InformedChoiceWA is an organization of citizens from all walks of life, and all corners of the state. We are more than 1,000 strong and growing. We are proud members of the Coalition for Informed Consent, in support of the national organization, Physicians for Informed Consent.

The February 6, 2017 Senate Work Session on Vaccination presentation contained so many errors of fact and troubling statements, that we, the members of InformedChoiceWA, have prepared an in-depth fully cited and hyperlinked FACT CHECK to ensure legislative decisions are based firmly on published and evidence-based science.

We are concerned that the current science of genetics, epigenetics, immunity, neurotoxicity, and environmental exposure risk factors are not being incorporated into current vaccine design, policy, or the education of physicians we trust to guide us.

FACT CHECK: Senate Work Session on Vaccination

6 February 2017

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Location of Work Session

2017 Legislative Session
J.A. Cherberg Building, Capitol Campus, Olympia

Video link: http://www.tvw.org/watch/?eventID=2017021086 (begins at minute 38)

In Attendance

Senate Health Committee Members:

- Ann Rivers (R) Chair
- Randi Becker (D) Vice Chair
- Annette Cleveland (D) Ranking Minority Member
- Patty Kuderer (D) Asst Ranking Minority Member
- Barbara Bailey (R)
- Steve Conway (D)
- Karen Keiser (D)
- Steve O'Ban (R)
- Maureen Walsh (R)

Guest speakers:

- Dr. Riyad Karmy-Jones – PEACEHEALTH
- Dr. George Dulabon, PEACEHEALTH
- Paul Throne, Health Promotion and Communication Section Manager, HHS
- Dr. Scott Lindquist, State Epidemiologist for Communicable Diseases, DOH (via phone)

INTRODUCTION

(Fact Checking Statements begin on page 10)

Censoring of Public Dialogue

In the February 6th Senate Work Session on Vaccination, **Dr. George Dulabon** stated: ". . .we live in a world of alternative facts, is the present term, that needs to be sequestered and eliminated, alternative facts are untruths, unfortunately credence is given to people who aren't scientists in this field and he [Robert F. Kennedy, Jr.] is somebody that is swaying that argument in the wrong direction."

Dr. Dulabon incorrectly uses the catch phrase, "alternative facts," in his statement about Robert Kennedy, Jr. and a public discussion of vaccine risk. This fully referenced FACT CHECK will provide ample data to support the legitimacy of a discussion on vaccine science and policy.

Dr. Dulabon appears to be calling for censoring free speech on science, simply because the people publicly discussing it are not scientists. This is alarming.

No one publicly enters the vaccine conversation without first taking a deep breath and weighing the consequences very seriously. No one begins to speak about vaccine risks for personal gain; speaking often comes with great personal and professional sacrifice. Most notable are the doctors who have lost their careers over asking questions and the parents whose children are already injured by vaccines who speak out to prevent harm to other children.

Marketing and Liability

Why would speaking about vaccine safety be controversial and professionally dangerous? Who loses if safety issues are revealed?

Vaccines are for-profit products *that come with no liability for injury or death*. While the vaccine market represents a small percentage of overall pharmaceutical industry profits, the income is significant. For example, in 2016, Merck lists their Gardasil, MMR, Varicella, and Pneumovax23 vaccines among their top most profitable products, with combined sales in just one quarter reaching nearly $1.2 billion. Marketing budgets are commensurate, and vaccine makers hire the best in the world to use traditional and social media to systematically keep the fear of disease high, perception of vaccine risk low, and those who speak-out discredited. In response to the media outcry over his announcement of a vaccine safety commission, Robert Kennedy, Jr. said that he'd been warning of the dangers of mercury in fish for years, and nobody was calling him "anti-fish."

Government health agencies such as the CDC, whose influence carries to every clinic in the country and every corner of the globe, also work to minimize dialogue on risk in order to maximize vaccine uptake. This has been the policy for decades.

Federal Register in 1984 (vol 49, no 107):

> **". . . any possible doubts, whether or not well founded, about the safety of the vaccine [polio] cannot be allowed to exist in view of the need to assure that the vaccine will continue to be used to the maximum extent consistent with the nation's public health objectives."**

The above statement calls for a policy of censorship of critical scientific data, which puts individual children at risk of vaccine injury. This unofficial policy permeates every message from every government health agency and mainstream media outlet. Investigation and reporting on vaccine risks, vaccine flaws, and vaccine injuries have become taboo; belittling and shaming anyone who speaks about risks has become the norm.

The classification of a product as a "vaccine" does not automatically confer the status of "safe and effective." Yet "safe and effective" is how health agencies and the media portray vaccines, even when the Supreme Court has labeled them "unavoidably unsafe." As more vaccines are licensed and added to the pediatric schedule, and increasingly aimed at adults, more individuals are experiencing adverse health outcomes, ranging from subtle to catastrophic, following a vaccine or set of vaccines. This leads them to search for help and answers. When they find studies that support their concerns, such as those we present in this fact check, they feel betrayed and begin to speak out, and are then accused of endangering the rates of vaccine uptake.

Fear of the reduction of vaccine uptake has always impacted the decisions and messages coming from the CDC and other health agencies. In 2001, when autism prevalence was 1 in 150, a closed-meeting discussion by an IOM committee about MMR and thimerosal-vaccines revealed the very heart of where we find ourselves today.

Dr. McCormick (pg 33):

> ". . .an issue that we may have to confront, and that is actually the definition of what we mean by safety. It is safety on a population basis, but it is also safety for the individual child. I am wondering, if we take this dual perspective, we may address more of the parent concerns, perhaps developing a better message if we think about what comes down the stream, **as opposed to CDC, which wants us to declare, well, these things are pretty safe on a population basis"** (emphasis added).

Dr. Stratton said (pg. 53):

> "They [the CDC] say – and I believe them – that **people are getting immunized when they really shouldn't**. What if there really is a terrible hidden truth

> about one of these things? Of course, they are worried about immunization rates and whether they are going to go up or down."

Dr. McCormick later said (pg. 97):

> "What I am trying to get at is, do we want to simply, on our gut, say looking at the significance of the wild disease that you are protecting, and the seriousness and *potential* association with the vaccine – **because we are not ever going to come down that it [autism] is a true side effect** – is that going to be sufficient for you to judge public health impact?" (emphasis added).

Why would Dr. McCormick say that they would never "come down that it is a true side effect" before the committee had *even begun to look at the published data*? Before they saw that biological studies and adequately designed epidemiological studies had not yet been done? The CDC wanted the committee to determine MMR and thimerosal were safe on a population basis. That was the final outcome of their reports. Individual safety was sidelined.

As a result, moving forward, individual children were harmed because the factors determining individual risk were not made a priority by the CDC, they were not studied by the CDC (even though CISA was established to locate susceptible populations), and the message became "safe and effective" with the implied meaning of "for all" with those at risk just "one-in-a-million."

Sixteen years later, certain groups of children are still being vaccinated even though the CDC knows they really shouldn't be.

This is about far more than autism. Autism is the hot-button controversial association that deflects from all the other injuries susceptible children are sustaining: seizure disorders, learning disorders, neurological disorders, asthma, allergies, diabetes, tics, autoimmune disorders, and more. The science on these issues is NOT disputed, neither is it being discussed by those who should be looking closely: pediatricians and policy makers.

The control and withholding of scientific data on the subject of vaccine risk has created deep factions in the country, pitting those who look deeply into the science against those who implicitly trust the message of "safe and effective."

Physicians are trained using materials heavily influenced by pharmaceutical companies. Once in practice, physicians are guided by the CDC, AMA, and AAP who all work to perpetuate the one-sided, singular message of "safe and effective."

Since the guidance does not provide accurate and full details of contraindication and risk, physicians cannot be the "learned intermediaries" they are required by law to be. They are not providing a setting in which patients can truly give fully informed consent. The financial success of their practices relies heavily upon 7-minute "well-child visits" and the administration of vaccines for which they, too, have no liability.

It is a dangerous situation. Imagine this happening with any other pharmaceutical category. Most physicians sincerely believe and follow the guidance they are given. They don't have time to research on their own. The few that have, such as Dr. Paul Thomas of Oregon, now practice a personalized approach to vaccination, and success can be measured in zero cases of autism or ASD in the more than 1,000 children born into Dr. Thomas's practice whose vaccination schedules were personalized. Using the CDC autism rate of 1 in 50, this group of over 1,000 children should have had 22 cases of autism.

Dr. Poland's $1 million "grants"

Money is aimed at more than marketing. Last January, a proponent of vaccines, Dr. Gregory Poland, who ironically also coined the term "adversomics," the study of vaccine adverse reactions, spoke to a national organization of state legislators called Women in Government. Following a presentation in which he emphasized the need to greatly increase vaccination in adults, and the need for state leaders to act to increase vaccination, he proposed this:

> If a private donor could be identifies(sic) who would provide each of you a $1,000,000 "grant" IF you developed legislation and policies that materially improved the health of your states and communities –could/would you do it?

Could they? Would they? And who, other than pharmaceutical companies who hope to increase revenues from 24 to 61 billion in the next three years, liability-free, has the money to pay such high rewards to so many people? The legality of such overt pandering – and perhaps bribery – is under scrutiny.

The Regulatory Vacuum and Criminal Fraud

The National Childhood Vaccine Injury Act of 1986 Under Section 22(b)(1) of the NCVIA:

> *"No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings."*

Ruling: On October 12, 2011, in Bruesewitz v. Wyeth, the Court decided Section 22(b)(1) of the 1986 NVICA categorically barred state-law claims alleging that a vaccine was defectively designed. Justice Sotomayor (and Ginsberg) dissented, saying:

> ***"Its decision leaves a regulatory vacuum in which no one ensures that vaccine manufacturers adequately take account of scientific and***

technological advancements when designing or distributing their products."

This means that discoveries about the microbiome, immune system, central nervous system, neurological disorders, genetics, epigenetics, environmental factors that impact mitochondria, and more, are not required to be incorporated into vaccine design or administration.

Medical mistakes are the 3rd leading cause of death in the U.S., according to an analysis published May 2016, in BMJ. Pharmaceutical companies are included in the top 100 False Claim Act cases, and the fines/settlements are in the billions, and hundred-millions. Those with criminal penalties include: GlaxoSmithKline, Pfizer, Merck, Novartis, and Sanofi. These companies all make vaccines. If they are willing to take chances with products for which they have full liability (Vioxx has cost Merck more than $6 billion in fines and fees) what sort of chances are they willing to take with products for which they have no liability?

Doctors also cannot be held responsible for injury or death from the administration of vaccines, and they are under financial pressure to "stick to the schedule" because their practices rely heavily on the income from well-child visits at which vaccines are administered.

Whistleblowers are beginning to step forward. In 2005, two Merck virologists brought forward accusations that they were pressured to falsify efficacy data of the mumps vaccine by adding rabbit antibodies to human serum samples. Merck's stalling has held off trial until now. Discovery is set for end of 2017.

In 2014, a separate whistleblower, Dr. William Thompson of the CDC brought Congressman Posey thousands of pages showing data had been manipulated and falsified in the 2004 MMR-Autism study. Jason Chaffetz, Chair of the House Oversight Committee, is investigating.

In 2016, a group self-named CDC Scientists Preserving Integrity, Diligence and Ethics in Research, or (CDC SPIDER), filed an ethics complaint which they made public, citing corporate and political pressure undermining scientific integrity.

THE SCIENCE IS **NOT** SETTLED

The FDA states:

> ***"Post-marketing surveillance is a necessary component of vaccine safety monitoring" and "because vaccine pre-clinical trials are relatively small and controlled, previously unstudied components of a patient's social or medical history may be risk factors which could impact the outcome of vaccination and contribute to the development of adverse events."***

In other words, it is not known until a vaccine hits the market what genetic, health, or environmental exposures will cause individuals to experience adverse reactions and injuries that were not found during the licensing trials.

The majority of vaccine adverse reactions are not known until *after* the vaccine is approved by the FDA. This means that every child receiving a newly licensed vaccine is a test subject for that vaccine. Parents are not aware of this. Increasingly, doctors are not aware of this, either. They assume once a vaccine is approved by the FDA, it has proved itself safe and effective. They assume that because there were clinical trials that looked at the administration of multiple vaccines at once, that such combinations are safe and effective. When adverse events occur, they do not consider the vaccine(s) as a possible cause. But the licensing and concomitant studies are far too small to predict real world outcomes with real kids with so many factors that were not included in the studies.

