organization with which the employee is negotiating or has any arrangement concerning prospective employment.18 Because SGEs typically have substantial outside employment and other interests, which are often related to the subject areas for which the Government desires their services, issues under section 208 frequently arise. In certain circumstances, however, SGEs are eligible for special treatment under section 208. SGEs who serve on advisory committees, within the meaning of the Federal Advisory Committee Act (FACA), 5 U.S.C. app., are uniquely eligible for a particular waiver of the prohibitions of section 208(a). Under 18 U.S.C. § 208(b)(3), an SGE serving on a FACA committee may be granted a waiver where the official responsible for his or her appointment certifies in writing that the need for the SGE's services outweighs the potential for a conflict of interest posed by the financial interest involved. 18 U.S.C. § 208(b)(3). https://ethics.od.nih.gov/topics/OGE-SGE.pdf

[47] ACIP members are to refrain from Conflict of Interests but apparently define that concept in a way that allows vast personal and industrial gain. https://www.cdc.gov/vaccines/acip/apply-for-membership/index.html

PCV1 has not been associated with clinical disease in pigs but PCV2 is a lethal pig virus that causes immune suppression and a se4rious wasting disease in baby pigs that damages lungs, kidneys, the reproductive system, brain and ultimately causes death. When PCV2 was identified in Rotarix, FDA did not call for suspension of the use of RotaTeq vaccine although after PCV1 was found in RotaTeq FDA recommended suspension of its use. No steps have been taken following the discovery of the much more potentially dangerous PCV2.[48]

Tragically, Dr. Offit's zealous promotion of vaccines from which he profits directly is not unique on ACIP. Vaccine drug companies, their collaborators, employees and representatives, along with their lobbyists are, in plane language, running the hen house and gobbling up whatever hens they can find. The recommendations and anti-science pronouncements supporting those recommendations are not surprising, but they are decidedly dangerous, especially for people with any compromise in their ability to handle toxins, which includes the nearly 50% of humanity with hetero or homozygous MTHFR genetics impairing methylation and heavy metal metabolism (e.g., aluminum)[49, 50, 51, 52, 53, 54]
MTHFR alterations are, of course, not the only genetic configuration predisposing for likely vaccine injury. Super Oxide Dismutase, Glutathione Transferase, Cytochrome P45 and many others fall into this category, making such recommendations dangerous and unwise even if the members of the Committee were all acting out of the purest public health motives.

Of all the places that One Size Fits All does not fit, vaccine policy is the most extreme example of its dismal failure.

If "the science is (ever) settled" it is settled regarding vaccine safety – there is nil to none. Where there is unavoidable risk in health care there must be Informed Consent choice.

Some relevant history is in order. In the mid-1970s the United States experienced the first "Swine Flu Panic." The pharmaceutical industry was pushing its dangerous flu vaccine claiming

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[48] https://therefusers.com/us-govt-admits-paul-offits-rotavirus-vaccine-causes-deadly-adverse-reactions/
[49] Wu Z *et al*., 2012. *Aluminum induces neurodegeneration and its toxicity arises from increased iron accumulation and reactive oxygen species (ROS) production*. Neurobiol Aging. 2012 Jan;33(1):199.e1-12.
[50] See for example, Boris, M, *et al*, *Association of MTHFR Gene Variants with Autism*, https://www.jpands.org/vol9no4/boris.pdf
[51] El-baz, *et al*, *Study of the C677T and 1298 AC polymorphic genotypes of MTHFR gene in autism spectrum disorder*, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5633227/
[52] Rai, V, *Association of methylenetetrahydrofolate reductase (MTHFR) gene C677T polymorphism with autism: evidence of genetic susceptibility*, https://link.springer.com/article/10.1007%2Fs11011-016-9815-0
[53] Rady PL *et al. Genetic polymorphisms of methylenetetrahydrofolate reductase (MTHFR) and methionine synthase reductase (MTRR) in ethnic populations in Texas*; a report of a novel MTHFR polymorphic site, G1793A. Am J Med Genet. 2002 Jan 15;107(2):162-8.
[54] Mech, AW and AF Farah. *Correlation of clinical response with homocysteine reduction during therapy with reduced B vitamins in patients with MDD who are positive for MTHFR C677T or A1298C polymorphism: A randomized, double-blind, placebo-controlled study*. J Clin Psychiatry 77:5.

a new strain of pandemic swine flu was about to kill millions across America if all were not vaccinated immediately. Many people, believing the propaganda, got the shot and, over a couple months, over 400 died and nearly three times that number developed Guillain Barre Syndrome. As the law suits were filed against the vaccine drug companies, they rapidly withdrew their vaccines. The public record shows no pandemic occurred. Were the vaccine objectors right? Does the vaccine trigger the pandemic? Certainly, it is well documented that viral shedding of potentially infective particles takes place for at least 3 weeks after vaccination, but the shedding may go on for decades.[55],[56],[57],[58]

The vaccine manufactures lobbied the US Congress to permanently absolve then of all liability for anything that might go wrong following the sue of their vaccines, up to, and including, death. They changed the law to exempt the companies, hospitals, doctors and nurses from legal liability for the use of these dangerous products. The 1986 Childhood Vaccine Injury Act took away Americans' First Amendment right to petition the courts for redress for vaccine injuries. Instead Congress ordered that future vaccines must be safer than current vaccines and that a special tax be paid by those who buy vaccines to compensate those injured or killed by vaccines. Since then the "Vaccine Court" agency has paid increasing amounts to the injured -- now over $4.1 billion dollars. When you look at the increase in injury payments it looks the same as the increase in mandated vaccines -- more unavoidably unsafe vaccines, more injuries.