If nothing is reported, nothing is learned, nothing is known, and no changes are made to improve vaccine design or administration.

The CDC estimates that only a small fraction of all adverse reactions are reported to VAERS. It is a passive, unenforced system; doctors face no consequences for failing to report an adverse event, even though both the CDC and the VAERS websites both direct doctors to file a report whether or not they believe the vaccine had anything to do with the medical symptoms being witnessed. Doctors tell parents that their child's symptoms are coincidental – that they have nothing to do with the vaccines recently administered -- even when a quick look at the federal table of vaccine injuries would show, in many cases, that the adverse event is listed on the table. Unfortunately, many pediatricians don't even know about the federal table of injuries. The result is that parents are admonished and made to feel foolish for even suggesting a connection to the vaccine.

Note: The U.S. does have another vaccine adverse event tracking system: Vaccine Safety Datalink (VSD) but access by independent researchers is extremely limited. Greater access by independent researchers to this critical data must be allowed.

The "gold standard" of drug safety testing is the double-blind placebo study, but vaccines are not routinely tested against true placebos; aluminum adjuvants or other vaccines are commonly used in control groups as placebos instead of saline.

Adjuvants are not inert substances, nor have the ones in current use been adequately tested for safety; they have been in use for so long, they are allowed as vaccine ingredients without modern safety studies. Nikolai Petrovsky states in *Comparative safety of vaccine adjuvants: a summary of current evidence and future needs*:

> "Both aluminum and squalene oil emulsion adjuvants already in broad human use can be shown to induce major adverse effects in animal models, although relevance of such findings to humans remains unknown. Hence, data from such models is largely ignored when safety determinations are made on new vaccines containing these 'grandfathered' adjuvants."

Petrovsky goes on to say:

> "Regulators instead focus on vaccine safety data collected in rabbits or guinea pigs together with data from human clinical trials to assess vaccine safety. Notably, there remains a need for better scientific explanation as to why specific animal model data showing adjuvant toxicity is not relevant to human use. For example, it has been know(sic) for many years that squalene oil emulsions either alone or when formulated with relevant antigens can induce autoimmune conditions, e.g. adjuvant arthritis, in genetically-susceptible animals. Hence, a consumer might reasonably ask why this animal toxicity data does not predict the possibility of the adjuvant causing autoimmune disease in human subjects who are also genetically susceptible. There is not currently any good answer to this question."

The number of published, peer-reviewed studies on aluminum adjuvant neurotoxicity mounts, and yet the practice of using adjuvants, and other vaccines, as placebos continues. If saline is ever used in a control group, the results are often mixed with the adjuvant control group, making comparison outcomes meaningless. For example, consider the HPV vaccines. They are one of the most controversial vaccine categories worldwide because of reported injuries and death and lack of adequate safety testing. The gold standard of double-blind true placebo testing for Gardasil was only minimally done; for Gardasil 9 and Cervarix it was was never done. Here is a summary of the licensing trials from the FDA:

- Clinical trials supporting licensure evaluated GARDASIL against **predominantly adjuvant only** as well as saline placebo.
- Clinical trials of Cervarix supporting licensure **used the Hepatitis A Vaccine as the control vaccine.**

- GARDASIL 9 was studied in 6 clinical trials, but three of them were co-administration trials; one used **GARDASIL as comparator;** one was an "immunobridging study" for children 9 through 15 years of age, but no testing was actually done in that age group because "evaluation of clinical efficacy was not feasible"; and there was an additional immunological bridging study **comparing GARDASIL 9 and GARDASIL.**

When the results of such studies conclude, "rates of adverse reaction were similar to the placebo group," the results are meaningless. No other pharmaceutical products are allowed to be tested this way. Why do we allow it for products injected into our children?

Once a vaccine is approved and used in the general population, slowly evolving adverse reactions, such as chronic illness, cannot be observed in epidemiological studies that compare partially vaccinated groups to each other. A randomized, prospective vaccinated verses non-vaccinated study is desperately needed.

And finally, the science on the safety and impact of vaccines cannot be declared "settled" in the face of so many scientific discoveries that have not yet been fully explored, such as this:

"They'll Have to Rewrite the Textbooks"

The University of Virginia announced in the March 21, 2016 issue of UVAToday the discovery that the lymphatic system is directly connected to the brain.

> *"It's a stunning discovery that overturns decades of textbook teaching: researchers at the School of Medicine have determined that the brain is directly connected to the immune system by vessels previously thought not to exist."*
>
> *"The brain and the adaptive immune system were thought to be isolated from each other, and any immune activity in the brain was perceived as sign of a pathology. And now, not only are we showing that they are closely interacting, but some of our behavior traits might have evolved because of our immune response to pathogens,"* explained Jonathan Kipnis, chair of UVA's Department of Neuroscience."
>
> *"But the true significance of the discovery lies in its ramifications for the study and treatment of neurological diseases ranging from autism to Alzheimer's disease to multiple sclerosis."*

Everything about vaccines and vaccine administration should be reevaluated based on this and other recent scientific discoveries. The true scope and magnitude of adverse events are not known. The science is not settled.

FACT-CHECKING STATEMENTS

Vaccines and Autism

Dr. Karmy-Jones: ". . . there is anecdotal linkages there's really no systemic evidence that vaccines are linked to autism; autism is a genetic based disorder that can have environmental triggers that effect different children differently in different ways, but it's genetic and vaccines are not the environmental trigger . . ." And a later comment: ". . . a lot of theories behind it [rise in autism rates], obviously environmental triggers, but also if you knew me and George a little more and you knew our wives, you'd say, yes that couple could have an autistic kid- they tend to get together – and then the high tech, there's all this stuff about Microsoft and 'autism city' . . ."

FACT CHECK:

- We agree that genetics and the environment are involved; however, the latest science shows that autism is not predominantly a "genetic disorder" but rather genetic susceptibility to environmental exposures. PMIDs: 25327347, 26781481, 26725748
- "A comprehensive literature search has implicated several environmental factors associated with the development of ASD. These include pesticides, phthalates, polychlorinated biphenyls, solvents, air pollutants, fragrances, glyphosate and heavy metals, **especially aluminum used in vaccines as adjuvant.**" Environmental factors in the development of autism spectrum disorders [PMID: 26826339]
- There is no such thing as a "genetic epidemic." The marriage of software engineers or doctors who have similar traits may produce children with similar traits – but we are not discussing an increase of quirky, brilliant children. We are discussing an increase of children with serious, debilitating behavioral, cognitive, immune system, neurological, and gastrointestinal issues.
- We recognize that in the past there were some who were said to have mental retardation, but who turned out to be more similar to "Rain Man" as was mentioned in the Work Session. And yes, there have been those individuals who grew up in the earlier part of the 20th century who were likely misdiagnosed. But those individuals were far fewer and farther between than the numbers of autistic people we see today, and those older individuals' ranges of symptoms do not reflect the devastating symptoms of today's exponentially increasing autistic population, who are suffering from toxic overloads, immune system dysfunctions, seizure disorders, allergies, tics, gastrointestinal issues and many other often ignored physical disorders that add pain and trauma to an autistic individual's life. We do not have a comparable older population of autistic

individuals who have constant seizures, who need to wear helmets to protect them from head-banging and injury due to their seizures, who wear diapers, who throw their feces at the wall, who have rages and breakdowns on a regular basis, and who need constant monitoring and protection from self-injury. These autistic individuals deserve biomedical healing, and we believe that it is medical neglect to fail to look into the medical issues at the root of this population's struggles. It is not enough to say we value them as individuals. Of course they are valued, and they deserve to have their medical issues addressed.

- Epidemics *can* be caused by genetic susceptibility to changed environmental factors. A wide variety of genes have now been found to be autism-susceptibility genes, and they cover a wide variety of sub-populations. The very genes responsible for creating the types of people who succeed in medicine and engineering may also render them a population subgroup susceptible to modern-day toxins and factors, including vaccines, which have increased substantially in the past several decades.
- A 2011 paper titled UNANSWERED QUESTIONS FROM THE VACCINE INJURY COMPENSATION PROGRAM: A Review of Compensated Cases of Vaccine-Induced Brain Injury states: "This preliminary study suggests that the VICP has been compensating cases of vaccine-induced encephalopathy and residual seizure disorder associated with autism since the inception of the program. Through this preliminary study, the authors have found eighty-three (83) cases of autism among those compensated for vaccine-induced brain damage. This finding raises fundamental questions about the integrity, transparency, and fairness of the program."
- The subject of autism is too complex to present in full here. We have arranged for each member of the Senate Health Committee to receive a copy of a comprehensive new book on the subject: THE ENVIRONMENTAL AND GENETIC CAUSES OF AUTISM by Dr. James Lyons-Weiler, *Ph.D., Evolutionary Biology, with postdoctoral studies in molecular evolution and functional genomics*. Citations in the book can be found online at https://envgencauses.com/author/envgencauses/

Dr. Karmy-Jones – ". . . but it really came down historically and emotionally it came down initially to the MMR vaccine and the argument that the thimerosal was the toxic element in it because these vaccines were stored with a bit of mercury in it, and there's enough environmental mercury around in our drinking water and arsenic and everything else, but it just was never shown to be true, but that's it, it was predominantly the MMR and then the other vaccines that go along with it."

FACT CHECK: There is not, nor has there ever been, thimerosal in the MMR.

- Live virus vaccines would be destroyed by thimerosal. We don't understand the point Dr. Karmy-Jones was attempting to make by saying there is

mercury in drinking water. The federal limit for mercury in drinking water is .001mcg/.50ml. Some flu vaccines contain between 1-25mcg per .50ml dose. That's between 1,000 and 25,000 times more mercury. It is estimated that for the 2016-17 flu season, vaccine makers will produce between 37-48 million doses of vaccines with 25mcg thimerosal per dose. The other 120 million doses are estimated to be "preservative free" but some contain up to 1mcg per dose. Millions of children and adults will receive a full dose or small dose of thimerosal this flu season.

- Before the surge of parental reports of severe adverse reaction to MMR began, the DTP vaccine injuries had begun to undermine faith in the safety of vaccines, as well as faith that health authorities were telling the truth about individual risk. Here is an NBC special news program about the topic. Such programs on vaccine risk are not allowed to be aired today.

The Danish Study

Dr. Karmy-Jones: "Numerous large studies, the classic which you could argue some points, was the Danish study, which was done in the face, it was done by NAAR, which is the National Alliance of Autism Research, which is the seed group to fund legitimate research, they have the autism brain program, and everything like that, they were just scientists, people who want good science, they didn't care what the result was they just wanted the studies to be good, and although the Denmark study has a little bit of question marks to it, they took the entire population of Denmark for eight years and compared those children who did not receive vaccines verses those who for the entire eight year period did, and there was no difference in the incidence of autism in the entire population."

FACT CHECK:
The Danish study (see details below) did not compare vaccinated children to non-vaccinated children. The study compared children vaccinated with other pediatric vaccines including the MMR against children vaccinated with other pediatric vaccines not including MMR. For population groups susceptible to vaccine injury, such a study could never conclude, as Dr. Dulabon suggested, that "vaccines don't cause autism."

Only one vaccine—MMR—and one ingredient—thimerosal—have ever been studied for their connection to autism, and only with epidemiological studies despite biological mechanistic evidence showing plausibility—and never using a fully non-vaccinated control group.

MMR:

- In a 2001 closed IOM meeting, Dr. Wilson gave several theories as to biological plausibility of MMR leading to autism, pages 160-166: ". . .we know that each of these three viruses is, in fact, neurotropic."
- The IOM committee stated in the Adverse Effects of Vaccines: Evidence and Causality (2012) report:
    - "The MMR vaccine has been hypothesized many times over the years to cause neurologic disorders, including encephalitis or encephalopathy. A demonstrated biologic mechanism exists for this association, because natural (wild-type) measles clearly infects the central nervous system (CNS) and can lead to clinical neurologic events. In addition, maternal rubella virus is known to produce CNS-related birth defects."
    - "Although biologic mechanisms exist for neurologic effects, the totality of biological, clinical, and epidemiological data led previous IOM committees to conclude that the evidence was inadequate to accept or reject a causal relationship between MMR vaccine and encephalopathy, subacute sclerosing panencephalitis (SSPE), or residual seizure disorder (IOM, 1994a)." **IFCWA Note: inadequate evidence simply means the**

studies had not been done, not, as the CDC has co-opted it to mean "No Study Has Shown", implying incorrectly that the appropriate studies have been conducted. The absence of evidence is not evidence of absence of an effect.

- Vaccine-induced encephalopathy is listed in the specific injuries recognized by the Special Masters "Vaccine Court", and these conditions are listed as possible adverse events on the MMR vaccine product insert. Autism has been ruled a consequence of, or sequela of, encephalopathy by the Vaccine Court. Transitive logic dictates, "If A causes B, and B causes C, then A is a cause of C." If vaccines cause encephalopathy, and if encephalopathy causes autism, then vaccines are a cause of autism.

THE DANISH STUDY

The Danish study referred to is *"A population-based study of measles, mumps, and rubella vaccination and autism."* N Engl J Med. 2002 Nov 7;347(19):1477-82. PMID: 12421889

The study was supported by grants from the Danish National Research Foundation; the National Vaccine Program Office and National Immunization Program, Centers for Disease Control and Prevention; and the National Alliance for Autism Research. This was not a vaccinated vs. non-vaccinated study. The study looked at MMR vaccination status only. The "points" that could be argued are widely known and, in our view, invalidate the study.

- In 2004, the Institute of Medicine (IOM) Immunization Safety Review committee said of the Madsen study, "However, despite the reanalysis the authors stated that autism incidence after 1995 may have been exaggerated due to the change in including outpatient cases into the Danish Psychiatric Central Register. This limits the study's contribution to causality."

- The study included children who weren't in the study long enough either to have been given the MMR vaccine or for autism status to be known following MMR vaccine exposure. More flaws described HERE.

- Many experts analyzed the Madsen study and found serious weaknesses that undermined the validity of the study. Some of these were presented to Congress in 2002. Overall it was found that the Madsen study was not designed to be able to determine if MMR was responsible for autism in any subgroup of children. While it could possibly determine that MMR was not the cause of all cases of autism, it could not determine if MMR was responsible for a portion of autism. See Committee on Government Reform Hearing.

- When the IOM in 2012 again included this study in their Adverse Effects of Vaccines: Evidence and Causality (2012) report they noted, "One of the authors

of this article, P. Thorsen, was indicted for embezzlement on April 13, 2011. The implications for the integrity of the study are unknown at this time." Thorsen is still a wanted man.

- This study is a clear example of data over-analysis, which plagues vaccine research. The association of vaccines with autism was originally found in the data, but could only be diminished after adjustment for potential confounders, including the age of vaccination. Age of vaccination is not a confounder; as with all other pharmaceutical products, it is a critical risk factor. Age at which vaccination was given was also manipulated in other studies suspected of fraud (DeStefano et al., see whistleblower statement by Dr. William Thompson), or their results dismissed as a clustering of concerned parents, without further evaluation of whether that clustering had an artifactual or real basis—such as exposure to MMR.

Other Studies: Limited in number, power, and accuracy

Dr. Karmy-Jones: " . . . many other datas (sic), and you can say, you can argue with some of the studies, question this, what about the partially vaccinated, but you have these wealth of huge, thousands of patients studied that say there is no link, compared to 13 anecdotal non-studied patients with flukey connections"

FACT CHECK:

- It is essential in a conversation that impacts the health of children to stick to facts. The numbers of studies—all of them epidemiological—are limited. When in 2012, the IOM surveyed the entire body of published works to examine the possible connection between MMR and autism, they found just 22 studies that met their parameters. Upon closer examination, 17 of those "**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.**" Of the 5 remaining, one, Madsen et al, as explained above, came with a footnote explaining the unknown integrity of the study. More flaws described HERE. Of the remaining 4: Taylor et al included just 498 children; Farrington et al was a reanalysis of Taylor (and a close reading reveals they dismissed a rise in autism following MMR as due to increased parental reporting); Smeeth et al included just 4,469 children; Mrozek-Budzyn et al, just 96 children, and IOM said, "This study was rated as having serious limitations."

Since 2012, several other studies have emerged. See "Analysis of two recent vaccine-autism studies."

- The number of anecdotal connections between vaccination and autism is unknown, but they exceed 13. They exceed 13,000. They exceed 130,000. Far from being "flukey," they are consistent with the diagnosis of encephalopathy, with recognizable symptoms ranging from high fever, high-pitched inconsolable crying (a well-known sign of encephalitis), head-banging, followed by loss of language and loss of previously acquired skills, to reports of health and development progressively diminishing with each successive round of vaccinations.
- **These anecdotes are dismissed as coincidence even though, as was said above, post-marketing surveillance is critical to discovering adverse reactions in real-world situations.**
- Observation is the first step in science. Correlation is not causation; correlation is observation and a strong signal further investigation is needed. Studies to date have been epidemiological, comparing partially vaccinated groups to each other, have used incorrect placebos, and suffer from the major drawbacks we have cited.
- Autism is primarily a result of genetic susceptibility to environmental factors. Epidemiological studies are not designed to identify susceptible individuals, and cannot reliably detect the effect when the reaction is, at the population level, rare (1 out of 50 equates to 2% of population.) Such studies treat autism as if it were a whole-population effect, and, further, they rarely (if ever) publish power calculations to show that they were large enough to detect relatively rare events at 1-2% of the population.
- Subsequent meta-analyses conducted, which are cited as "large studies" (because they combine results from many smaller studies) used the results from studies that the IOM found to be flawed, and are no more powerful than the least-powered study included. In other words, combining results from many low-powered studies, each of which failed to detect an effect, does not make the meta-analysis more powerful.
- The CDC has only looked at MMR and thimerosal in relation to autism, and never with a fully non-vaccinated control group. The CDC schedule now includes vaccinations against 14 diseases, many with boosters, using excipients and adjuvants that have never been studied for safety when injected in infants and children whose central nervous, immune, and reproductive systems are developing. Children receive 23 injections (some multi-valent) before age 18 months, and a total of 53 injections (some multi-valent) by age 18. To claim "vaccines don't cause autism," when using partially-vaccinated children as a control group and epidemiological studies based on one vaccine and one ingredient, is intellectually dishonest, and is unscientific. It is neither deduction, nor induction. It is just making an unwarranted claim.

Scourge of Disease

Dr. Dulabon: "We've seen recently in years where vaccines have been avoided by parents where outbreaks of measles which is such a highly communicable disease has spread, mumps recently here locally, and people forget the scourge of these diseases, the deaths it caused, blindness, deafness, heart disease, that is associated with these diseases that we don't have modern memory for."

FACT CHECK:

- Dr. Dulabon refers to the pre-vaccine era "scourge" as if all these deaths and complications from disease were suddenly stopped only once vaccines were introduced. But he neglects to mention the period of history that directly preceded the vaccine era, in which the introduction of water chlorination, the mitigation of vitamin deficiencies, and new understandings of sanitation and hygiene caused the death and complication rates of disease to drop significantly before the vaccines were even introduced.
- Vaccination rates are high, at nearly 97% complete or in the process of becoming complete for all required vaccine series for school children in WA state. Driving rates higher cannot prevent all incidence of infection.

  The recent mumps outbreak is in highly or fully vaccinated populations.
- All diseases for which vaccines have been invented cannot be lumped together and called a "scourge." Dr. Dulabon says we have no modern memory for these diseases; he should perhaps review the medical and popular literature of the 1950's and early 1960's, as well as social-attitude indicators such as television programs of the era, to see that measles, mumps, rubella, and chicken pox were considered mild, extremely common, and part of normal childhood.
- Before the introduction of vaccines, parents intentionally exposed their children to infected friends and siblings in order to ensure that several common infections were experienced at the appropriate age, thereby attaining lifetime immunity (or as in the case of chicken pox, protection that lasted well into adulthood when natural 'boosters' in the form of exposure to children with chicken pox prevented cases of shingles.) This was immunization before the age of vaccination.

It is important to understand the definitions of efficacy and effectiveness in a discussion about the impact of vaccination on a population. The CDC uses these terms as if they are interchangeable: they are not. An accurate definition can be found in the 2012 study, *Distinguishing Vaccine Efficacy and Effectiveness*, which states:

"The interchangeable use of terms used to measure and parameterize vaccine efficacy and effectiveness can lead to inaccurate parameterization of epidemiological

models and needs to be made explicit. Vaccine efficacy measures the protective effects of vaccination by the reduction in the infection risk of a vaccinated individual relative to that of a susceptible, unvaccinated individual. In contrast, depending upon the study design of clinical trials, population-level vaccine effectiveness can be further categorized into the 'direct', 'indirect', 'total' and 'overall' impact of the vaccine."

It is important to look at the "overall" impact of any vaccine on a population to truly measure risks verses benefits.

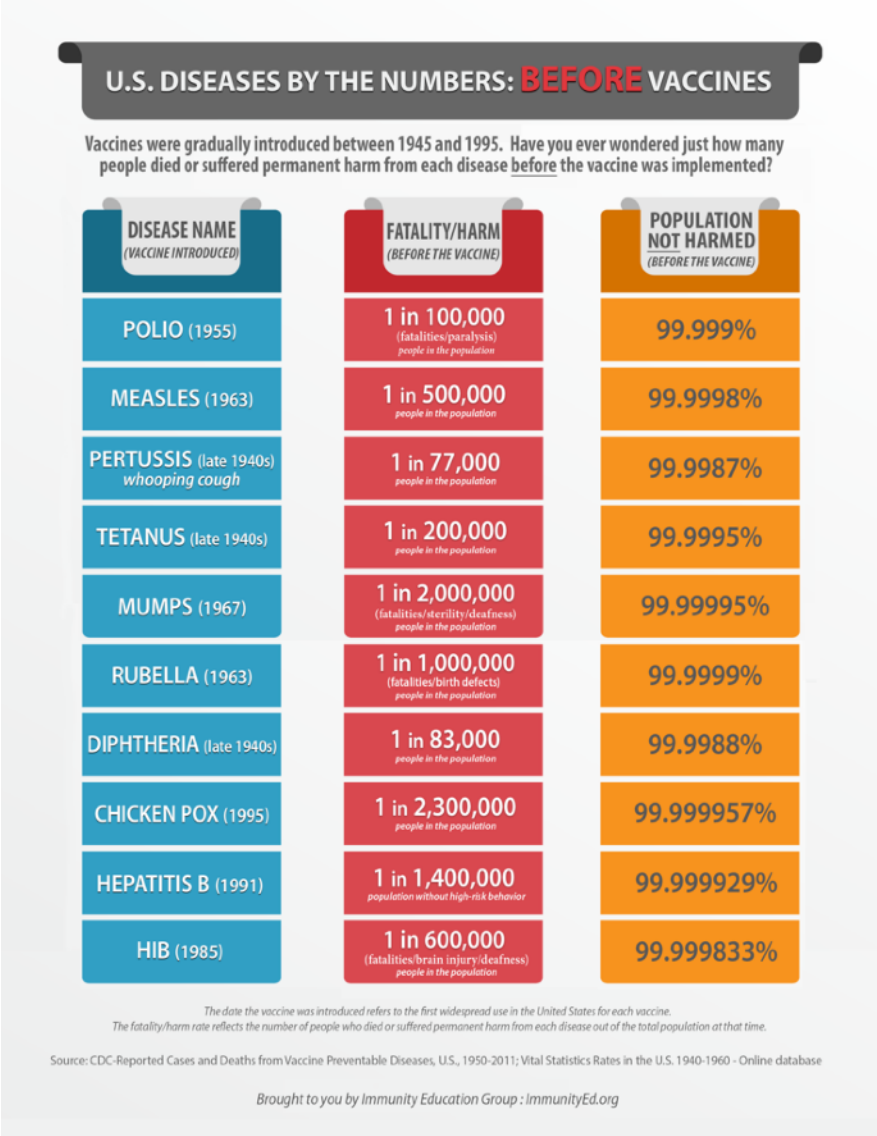
- While we have all seen charts that highlight the reduction in disease incidence after the introduction of vaccines, it is important to understand that these are *absolute numbers*, reflecting the reduction in the number of cases of a particular disease diagnosed. These charts do not reflect changed diagnostic criteria, nor the actual *overall effectiveness* of the vaccine—whether disease burden is reduced, as one might measure in days missed from school or work, whether the financial and human burden of adverse events (grossly underreported) is taken into account, or whether the financial burden of administering the vaccine is greater or less than the financial burden of the disease itself.
    - For example, disease reduction charts do not account for changes in diagnostic criteria after the introduction of a vaccine, which was the case with polio. Many patients who would have been diagnosed with polio in the pre-vaccine years were diagnosed with "aseptic meningitis" after the vaccine was introduced. As polio cases went down, aseptic meningitis cases went up.
    - Similarly, in India, the incidence of acute flaccid paralysis has risen in direct proportion to the rate at which polio has been reduced.
    - In terms of the flu, a recent study has shown *Increased risk of noninfluenza respiratory virus infections associated with receipt of inactivated influenza vaccine*.
    - Other countries have decided against adding the chicken pox vaccine to the schedule because of its contribution to the increased rate of shingles, which is much more expensive to treat. PMID: 22659447 No re-calculation of the cost to society due to morbidity associated with shingles effecting lost work days has, to our knowledge, been considered in rendering public health policy on chicken pox vaccination.
    - As for HPV, vaccine-strain infections have declined, **but non-vaccine strain infections have increased** because of strain replacement. It is unknown the impact these other strains will have on cancer rates.
    - Type replacement is also an issue with the Hib vaccine: "Following routine childhood vaccination against Haemophilus influenzae type b (Hib) disease in Brazil in 1999, passive laboratory surveillance reported

increasing numbers of non-b serotypes and nontypeable H. influenzae (NTHi) from meningitis cases."