This is not just relevant to the history of medicine. The failure of IOM-reported and repeated concern has consequences today inside the US and outside of it.

Various jurisdictions such as the State of New York seek to restrict redress for vaccine risks by restricting physician-issue medical excuses from vaccination to only a small portion of actual vaccine injuries.

The New York regulation forces conscientious doctors to commit malpractice by preventing them from expressing the information a patient needs to grant, or withhold, Informed Consent.

The Reports indicate that the "public health" bureaucracy knew or should have known for decades that vaccines are unavoidably – and increasingly – unsafe.

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[55] David Jackson, et al, *Viral Shedding in Recipients of Live Attenuated Influenza Vaccine in the 2016–2017 and 2017–2018 Influenza Seasons in the United Kingdom*, Clinical Infectious Diseases, , ciz719, https://doi.org/10.1093/cid/ciz719

[56] Nestibo L, et al. *Differentiating the wild from the attenuated during a measles outbreak*. Paediatr Child Health. 2012;17(4):e32–e33. doi:10.1093/pch/17.4.e32

[57] Alexander, J.P. Jr., Gary, H.E. Jr, and Pallansch, M.A. **Duration of poliovirus excretion and its implications for acute flaccid paralysis surveillance: a review of the literature.** *J Infect Dis*. 1997; 175: S176–82

[58] orba, J., Diop, O.M., Iber, J., Henderson, E., Zhao, K., Sutter, R.W. et al. **Update on vaccine-derived polioviruses - worldwide, January 2017–June 2018.** *MMWR Morb Mortal Wkly Rep*. 2018; 67: 1189–1194

What these same authorities have done with that knowledge is to attempt to prevent conscientious doctors from speaking truthfully about vaccine risks.

For example, the 2019 New York regulation requires that doctors only speak the government's falsity about vaccine risks. They have done that by requiring the good doctors to only write Medical Excuses for the very limited number of adverse reactions recognized by the federal health bureaucracy -- chiefly the AICP agency that "recommends" vaccines. The State statute permitting physician-issued medical excuses does not contain the restrictions, but the regulation does. Thus the regulation restricts the Free Speech Right of physicians to do what is ethical: acting as learned intermediary, provide Medical Excuses where appropriate under the current state of medical knowledge.

That is where the IOM comes into the picture. They clearly show that there is no adequate science regarding either the safety of vaccines or the claimed lack of link to serious medical adverse reactions, such as autism.

Rather, the evidence shows the continued lack of safety and probable link to conditions such as autism. The evidence further shows that the AICP has failed to list numerous vaccine risks thereby restricting licensed physicians as "learned intermediaries" from freely expressing their understanding and issuing justified Medical Excuses.

Dozens of studies reviewed by the IOM show no adequate science to back up the claims of the vaccine drug pushers. There is no proof of efficacy and no proof of safety. This is the smoking gun that reveals the horrific - damaging and deadly - truth behind vaccine industry deception and regulatory agency compliance.

Using the legal concept of an Advance Medical Directive, asserting each person's right under the law to refuse any unwelcome medical intervention, including vaccination, vaccine conscientious objectors developed a specialized Advance Medical Directive specifically for vaccines.
It is a convenient card that can be carried (as some people carry medical cards telling that they are, say, diabetic, or allergic to certain common drugs). The Advance Vaccine Directive card helps express the right of Informed Consent[59]. American courts have said that if the person does not express the lack of Informed Consent, the right is "deemed waived" and that includes if the person is not conscious! However, if one is not conscious medical personnel are supposed to look for any Advance Medical Directive cards on the person and note them on the Medical Chart. To fail to do so – and to fail to honor Informed Consent – would be malpractice.

[59] See: https://tinyurl.com/AVDcard

The right of Informed Consent is, of course, based on the Geneva Convention and the international standards recognized in such documents as the Nuremburg Code[60] and UN Declaration of Human Rights.[61]

In summary, the one contraindication that a medical doctor in certain jurisdictions is to rely upon the ACIP recognition of "previous anaphylaxis shock." This is demonstrably incomplete and out-of-date, adding to the reality that medical doctors, under such regulations, are unable to perform their licensed duties, and unable to serve in the role of informed intermediary in managing vaccine safety for their patient, as required by well-established ethical and legal standards.

The authors of this paper, relying on their combined near century of professional experience, have concluded that the IOM studies show not only the failure of the responsible "public health" authorities, such as CDC and AICP, to accurately recognized serious adverse reactions to unavoidably unsafe vaccines, but also the actual duplicity of those authorized to protect the public from unsafe vaccines, to the extent that national and international laws protecting Informed Consent and the licensed physician as learned intermediary are being knowingly violated. It is ethically intolerable for the current public health policy of favoring mass vaccination to continue to be promoted without regard for the significant level well-documented harm to individuals, generally our most vulnerable citizens, our children. Where there is risk, there must be Informed Consent.

Further, because appropriate (and, in the US, statutorily required) research to test both the safety and efficacy of vaccines and vaccine schedules has not been done, no recommendations can logically or ethically be made by physicians, as learned intermediaries, or public health bodies affirming either the safety or scientific validation of vaccines and any vaccine administration schedule.

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[60] https://history.nih.gov/research/downloads/nuremberg.pdf
[61] https://www.un.org/en/universal-declaration-human-rights/index.html