- And as for the acellular pertussis portion of the DTaP and the Tdap, in the 2013 meeting of the Board of Scientific Counselors at the CDC, "Findings indicated that 85% of the isolates [from six Enhanced Pertussis Surveillance Sites and from epidemics in Washington and Vermont in 2012] were PRN-deficient and vaccinated patients had significantly higher odds than unvaccinated patients of being infected with PRN-deficient strains."
- When a vaccine is introduced, it is not enough to look only at the reduction in cases of the disease; one must always consider the unintended consequences that may result in the shifting of the financial and human burden from one category or age group to another, without any net benefit.

- It is true that a small percentage of cases of naturally acquired diseases resulted in severe reactions, and we don't mean to make light of those cases or say that vulnerable populations don't need protection. We simply want decisions about vaccination to be based on true historical, medical, and scientific fact.
- The Disneyland measles outbreak has been used to attempt to raise panic, but it should have been hailed as a public health success story. In all, just 147 cases of measles occurred among vaccinated, non-vaccinated, and those whose status was unknown. There were no deaths, and rapid notification of those potentially exposed stopped the spread.
- It is impossible with today's measles vaccine design to eradicate all incidence of measles. It does not confer full immunity to everyone, immunity wanes, and some fully vaccinated people will still catch and carry measles.
- The mumps vaccine (now facing fraud litigation) is not able to prevent all incidence of mumps. For most people, mumps is a mild infection, and experiencing it confers lifetime immunity.
- Pertussis (whooping cough) vaccine is for personal protection only. It's about 70% effective, wanes after five years, and does not prevent the colonization or transmission of pertussis, thereby creating atypical carriers. More vaccination simply creates more atypical carriers; it is a dilemma scientists are working on. Use of rapid diagnostic technologies should be explored and further developed.
- Panicking everyone with exaggerated fear is not a solution and does not improve public health. These diseases are only dangerous among certain vulnerable populations. Unwarranted panic is not useful, unless one's only goal is to sell more vaccines to an already highly vaccinated population—some of whom, as we have explained, should not be vaccinated.

- It is no longer justifiable to continue to focus solely on the protection of those who are vulnerable to a complication and bad outcome from disease at the expense of those who are vulnerable to vaccine injury.
- **Lawmakers and health authorities now find themselves in the very dangerous position of being responsible for any incidence of a vaccine-preventable disease, no matter how minor, while having absolutely no responsibility for the incidence of adverse reaction to vaccines.**
- Ignoring the fact that Dr. William Thompson of the CDC confessed to fraud in the 2004 MMR-autism study is not the answer.
- Ignoring the fact that Merck is on trial for falsifying data on the MMR is not the answer.
- Keeping the MMR as the only choice for measles, mumps, and rubella vaccination in the face of whistle blower testimony, in the face of parental reports of adverse reaction, in the face of the biological plausibility that MMR adverse reactions can lead to neurological disorders, is not the answer.



Thimerosal

Dr. Dulabon: In response to a question about the type of mercury in vaccines, Dr. Dulabon said, "Thimerosal component has been removed from the vaccines so it is no longer an issue now, and retrospective studies looking at whether that was linked . . . and the answer is no, so they removed it anyway just to take it out of the equation but in retrospect it was not a causal agent, so it's kind of a moot point."

FACT CHECK:

- Thimerosal remains in multi-dose flu vaccines, and some single doses. FDA table.
- See the Simpsonwood transcripts:

  - Thimerosal does cause autism and other neurological disorders. "...the earlier you work with the central nervous system, the more likely you are to run into a sensitive period for one of these effects, so that moving from one month or one day of birth to six months of birth changes enormously the potential for toxicity. There are just a host of neurodevelopmental data that would suggest that we've got a serious problem. The earlier we go, the more serious the problem."
  - "The second point I could make is that in relationship to aluminum, being a nephrologist for a long time, the potential for aluminum and central nervous system toxicity was established by dialysis data. To think there isn't some possible problem here is unreal."

- To learn about the history and science of thimerosal, visit the World Mercury Project.

  Excerpt from Thimerosal FAQ page:

  Myth: But the ethyl mercury in Thimerosal is less toxic than the methyl mercury in fish. After all, humans can drink ethyl alcohol even though methyl alcohol is poisonous.

  ***Fact**: The science shows that ethyl mercury is actually more toxic than methyl mercury. . . Ethyl mercury is 50 times more toxic than methyl mercury (Guzzi et al, 2012 PMID 23554557) and twice as persistent in the brain (Burbacher et al, 2005 PMID: 16079072).*

- May 2016, cancer researchers discovered that thimerosal downregulates a protein called ERAP1, which is responsible for peptide trimming. Errant peptide trimming is a hallmark of autism. *Screening Identifies Thimerosal as a Selective Inhibitor of Endoplasmic Reticulum Aminopeptidase 1.* PMID: 27437077
- January 2017, the CDC published this study which states: "The alkyl mercury compounds methylmercury (MeHg) and ethylmercury (EtHg) have been shown to be toxic to humans and non-human animals as well (Driscoll et al. 2013). Both of those compounds have similar chemical properties, and both have been shown to disrupt the normal function of the CNS in a variety of animal species. The details of this study include the mechanisms of thimerosal toxicity. *Alkyl Mercury-Induced Toxicity: Multiple Mechanisms of Action*. PMID: 27161558
- In 1999, "FDA's Center for Biologics Evaluation and Research (CBER) was responsible for adding up the cumulative exposure to mercury from infant vaccines, a simple calculation that, astonishingly, had never been performed by either the FDA or the CDC. When the agency finally performed that basic calculation, the regulators realized that a six month-old infant who received thimerosal-preserved vaccines following the recommended CDC vaccine schedule would have received a jaw dropping 187.5 micrograms of mercury." Read more here: CDC Knew Its Vaccine Program Was Exposing Children to Dangerous Mercury Levels Since 1999

Flu Vaccine

Dr. Karmy-Jones: ". . .flu vaccine does not guarantee you against the disease, it can't mitigate against it but as the population increases and more and more children are not vaccinated, the vaccinated children and their families are at risk, too."

FACT CHECK:
We agree that the flu vaccine is not a guarantee against the flu and can't mitigate against it. We disagree that increasing flu vaccination rates would positively impact community or individual health because of the limitations and risks of the flu vaccine.

- Effectiveness rates range 10-60% per the CDC
- Annual vaccination lessens effectiveness. PMID: 25270645
- Mandatory vaccination of health workers not supported by data. PMID: 28129360
- *Increased risk of noninfluenza respiratory virus infections associated with receipt of inactivated influenza vaccine*. PMID: 22423139
- A healthy person with a robust immune system can resist influenza infection without vaccination. A healthy person will not spread infection. It's unscientific to say that everyone must accept the known risks of a vaccine to protect the community. Maintaining immune health, avoiding immune-suppressing drugs such acetaminophen, and staying home when infectious, are proven ways responsible citizens can protect themselves and the community. Vaccination should be undertaken only with fully informed consent.
- The FDA has not licensed the flu vaccine, or any vaccine, for use during pregnancy. CDC recommendations are given despite the fact that the sort of safety studies required by the FDA for licensing for pregnant women, studies that ensure the safety of the fetus, have not been done.
- The flu vaccine is new each year and even more experimental than other vaccines. Safety and effectiveness are never known until the season has passed.
- Thimerosal is found in multi-dose and some single doses. FDA table.
- "As of June 30, 2016, there have been more than 128,194 reports of reactions, hospitalizations, injuries and deaths following influenza vaccinations made to the federal Vaccine Adverse Events Reporting System (VAERS.)" See more details at NVIC.org

Rubella

Dr. Karmy-Jones: "And if you have a daughter whose having her second child, is pregnant, is dropping off their kid at pre-K and comes exposed to a child who's pre-dromal (sic) with rubella and now you've been exposed to rubella with a 1 in 5 chance of having significant birth defect that's a major health impact."

FACT CHECK:
We agree that rubella is dangerous to a fetus; caution and protection should be afforded pregnant women. The single rubella vaccine should be made available to young women of childbearing age who either did not experience wild rubella in childhood, when it is a minor illness and confers lifetime immunity, or who were not vaccinated in childhood.

Currently, the rubella vaccine is only available in the controversial MMR vaccine, the efficacy of which is now seriously in doubt due to Merck's alleged spiking of human serum samples with rabbit antibodies, and the safety of which is in serious doubt (See CDC whistleblower Dr. William Thompson).

Debunked Science

Dr. George Dulabon: " . . . debunked concept that vaccines are associated with autism, that is clearly debunked, science can't always tell us why, but can rule out vaccines"

FACT CHECK:
Again, studies based on one vaccine (MMR) and one ingredient cannot rule out an association with autism when the vaccine schedule includes many more vaccines and ingredients than the MMR and thimerosal.

The use of the term "debunked" in this context is always meant to deflect the conversation from current science toward Dr. Andrew Wakefield in order to engage emotions and close minds to the factual landscape of the subject. Most people are not familiar with the details of the Lancet paper nor its conclusion, so we provide a few details here, and links to explore, so that opinions can be formed based on full knowledge, not hearsay. We'll mention key points:

- The 1998 paper entitled "Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children" stated, "We did not prove an association between measles, mumps, and rubella vaccine and the syndrome described. Virological studies are underway that may help to resolve this issue." There is nothing in this paper to "debunk" as it clearly does not claim a causal link; it merely states a hypothesis.
- The paper had 13 authors, and was a case series, not a clinical trial study.
- The controversy arose from articles written by a journalist and published in the BMJ. It has been speculated that financial ties to Merck, the makers of MMR, by many parties involved, influenced the unfolding of events.
- Dr. Wakefield never proposed stopping vaccinating for measles. He suggested separating out the M, M and R, and use of the single measles vaccine while further studies were conducted on the MMR. He has stated his own position on vaccines very clearly: he is not "anti-vaccine."
- MMR hesitancy resulted not because of the Lancet paper, but because of new parents having friends and family whose child regressed after MMR.
- Despite the claims that thousands died as a result of the slight lowering of MMR rates in some places, the actual data shows measles deaths since 1998 in both the US and England somewhere between 20-40 (depends on if measles was actually confirmed). Measles data from third-world nations does not correlate at all to conditions in the U.S.
- Rather than ensure individual measles, mumps, and rubella vaccines were made available while parental reports of adverse reaction were thoroughly

investigated, inexplicably, **Merck pulled single vaccines from the market**, leaving parents with the MMR or nothing. Merck lists the MMR as one of their top most profitable products (for which they have no liability for injury or death). And the suit against them for potential fraud re: efficacy is going forward in spite of their attempt to secure dismissal.

- The Lancet paper itself, and one of the authors who had the resources to afford a legal appeal, were fully exonerated. A British High Court stated: *"For the reasons given above, both on general issues and the Lancet paper and in relation to individual children, the panel's overall conclusion that Professor Walker-Smith was guilty of serious professional misconduct was flawed, in two respects: inadequate and superficial reasoning and, in a number of instances, a wrong conclusion . . . The panel's determination cannot stand. I therefore quash it. Miss Glynn, on the basis of sensible instructions, does not invite me to remit it to a fresh Fitness to Practice panel for redetermination. The end result is that the finding of serious professional misconduct and the sanction of erasure are both quashed."*
- Regardless of the Lancet study, and the many issues with the studies that the CDC uses to claim that vaccines don't cause autism, there are more recent studies that must not be ignored, that provide compelling insights into the immunological and environmental causes of autism. Much of this research has been compiled into THE ENVIRONMENTAL AND GENETIC CAUSES OF AUTISM by Dr. James Lyons-Weiler, which we have provided for each member of the Senate Health Committee, as well as a new article that can be read here.
- For doctors and media outlets to carelessly and repeatedly use the word "debunked" and refer back to the old controversy is irresponsible. Science has moved forward. The conversation needs to move forward, too.

Vaccine Side Effects

Dr. Karmy-Jones: "**.** . . vaccines can have some side effects, not autism, but other side effects,"

FACT CHECK:

Side-effects should not be swept aside as minor or infrequent occurrences.

With autism, again, studies based on one vaccine and one ingredient cannot rule out an association when the vaccine schedule includes many more vaccines and ingredients than the MMR and thimerosal, and when the studies considered by the CDC for MMR & thimerosal are inadequate (please see sections on MMR and thimerosal.) Autism is a "side effect" of vaccination for some susceptible individuals. Please see THE ENVIRONMENTAL AND GENETIC CAUSES OF AUTISM by Dr. Lyons-Weiler.

The subject of vaccine adverse events/reactions is vast and far beyond the scope of this Fact Check. Because autism's connection to vaccination is controversial, it tends to override the many other chronic health issues associated—medically validated and scientifically proven—with vaccination.

The following are a just a few examples, taken from the CDC's Vaccine Information Sheets:

--Severe problems have been reported after DTaP vaccine. These include: long-term seizures, coma, or lowered consciousness, permanent brain damage.

--There may be a small increased risk of Guillain-Barré Syndrome (GBS) after inactivated flu vaccine.

--Severe problems have been reported after a child gets MMR vaccine, including: deafness, long-term seizures, coma, or lowered consciousness, permanent brain damage.

--Other serious problems, including severe brain reactions and low blood count, have been reported after chickenpox vaccination.

While the CDC states that the above reactions are rare, there is no basis on which to determine the actual frequency of these adverse events. As was mentioned earlier, the Vaccine Adverse Events Reporting System is a passive reporting system and it is estimated that only a small percentage of adverse events actually make it into the VAERS database.

Most doctors pre-judge the adverse event as having nothing to do with the vaccine, and therefore do not report it, even though the CDC and VAERS websites direct doctors to file reports whether or not they think that the patient's symptoms have anything to do with the vaccine.

More information on adverse events:

- See vaccine inserts, available at the FDA.
- The Vaccine Adverse Event Reporting System (VAERS) injury table
-

Chronic illnesses striking children today in ever-rising numbers are associated with environmental factors, including vaccination. Studies reveal that Asthma, ADHD, Seizures, Autoimmunity, Tics, Developmental Delay, Psychiatric Conditions, Diabetes, Food Allergies, Neurological disorders, and more are linked to vaccines and vaccines components. We are building a database of studies that will be available on our website. Available now are pages on Aluminum and Mitochondria.

As an example, consider Food Allergies, which CDC says now effects 1 out of 14 children:

- Evidence that Food Proteins in Vaccines Cause the Development of Food Allergies and Its Implications for Vaccine Policy
- "The above-mentioned antigens [gelatin, ovalbumin, casamino acid] do occasionally induce IgE-mediated sensitization in some individuals and subsequent hypersensitivity reactions, including anaphylaxis." Adverse Effects of Vaccines: Evidence and Causality (2012) report.
- How do you give mice food allergies? Inject them with the same aluminum adjuvant used in vaccines. *Novel insights into mechanisms of food allergy and allergic airway inflammation using experimental mouse models*. PMID: 23106364
- The Effects of Environmental Toxins on Allergic Inflammation. Allergy Asthma Immunol Res. 2014 Nov;6(6):478-484. https://doi.org/10.4168/aair.2014.6.6.478

Contraindications

Dr. Karmy-Jones: " . . . if your child happens to have the flu, you probably don't want to get a vaccine right then you may want to put it off, so there is some scope for a little bit of moving it around."

FACT CHECK:
We agree that vaccination at the time of a current illness is contraindicated, but it happens all the time. Medical staff are now ignoring all sorts of contraindications and warning signs.

Recently, the CDC proposed weakening the MMR Vaccine Information Sheets; when the public objected (in public comments), the CDC censored the opposing comments (completely, or partly). This censoring was reversed after citizens objected to their loss of First Amendment rights. A sensible risk-minimization plan that would identify the need for medical exemptions for certain patients is a major area of vaccine safety reform that must be addressed.

Vaccination in the presence of a mild virus infection, displaying no or minimal symptoms, may be related to current cases of Acute Flaccid Myelitis (AFM). This paper, *Polio provocation: solving a mystery with the help of history*, explains how vaccination in the presence of wild polio virus can lead to paralysis. The author did not consider that the presence of other wild viruses at the time of vaccination may also lead to paralysis via the same mechanism. AFM has been linked in some cases to Enterovirus D68, which belongs to the same enterovirus family as polio. But with doctors refusing to consider recent vaccination as a possible factor in AFM, the science will never be done, and proper precautions not taken.

There are known health and environmental exposure situations that either compromise or suppress the immune system temporarily, and/or impair mitochondrial function, but AAP and CDC guidelines do not reflect the current science, and in fact increasingly push for vaccination without due caution.

It has been established that having a compromised immune system or impaired mitochondria increases risk of adverse vaccine reaction, including autism (Hannah Poling case), but no safe level of suppression or impairment has ever been established. The precautionary principal indicates that vaccination in the presence of these factors should be avoided until the immune system has had sufficient time to fully recover. Changing CDC and AAP guidelines on just these two products: acetaminophen (Tylenol) and antibiotics could reduce vaccine injuries. A full list of common drugs that impair mitochondria can be found at Mitoaction.org.

It must be noted that acetaminophen appears to be one contributing cause of autism.

- Here are a few of many studies:
  - “Prenatal acetaminophen exposure was associated with a greater number of autism spectrum symptoms in males and showed adverse effects on attention-related outcomes for both genders. These associations seem to be dependent on the frequency of exposure.” PMID: 27353198
  - *Autism genes are selectively targeted by environmental pollutants including pesticides, heavy metals, bisphenol A, phthalates and many others in food, cosmetics or household products* PMID: 27984170
  - *Acetaminophen study yields new insights into neurobiological underpinnings of empathy*. PMID: 27707814

The Pediatric Schedule

Dr. Dulabon: “The concentration in the vaccination schedule has been determined by pediatric and infectious disease experts as to be the safest once again for the population basis . . .”

FACT CHECK:
The AAP also makes this claim. In their "Countering Vaccine Hesitancy" guide, the AAP states: “THE CURRENT VACCINE SCHEDULE IS THE ONLY RECOMMENDED SCHEDULE. It is extremely important that the pediatrician remain up to date on the current recommended vaccine schedule and support it as the only evidence-based schedule that has been tested and approved by multiple authoritative experts for safety and efficacy.”

Their footnote citation, the 2013 IOM Childhood Immunization Schedule and Safety: Stakeholder Concerns, Scientific Evidence, and Future Studies, actually refutes this conclusion. IOM states:

> "Providers are encouraged to explain to parents how each new vaccine is extensively tested when it is approved for inclusion in the recommended immunization schedule. However, **when providers are asked if the entire immunization schedule has been tested to determine if it is the best possible schedule, meaning that it offers the most benefits and the fewest risks, they have very few data on which to base their response.**"
>
> And:
>
> “Although the committee identified several studies that reviewed the outcomes of studies of cumulative immunizations, adjuvants, and preservatives (see Chapter 5), **the committee generally found a paucity of information, scientific or otherwise, that addressed the risk of adverse events in association with the complete recommended immunization schedule**, even though an extensive literature base about individual vaccines and combination immunizations exists.”

We question why the AAP deliberately misrepresents the IOM’s findings. Dr. Dulabon’s belief in the AAP’s position reveals the extent of the influence the organization has on the education of physicians. There’s a huge difference between “tested and approved” and a “paucity of information, scientific or otherwise.”

Pediatricians rely upon AAP and the CDC for guidance in their busy practices. If the guidance is not accurate, doctors cannot be the “learned intermediaries” they are required by law to be. The result is routine denial of patients’ rights to informed consent for medical procedures.

And we remind readers that clinical trials have limited subjects that do not represent the spectrum of genetic, health, and environmental factors found in the general population. Physicians should know, and parents should be told, that not all reactions are known, that they should all be alert to any reaction, to report and monitor and treat any reactions, and to proceed at a pace based on the INDIVIDUAL CHILD'S RESPONSE. Licensure trial studies lead to the introduction of a vaccine to the public but are not a guarantee that all populations in all situations will respond positively. Physicians should know this. Parents should be told. That is the basis of fully informed medical consent. This is NOT happening in America today. Reactions are happening, they are being disregarded and dismissed. Children are being injured. Because of the regulatory vacuum, no one is responsible. No one.

The same AAP publication also states:

> "The opposition to the presence of aluminum as an adjuvant in some vaccines can be addressed by providing evidence for both the necessity of the aluminum for a vigorous immune response and the lack of evidence for its toxicity."

We refer readers to the Aluminum page on our website for published studies on aluminum neurotoxicity. The amount of aluminum in vaccines exceeds the federal limit for all other parenteral products. Ingested aluminum is poorly absorbed (0.1-0.2%), whereas ALL parenteral aluminum, including from vaccination, is absorbed 100%. The limits set for pediatric vaccines are based on studies of ingested not injected aluminum, and on adult body weight and exposures. The results of a soon-to-be-published study on the topic will be presented at THE FUTURE OF IMMUNITY conference on March 11.

It's important to note that Dr. Dulabon qualified his statement with the term "on a population basis." He is acknowledging, and he states clearly later, that some individuals do NOT benefit from the one-size-for all vaccine schedule.

It is unethical to vaccinate all children as if their health situations are identical. We cannot continue sacrificing individual children to a program that is not designed to serve their needs.

Personalized medicine, personalized vaccination schedules, respect for parents' decisions: those are the only ethical approaches.

Individual Risk

Dr. Dulabon: ". . . what's best for the population may not be best for every single individual child but this is where the cost-benefit ratio has to be weighed."

FACT CHECK:
It may have been acceptable in the past, when little was known about the immune system and individual risk factors, to accept the collateral damage of a blanket vaccination policy. Today, when much is known, when personalized evaluation can minimize individual risk while maximizing community benefit, it is unethical to push a one-size-for-all agenda.

Not all families share the same burden of risk, and as a potentially identifiable minority (identified unfortunately by their vaccine injuries) those who are at risk of vaccine injury are entitled to equal protection under the law.

Former National Institute of Health Director Bernadine Healy wrote in 2008, wrote:

> " . . .are certain groups of people especially susceptible to side effects from vaccines, and can we identify them? Youngsters like Hannah Poling, for example, who has an underlying mitochondrial disorder and developed a sudden and dramatic case of regressive autism after receiving nine immunizations, later determined to be the precipitating factor. Other children may have a genetic predisposition to autism, a pre-existing neurological condition worsened by vaccines, or an immune system that is sent into overdrive by too many vaccines, and thus they might deserve special care. **This approach challenges the notion that every child must be vaccinated for every pathogen on the government's schedule with almost no exception, a policy that means some will be sacrificed so the vast majority benefit.**

Dr. Healy added:

> "Less than a year ago, the National Institutes of Health put out a call for expanded research on vaccine safety that contains many of the very things that parents are asking for: examination of the way the immune system handles different vaccines, the impact of nonvaccine components (like mercury and aluminum), and better understanding of susceptibility to vaccine side effects. The government laid out the need for markers that might predict vulnerable groups and proposed research on the comparative effect of different vaccine schedules and combinations of vaccines. This work is long overdue; shockingly, so is a study comparing groups of vaccinated and unvaccinated children."

Though a government-sponsored vaccinated vs. unvaccinated study has yet to be done, the Mayo Clinic's Gregory Poland has been studying the different ways that different groups respond to vaccines, acknowledging that an individual's genetic

profile determines whether or not a vaccine is even needed and the level of individual risk involved in using a particular vaccine:

> "This is really important in terms of how we deliver vaccines, how we design vaccines, perhaps the safety of vaccines, and this is new information in the biologic field that is going to change how we practice medicine. The vaccine in essence is working differently. The question is why – it's the same vaccine in human beings administered the same way, and yet it stimulates a very different set of gene expression and protein secretion -- that protein being antibody that protects us when we see the virus."
>
> "But the interesting thought occurs to me – maybe we only have to give African Americans half the size dose that we give to Caucasians. That's an example of individualizing our approach to somebody. Eventually what will happen is it won't be something as complicated as race; it will be genetically based. So we will look at somebody's genes that are important to developing immunity, and based on which ones they carry, say, you don't need the vaccine; you're not at any risk. Or you need twice the dose of the average person, or half the dose. Or you're at risk for this kind of side effect. And that changes how we practice medicine. It's an exciting new era in that regard. So we may be able to save cost. We may be able to reduce the amount of side effects. If you only need half as much vaccine to reach the same level of protection, we're adding cost and potentially risk by giving you double what you actually need."
>
> "Fundamentally, what it begins to do is build a scientific case and database for this idea. If we see these kinds of dramatic differences for this vaccine, will we see it with another vaccine, and the answer is yes." Dr. Gregory Poland, Mayo Clinic

Informed parents are well aware of the work of cutting-edge scientists such as Dr. Poland. Informed parents are angry when they continually witness their children's vaccine-related adverse events and are continually dismissed by doctors who have not been made up-to-date on the latest vaccine science that points to the necessity of a personalized approach. Informed parents are angry when, in the face of these new scientific advances, the mainstream narrative as delivered by doctors, politicians, and media alike, continues to hammer the doctrine of a one-size-fits-all approach to vaccination. The grossly underreported VAERS includes over 6,400 deaths attributed to vaccination. The callous disregard for vaccine injury is unconscionable.

More than half of American children have at least one chronic illness, including asthma, allergies, seizures, autoimmune diseases, ADHD, autism, seizures, and other neuro-developmental disorders. All of these are known to have environmental causes, including adverse reactions to vaccines, or are known to be secondary reactions to adverse reactions, and all of them are associated with aluminum toxicity, various immune reactions, and/or thimerosal. But no one is tracking long-term outcomes of the pediatric vaccination program, and there have been no studies with fully non-

vaccinated control groups. This, and the fact that the CDC and FDA rely so heavily on post-market surveillance, means that every person ever vaccinated has been enrolled in a clinical trial without their explicit consent. This violates several standing rules and regulations governing human subjects during experimentation, which are especially stringent for studies on pregnant women and children.

There are effective vaccination strategies that are safer at the individual level than mass vaccination programs, such as “ring” style vaccination (vaccinating at-risk-of-exposure populations) which should be explored to provide community protection while minimizing the number of vaccines used, and minimizing risk to injury-susceptible individuals who could be identified. This assumes, of course, that the vaccine currently available is safe and effective.

The pertussis vaccine, for instance, has been found to provide protection for only about five years before it begins to wane, and it does not prevent the colonization or transmission of pertussis, thus creating atypical carriers. This is why it is so important to understand the limitations of each vaccine, and the nature of the disease it is meant to prevent, and to convey these facts to health authorities and the public. Being vaccinated comes with the responsibility of understanding and respecting these facts. For instance, being vaccinated does not ensure you will **not** carry pertussis to a newborn.

Developing improved rapid-diagnosis technologies, employing tried-and-true isolation methods (staying home from school or work when ill), and health education to encourage robust immune systems based on current understanding of immunity, are several components of community health strategies that are low cost and non-invasive.

Delaying and Spacing Vaccines

Dr. Dulabon: "The problem being if you delay or change that vaccination schedule without data that's a problem. Anything changed should be supported by scientific data so that once again should be based on those that do this research."

FACT CHECK:
We agree. Yet the CDC has continually added vaccines to the schedule without sufficiently studying the overall safety of the entire schedule. As stated above, the full schedule has never been studied for safety or benefit.

There is no scientific consensus among developed nations regarding the vaccine schedule. For example, HepB vaccine, with 250 mcg of aluminum, exceeds by 74 mcg/kg/day the CFR/FDA limit of 5 mcg/kg/day, and is not given at birth in most other countries. HepA vaccine requirements differ around the world.

Some countries choose not to vaccinate for chicken pox at all because such programs increase shingles' rates, as has happened here. In fact, in the U.S., there is not even a consensus from state to state regarding the vaccines that are on the school-required schedule.

The only safe and beneficial schedule is the one tailored to fit an individual child's unique genetic, health, and environmental-exposure needs, while always respecting the informed choice of the parents. To NOT individually evaluate each child for susceptibility to adverse reaction risk before every vaccine administration is unethical.

Dr. Lindquist: " . . . choosing one vaccine over another to eliminate is not a reasonable choice."

FACT CHECK:
Not every vaccine was placed on the pediatric schedule for the individual child's benefit. For example:

- Varicella (chicken pox) vaccine was included for financial not health reasons, in order to reduce the number of days parents may have to stay home from work because of a sick child. Great Britain chose not to include the chicken pox vaccine because the nature of the disease meant such a program would increase chicken pox and shingles in adults, which is what has happened in the U.S. Unforeseen was the increase in shingles in the childhood population. PMID: 22659447 No re-calculation of the cost to society due to morbidity associated with shingles effecting lost work days has, to our knowledge, been considered in rendering public health policy on chicken pox vaccination.

- HepB vaccine birth dose was added, not because the majority of infants were at risk of infection, but because "efforts to vaccinate persons in the major risk groups have had limited success."

  "The three major risk groups (heterosexuals with multiple partners or contact with infected persons, injection-drug users, and men who have sex with men) are not reached effectively by targeted programs. Deterrents to immunization of these groups include lack of awareness of the risk of disease and its consequences, lack of effective public or private sector programs, and vaccine cost. Difficulty in gaining access to these populations is also a problem."

- Newborns that are not at risk of HepB exposure are nevertheless subjected to the risk of a vaccine with 250mcg of aluminum. It is unethical to subject a newborn to risks for which there is no individual benefit. Even if the child develops antibodies in infancy, protection will have waned before the child reaches the age at which risky behavior would lead to exposure.
- This study found HepB vaccine tripled the risk of autism in boys. *Hepatitis B Vaccination of Male Neonates and Autism*, Annals of Epidemiolgy, 2009.
- This study revealed HepB vaccine and human host epitope matches "among fundamental human proteins such as adhesion molecules, leukocyte differentiation antigens, enzymes, proteins associated with spermatogenesis, and transcription factors." The study concluded: "Given the premises illustrated under the Introduction, these data warn against adverse side-effects of active vaccination using entire HBV antigens. " *Hepatitis B virus and Homo sapiens proteome-wide analysis: A profusion of viral peptide overlaps in neuron-specific human proteins.* PMID: 2880343

Censoring Science

Dr. Dulabon: "Problem is we live in a world of alternative facts, is the present term, that needs to be sequestered and eliminated, alternative facts are untruths, unfortunately credence is given to people who aren't scientists in this field and he [Robert Kennedy, Jr.] is somebody that is swaying that argument in in the wrong direction. Quelling emotion, looking at science objectively is what really should guide decisions in this arena, and I am concerned about the sway of the general public's opinion based on someone who is essentially not scientifically trained in this field."

FACT CHECK:
As mentioned in the introduction, we find it alarming that Dr. Dulabon is calling for a censorship of science, simply because it is being discussed by a non-scientist, and because the science does not fit with his current opinions, which appear to be based on misinformation being dispersed by organizations such as the AAP. We do not doubt Dr. Dulabon's passion for this topic, nor do we fail to understand his personal connection. Many of us with InformedChoiceWA have children with autism and we fully understand the everyday stress and anxiety he must experience. But we must not allow public dialogue on vaccine risk to be censored, nor can we allow major organizations and agencies to disseminate misinformation about vaccine science. We are not calling for censorship of those organizations and agencies. We are calling for accountability.

It is also disingenuous for Dr. Dulabon to say that Robert Kennedy, Jr. should not speak about the science of vaccines while *he* speaks to the Senate Health Committee as an authority figure on vaccines. He admitted he is not an expert on the subject and said he deferred to the experts; yet he gave many statements as if they were fact. He was speaking about a subject he did not know in depth, certainly not the depth that should be required to help educate policymakers. He believes the MMR once contained thimerosal (he voiced agreement when Dr. Karmy-Jones gave the misinformation), and throughout this fact check, we provide ample evidence that his knowledge of vaccines is at best at the surface level, and full of common misconceptions that have no backing in science.

The silencing of public discourse on vaccine safety must end.

Dr. Peter Doshi, Associate Editor of the British Medical Journal (BMJ 2017;356:j661) wrote recently:

> *"....approaches that label anybody and everybody who raises questions about the right headedness of current vaccine policies — myself included — as "anti-vaccine" fail on several accounts....they lump all vaccines together as if the decision about risks and benefits is the same irrespective of disease....or vaccine type — live attenuated, inactivated whole cell, split virus, high dose,*

low dose, adjuvanted, monovalent, polyvalent, etc. This seems about as intelligent as categorizing people into "pro-drug" and "anti-drug" camps depending on whether they have ever voiced concern over the potential side effects of any drug....Contrary to the suggestion — generally implicit — that vaccines are risk free (and therefore why would anyone ever resist official recommendations), the reality is that officially sanctioned written medical information on vaccines is — just like drugs — filled with information about common, uncommon, and unconfirmed but possible harms."

Dr. Chandler said in a comment to this article:

"One problem that I have noted with medical journalism as well as with public health authorities regarding vaccines is the near complete avoidance to recognise the progress which has been made in the area of vaccine safety science.

There is an emerging field within vaccinology called adversomics which acknowledges the fact that adverse events following immunisation (AEFI) may be individually determined. This field is based upon the research that has identified that there is inter-individual variation in vaccine responses based upon differences in innate immunity, microbiomes, and immunogenetics."

Curing Autism

Dr. Karmy-Jones: ". . . if you talk to my son, well he can't talk but he can tell you he knows he can never be cured and he is concerned that all this drive to cure autism means that he is less than anyone else . . . I went to some of the early meetings, there was this organization called DAN, Defeat Autism Now, very nice people . . . so I went to one of their national meetings, and I can tell you that I got cornered by FBI conspiracy theorists, there was a plaintive attorney gave a talk about how we should sue all the vaccine companies . . ."

FACT CHECK:
Many members of InformedChoiceWA know the exhausting, frustrating, emotional journey a parent takes in trying to understand and help their child with autism. No member of our group believes that a child's autism means that he or she is less than anyone else. The goal isn't to get rid of a child's autism (although for some, losing the diagnosis is possible); the goal is to heal our children's underlying medical issues so that they can reach their full potential, whatever that potential may ultimately be. Attempting ABA (Applied Behavioral Therapy) to change behavior when a child is in constant pain, full of toxins and out of balance, is cruel. Behavioral interventions should only be attempted once a medical healing plan is underway.

We regret Dr. Karmy-Jones' experience at an early DAN conference was not a positive one. The field of functional medicine and the science of the gut-brain connection have grown tremendously in the past decade. We encourage him, and others with children impacted by autism and other neurodevelopmental disorders to explore biomedical approaches to heal the medical and physical issues that undermine health and happiness of those diagnosed with autism.

For some children, because of the gut-brain connection, healing medical issues also removes the behaviors and symptoms that led to an autism diagnosis. For others, their baseline after biomedical healing may still place them in the "neurodiverse" category. However, neurodiversity need not be emotionally, socially, or physically disabling. We can celebrate our children while healing their medical issues, and we can keep them well by protecting them from further exposure to the environmental factors to which they are genetically susceptible and that undermine their full potential.

Perhaps the difference between Vaccine-Risk-Aware parents and doctors who deny risk is that we have taken the time to look at more science. A percentage of the aluminum from vaccines (and any source) that makes it into our bodies goes to the brain, and stays there for decades. Both aluminum and mercury can contribute to mitochondrial dysfunction and to life-long chronic microglial cell activation. None of this is "safe."

Some of our members have found success with MAPS (Medical Academy of Pediatric Special Needs) doctors, and Functional Medicine.

- Emerging Roles for the Gut Microbiome in Autism Spectrum Disorder [PMID: 27773355]

- Autism, like cancer, is predominantly caused by genetic susceptibility to environmental factors. We know smoking, radiation, and certain chemicals cause cancer even though not everyone exposed to them gets cancer. We continue to search for cures for cancer, even though genetic susceptibility plays a large role in determining who may get it. We don't think any less of a person susceptible to cancer, we do all we can to protect them. It should be the same for those diagnosed with autism, and those susceptible to environmental factors that can lead to an autism diagnosis.

- It is unethical to vaccinate a child according to the full CDC schedule when that child is genetically or otherwise susceptible to vaccine injury. While not all susceptibility genes are known, some are, such as the MTHFR gene mutation, which impairs methylation and the ability to detoxify. Other known signs of susceptibility exist such as family history of seizure, autoimmune disease, eczema, and more. A personalized approach to vaccination, with each child uniquely evaluated and carefully monitored for severe or subtle reactions, is the only ethical policy.

Breast milk immune factors

Dr. Dulabon: In response to being asked if breast milk provided immunity to infants, Dr. Dulabon replied, “In regards to breast milk providing immunity against these diseases, it does not, and that is a thing that is inarguable, so the vaccines are required.”

We are astounded that Dr. Dulabon is not be aware of the depth of medical literature, from published studies to textbooks, on the passage of maternal antibodies to their babies during breastfeeding.

FACT CHECK:

- *Breastfeeding provides passive and likely long-lasting active immunity.* PMID 9892025
- *Mechanisms behind breastmilk's protection against, and artificial baby milk's facilitation of, diarrhoeal illness.* PMID: 22053500
- *Breastfeeding protects against illness and infection in infants and children: a review of the evidence.* PMID: 11550600
- *Human breast milk immunology: a review.* “Human milk is a bodily fluid which, apart from being an excellent nutritional source for the growing infant, also contains a variety of immune components such as antibodies, growth factors, cytokines, antimicrobial compounds, and specific immune cells. These help to support the immature immune system of the newborn baby, and protect it against infectious risks during the postnatal period while its own immune system matures.” PMID: 17269587
- The Science of Mother's Milk
-

Too Many Vaccines: Antigens

Dr. Lindquist, State Epidemiologist: "This concept that children receive too many vaccines, that's based on a theory that we now present 14 different diseases, that can be as many as 26 inoculations early in life and sometimes even 5 at once, but let me remind you, I studied the initial manuscript by Jenner . . .which was the first vaccine we had in this country against smallpox, and that smallpox disease presented well over 200 viral proteins . . . current advances in protein chemistry, protein purification, and recombinant DNA technology, all vaccines that I talked about, those 14 add up to a total of only 150 antigens so even with our current regimen, antigens that are presented in these vaccines, it's much less than the original . . .so there's really no scientific basis that children who receive too many vaccines . . . "

FACT CHECK:
It is not the overall number of antigens that today pose risks of adverse reactions.

- As antigens decreased, the amount of adjuvant increased. Please see these studies on aluminum neurotoxicity.
- Even though the number of antigens is fewer, the adjuvant ensures the immune response is strong. It is the *immune response* in some individuals, in some cases, that becomes excessive, leading to injury.
- Unlike Jenner's time, antigens now are altered and genetically modified. Long term effects for exposure to these modified viral antigens is not known.
- Antibodies produced are not the same as those produced from wild exposure. PMCID: PMC281321
- Bypassing the innate immune system (especially dendritic cells) to trigger the adaptive response with altered antigens combined with multiple ingredients does not elicit the same immune reaction, clearing of disease, or lasting protection as wild exposure.
- The full pediatric schedule has not been tested for safety, nor have all the variety of "catch-up" schedules. See the "Pediatric Schedule" section above. While the antigen count may be low, the immune system must mount a response to many types of disease antigens simultaneously. Studies have not been done for all combinations, nor in the diverse genetic and health groups found in the general population.

- Other vaccine components have not been tested for safety. Example: Polysorbate 80 (tween 80), an ingredient in many vaccines, and in one brand of synthetic Vitamin K shot administered at birth, has the known capability of crossing the blood-brain barrier and carrying substances with it. PMCID: PMC4279133 Polysorbate 80 has been linked with premature ovarian failure.

Too Young? Trillions of bacteria exposures vs vaccine antigens.

Dr. Lindquist: "The other concept people feel strongly about is that children are too young to be vaccinated. . . .we carry over a hundred trillion bacteria living on our skin, in the lining of our nose, throat, intestines, each of these bacteria contain between 2000-6000 immunological components that a child has to make up an immune response, if they didn't, these get infections . . . the food we eat isn't sterile, the water we drink isn't sterile, the dust we inhale isn't sterile, and in response, infants as well as adults make large quantities of immunoglobulins everyday to prevent colonization from these bacteria and viruses, so putting in that perspective, vaccines, these 150 antigen challenges are a drop in the ocean of what children encounter and manage every day. There is really just no scientific evidence that children are too young to be vaccinated."

FACT CHECK:
The immune response to disease antigens differs widely from the immune response to the bacteria that colonize us and are integral to the functioning of our immune system, and different from the immune response to such things as non-sterile dust and food.

- The hundred trillion bacteria that live in and on us are an integral part of our immune system, our "biomes." Not only are they not pathogenic, we can't live without them. Our immune response to them is not the same as it is to disease antigens. We need those bacteria to colonize.
- Infant immune systems are designed to allow trillions of bacteria to establish the gut microbiota, as well on the skin and in every orifice. Infants are not yet prepared to fight infection on their own (which is why immune protection passing from mother before, during, and after birth through breast milk are so important.) "A New Look at Immunity in Newborn Infants: A newfound role for active suppression."
- Infant immune systems are neither ready to fight infection NOR respond to vaccines.
    - "The fetus and newborn face a complex set of immunological demands, including protection against infection, avoidance of harmful inflammatory immune responses that can lead to pre-term delivery, and balancing the transition from a sterile intra-uterine environment to a world that is rich in foreign antigens. These demands shape a distinct neonatal innate immune system that is biased against the production of pro-inflammatory cytokines. This bias renders newborns at risk of infection **and impairs responses to many vaccines.** This Review describes innate immunity in newborns and discusses how this knowledge

might be used to prevent and treat infection in this vulnerable population." PMID: 17457344

- The non-sterile food we eat and dust we breathe initiate mucosal immune responses that involve gut-associated or bronchial-associated lymphoid tissues and produce primarily IgA for mucosal surfaces and secretions such as saliva and breast milk. In contrast, vaccination responses (via injection) involve lymph nodes and produce primarily IgG that goes into the serum. These two immune responses are very different in how they are orchestrated. For instance, different types of lymphocytes are involved. The number of antigens that can be handled via mucosal immunity differs from lymph node capability. When lymph nodes are handling something, they swell due to proliferation of lymphocytes there. We do not have swollen lymph nodes all the time when in a healthy state because we are not engaging them all the time, but only at times of emergencies, when there is an infection going on that has breached the mucosal surface. And remember the 2016 announcement that the lymphatic system is directly tied to the brain? We have to rewrite all the textbooks.

Clean Water

Paul Throne: " . . . vaccines are of medical history's most prominent miracle . . . perhaps with the exception of clean water . . ."

FACT CHECK:
We agree that access to clean water is the most important factor in the reduction of infectious disease fatalities. This graph from the CDC clearly shows that clean water had dramatically reduced rates long before the introduction of the Salk vaccine.

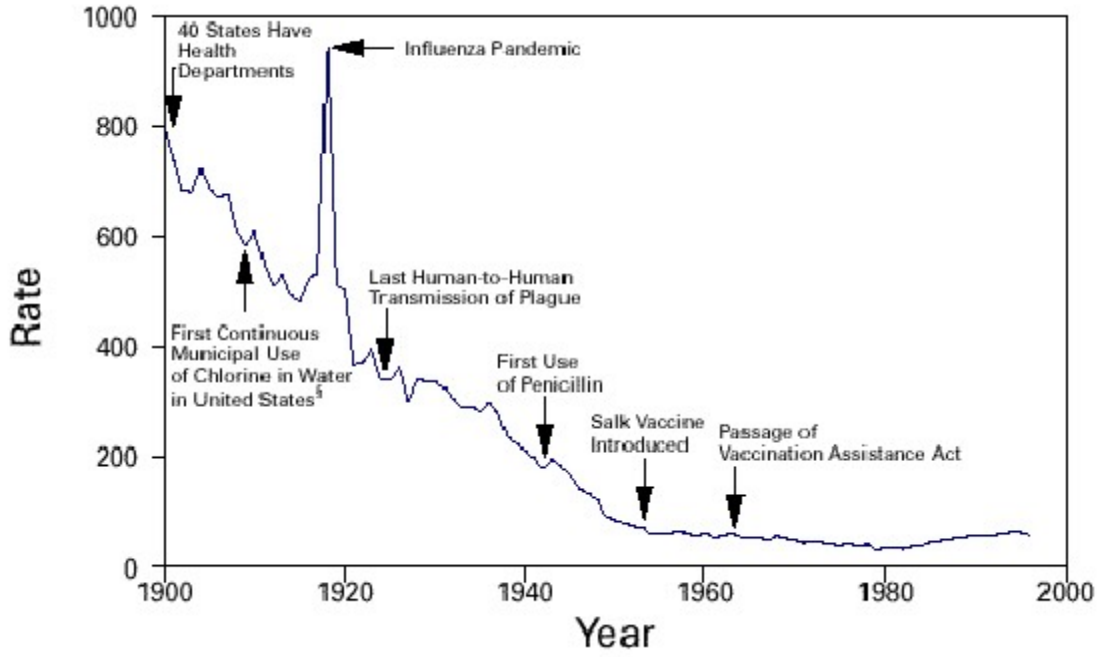


Figure 1. Crude death rate* for infectious diseases - United States, 1900-1996

Before the introduction of most vaccines, because of improved water, sanitation, and new understandings of the impact of nutritional deficiencies, mortality rates had already dropped to very low numbers in the U.S.

Calling vaccines a "prominent miracle" is a deliberate exaggeration of their role in reducing fatalities, and meant to minimize perception of vaccination risks.

Yes, we must protect those who are at risk of a severe reaction to an infection—to any infection, not just those that have corresponding vaccines. We must also protect those who are at risk of severe reactions to vaccination. We cannot put the lives of those who may succumb to disease ahead of the lives of those who may succumb to vaccination. We now have the ability to identify both groups; we must identify them and find the best methods of protection.

Morbidity—the rate of infection—and its impact on public health must be individually assessed *for each disease*. Vaccines have reduced the number of reported cases; this fact does not in itself mean improved public or individual health. Pre-1963, most cases of measles, mumps, rubella, and chicken pox were mild, experienced at the appropriate safe age, and conferred lifetime immunity. Parents did not see a need for vaccines for these infections, and they routinely intentionally exposed their healthy children to siblings or neighbors who had come down with them in order to be sure they were protected as adults. It was immunization before the age of vaccination.

Serious complications from disease did occur for some people; however, serious adverse reactions are occurring with vaccination at greater rates than are recorded. Our point is not to make light of the potential seriousness of infection, but rather to show the facts as they truly are.

We have replaced naturally acquired immunity through exposure to wild infection with artificially induced antibodies through injection of altered and genetically modified disease. And these artificially induced antibodies alone do not constitute immunity, see Correlates of Vaccine-Induced Immunity and FDA study. The two types of immunity are not equal in quality or duration, and the trade-off is not without risk.

Lawmakers and health authorities now find themselves in the very dangerous position of being responsible for any incidence of a vaccine-preventable disease, no matter how minor, while having absolutely no responsibility for the incidence of adverse reaction to vaccines.

The low efficacy of certain vaccines, and the possibility of Merck falsifying efficacy data on the MMR places lawmakers in an awkward position of having to try to understand how vaccine-preventable infectious diseases like measles and mumps have been spreading in highly vaccinated populations. Vaccines are far from perfect. They are not a miracle, but rather, a tool that must be used wisely.

Rate Data

Paul Throne: ". . . However, we have not yet reached the 80% goal, which is the herd immunity threshold that we think will protect people best, from most of these vaccine preventable diseases."

FACT CHECK:
The graph shown by Mr. Throne to indicate our state's overall "poor" vaccination rates was misleading. It was for all *recommended* (not school-required) vaccines for an age group *too young to start school* yet.

When one looks at the actual K-12 rates for vaccines required for school attendance, the vaccine with the highest rate of exemption is for Chicken Pox at 3.2%. The other vaccines are only exempted in the 2.9 - 3.1% range.

96.8% of Washington K - 12 students are not exempt for any school attendance required vaccine series. They are either complete or in the process of becoming complete.

97% are either complete or in the process of becoming complete for the MMR vaccine series.

Of the 3% with exemptions for the MMR vaccine, 2/3 of those exemptions have received the first of the two MMR injections in the series, which produces sufficient measles antibody titers in over 95% of those vaccinated with the first MMR.

What vaccination objective is not achieved with a 97% compliance rate?

Mumps And Current Outbreak

Paul Throne: Speaking about mumps: "It's an extremely serious disease . . ."

FACT CHECK:
Mumps can, very rarely, have serious complications. For most, it is mild and uncomplicated. the CDC states: "Some people who get mumps have very mild or no symptoms, and often they do not know they have the disease. Most people with mumps recover completely in a few weeks."

Paul Throne: "MMR is 88% effective with 2 doses."

FACT CHECK:
This 88% quoted effective rate from the CDC is currently in some doubt. "Former Merck Scientists Sue Merck Alleging MMR Vaccine Efficacy Fraud: Stephen A. Krahling and Joan A. Wlochowski, former Merck virologists blew the whistle by filing a qui tam action lawsuit in August 2010. The scientists allege that the efficacy tests for the measles, mumps, rubella vaccine (MMR) were faked. The document was unsealed in June, 2012." This case is still moving through the court system and discovery is expected by the end of 2017.

Dr. Lindquist: Summary of statements on Mumps: Mumps outbreak appears to have started in a local Marshallese community in south King County; medical histories revealed high levels of vaccination; transmission not happening in adults; born before 1957 not at risk; Health Department looking at the genetic makeup of the mumps virus that they're isolating and sent samples to the CDC to be fingerprinted; WA strain does match what's breaking out across the US; the CDC looking at whole genome sequencing to see if virus shifted from the current makeup of the vaccine.

FACT CHECK:
We agree with Dr. Lindquist that the mumps outbreak in fully vaccinated populations among school age children reveals the limitations of the mumps vaccine, and we believe it appears to confirm the Merck whistleblower accusations, and perhaps indicates a viral shift. Those born before 1957 likely have natural immunity because before the introduction of the vaccine, nearly every school age child was exposed to wild mumps (and measles and rubella) and developed lifetime immunity.

- In Spokane county, as of 2/17/17, 139 of 75,885 who were complete for 2 MMR injections got mumps; 6 of 3,256 exempt kids got mumps, which means **both the fully vaccinated and the exempt groups had the exact same infection rate of .18%**
- Because mumps is a mild illness for most school age children and confers lifetime immunity, a calm and common sense approach to mumps outbreaks should be taken.

- School attendance policies should be reconsidered for mumps outbreaks. Fully vaccinated children are allowed to attend despite the fact that at least 12% of them are considered susceptible. The degree of risk is not entirely dependent on vaccination status (in Spokane, the rate of infection of vaccinated and non-vaccinated populations are identical) and exposure affords the opportunity to acquire lifetime immunity. The parents of appropriately aged children not up-to-date on MMR, who are in good health, could be given the option of sending their children school during an outbreak. There are far more fully vaccinated students at school who are still susceptible to the mumps than there are students who are exempt from the second or both injections of the MMR series. Requirements to stay home from school when infected with mumps or any communicable illness should, of course, remain in place.
- Many schools now exclude non-vaccinated children during a mumps outbreak, yet they allow a child who gets the MMR vaccine same-day school access. There are three important problems with this policy. 1) It takes several weeks for antibodies to develop after MMR administration, so the newly vaccinated child is at risk for several weeks. 2) It discriminates against the non-vaccinated who are not allowed to be at school for any length of time. 3) MMR is a live vaccine, and viral shedding can occur. If the goal is to reduce the spread of mumps, or prevent exposure of mumps to those without antibodies, then allowing same-day access makes no sense.
- Titer checking can be done to see if a child has sufficient antibody levels; however, if levels are found to be low, care should be taken to not automatically and repeatedly re-vaccinate. Failed antibody reactions to vaccine antigens could indicate an ongoing, unresolved autoimmunological condition, indicating that vaccines should be avoided.
- Please visit our website to see a corrected version of the slide show presented at this session, as well as current mumps outbreak data, WA state historical data on disease rates, and current vaccination rates. http://www.informedchoicewa.com/historical-rate-data/

Influenza and HPV

Paul Throne: "The 2 diseases in our state that continue to kill the most people but could be prevented by vaccine are flu and HPV . . ."

FACT CHECK:

Flu:

- See Flu vaccine effectiveness and limitations. The CDC is reporting about 48% effectiveness for the 2016-17 season. It should be noted that effectiveness differs from efficacy.
- For the 2016-17 season to-date, the majority of deaths from flu have been in those 65+. Flu vaccines are even less effective in that population. Other strategies to prevent infection and to improve outcomes should be employed. Many senior citizens take one or more pharmaceuticals on a daily basis. One area in need of research is the impact of those prescriptions on the immune system and their potential role in compromising the ability to resist or overcome the flu.
- Tylenol/acetaminophen depletes a critical antioxidant called glutathione and impairs mitochondria, yet many people take this drug, or products that include this drug, upon first sign of illness, increasing risk of serious outcome. Greater public awareness and a change in product labelling are indicated.
- Evaluation of the role of over-the-counter and prescribed drugs, including Tamiflu, used by those who have severe or fatal influenza outcomes should be done.
- According to the Washington State Department of Health Immunization Office, there were 268 deaths attributed to the 2016-17 flu season. Of those, 119 had received the flu shot, 59 had not, and the vaccination status of 84 was unknown. Two hundred fifty-five had pre-existing conditions, 234 were over the age of 65.

HPV:

- The HPV vaccine has not yet been proven to reduce the rate of cancer.
- Cancer from HPV takes 30 or more years to develop. Gardasil entered the market in 2005; it is too soon to know if HPV vaccines will have an impact on cancer rates.
- "More than 200 types of HPV have been recognized on the basis of DNA sequence data showing genomic differences." The HPV vaccines include 2, 4, or 9 strains.

- Vaccine-strain infections have declined, **but non-vaccine strain infections have increased** because of strain replacement. It is unknown the impact these other strains will have on cancer rates.
    - Fischer et al 2016: Shift in prevalence of HPV types in cervical cytology specimens in the era of HPV vaccination. Oncol Lett. 12(1):601-610.
    - Guo et al., 2015. Comparison of HPV prevalence between HPV-vaccinated and non-vaccinated young adult women (20-26 years) American Association for Cancer Research Meeting, Apr 18-22; Philadelphia, PA. Philadelphia (PA): AACR; 2015. Abstract nr 844
    - Giambi C et al., 2013. A cross-sectional study to estimate high-risk human papillomavirus prevalence and type distribution in Italian women aged 18-26 years. BMC Infect Dis. 13:74. doi: 10.1186/1471-2334-13-74.
- Vaccination does not negate the need for Pap tests.
- Since 95% of HPV infections clear completely on their own without leading to pre-cancerous lesion, and since pre-cancerous lesions are treatable, the high cost ($150 per dose, 2-3 dose series) and risk of vaccination outweigh theoretical benefit. (No cancer has yet been proven prevented.) Studying the 5% who don't clear HPV infection to determine and address factors would be a more reasonable alternative to mass vaccinations.
- As mentioned earlier, the HPV vaccines have not been tested for safety using the gold-standard of double-blind placebo studies.
- "After Gardasil was licensed and three doses recommended for 11-12 year old girls and young women, there were thousands of reports of sudden collapse with unconsciousness within 24 hours seizures; muscle pain and weakness; disabling fatigue; Guillain Barre Syndrome (GBS); facial paralysis; brain inflammation; rheumatoid arthritis; lupus; blood clots; optic neuritis; multiple sclerosis; strokes; heart and other serious health problems, including death, following receipt of Gardasil vaccine." NVIC.
- Gardasil package insert. Gardasil 9 package insert.
- Class Action lawsuit going forward in Japan.
- HPV vaccination and premature ovarian failure: *New Concerns about the Human Papillomavirus Vaccine* American College of Pediatricians – January 2016
- *Are aluminum adjuvants plus Gardasil a uniquely damaging neuroinflammatory cocktail?* Children's Medical Safety Research Institute
- Dr. Diane Harper, lead investigator of Gardasil and Cervarix, speaks against deceptive marketing tactics.
- One More Girl documentary on HPV injuries.

In the absence of any proven benefit, with the possibility of increasing rates of infection of non-vaccine strains, which may negatively impact cancer rates, and in consideration of the worldwide legal actions and reports of injury, Washington State should cease recommending any HPV vaccines while many issues are investigated.

Special Note: Vaccinations not FDA approved for fetus

Vaccination during pregnancy was not mentioned in this Work Session, but we include it because it is a critical area lacking fully informed consent and safety studies.

No vaccine is currently licensed for protection of a fetus; no safety studies have been done to ensure the safety of the fetus.

Please read this carefully. FDA states:

> "Several licensed vaccines may be used during pregnancy to prevent disease in the mother, unless specifically contraindicated, Tdap & Influenza. Vaccines recommended for pregnant women were first licensed and approved for use based on safety and effectiveness data in non-pregnant women. These vaccines were then recommended by public health policy makers for pregnant women based on their **perceived** benefit and minimal risk for the mother and infant. Currently, no vaccine is approved specifically for use during pregnancy to protect the infant."

Administering of Tdap and Influenza vaccine began despite the lack of safety data; pregnant women were not informed the recommendation to vaccinate was based on "perceived minimal risk" rather than actual safety studies. Pregnant women were, and still are, in essence, subjects in a trial study without their knowledge. The retrospective studies now available do not provide the safety data needed for either licensure approval, or for maternal confidence of safety.

There are no long term outcome studies available to show if receipt of the Tdap, which contains 250mcg of aluminum, capable of crossing the placenta and blood-brain barrier, or receipt of the flu vaccine (some of which contain thimerosal), impacts neurological development.

Vaccine Inserts:

Tdap Vaccine:

- Tdap: "Safety and effectiveness of BOOSTRIX have not been established in pregnant women • Register women who receive BOOSTRIX while pregnant in the pregnancy registry by calling 1-888-452-9622."
- Each 0.5-mL dose contains aluminum hydroxide as adjuvant (not more than 0.39 mg aluminum 380 by assay), 4.5 mg of sodium chloride, ≤100 mcg of residual formaldehyde, and ≤100 mcg of 381 polysorbate 80 (Tween 80).
- http://www.fda.gov/downloads/BiologicsBloodVaccines/UCM152842.pdf

Flu Vaccine:

- "Safety and effectiveness of FLUVIRIN® have not been established in pregnant women, nursing mothers or children less than 4 years of age."

- "Pregnancy Category B: A reproductive and developmental toxicity study has been performed in rabbits at a dose level that was approximately 15 times the human dose based on body weight. The study revealed no evidence of impaired fertility or harm to the fetus due to FLUVIRIN®. There are, however, no adequate and well-controlled studies in pregnant women."
- "Nursing Mothers: It is not known whether FLUVIRIN® is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when FLUVIRIN® is administered to a nursing woman."
- "The 0.5-mL prefilled syringe presentation is formulated without preservative. However, thimerosal, a mercury derivative used during manufacturing, is removed by subsequent purification steps to a trace amount (≤ 1 mcg mercury per 0.5-mL dose). The 5-mL multidose vial formulation contains thimerosal, a mercury derivative, added as a preservative. Each 0.5-mL dose from the multidose vial contains 25 mcg mercury."
- http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM123694.pdf

Conclusion

This FACT CHECK represents just a small portion of the vaccine-related issues that we feel need to be given high priority consideration, and addressed with regard to public health issues in Washington State.

Vaccines are potent biologicals designed to provoke an immune response. They should be treated with as much respect and caution for their benefits and risks as any other pharmaceutical product.

All vaccines cannot be considered equal in either effectiveness or risk. It makes no sense for major medical organizations, physicians, or health authorities to make a general claim that "vaccines are safe and effective" just as it would make no sense to claim that "pain relievers are safe and effective."

It's very important not to allow the topic of vaccine risk to be deflected by benefit arguments. Just because many children benefit from penicillin doesn't mean we force it upon those who are allergic to it. The benefits of vaccines are not germane to a discussion of the risks and limitations of a broad range of vaccines now in use, especially in the context of the increasing rates of chronic illness now found in the United States. We cannot weigh the benefits of current vaccines or the current schedule if the risks and flaws are not fully known. Clinical trials include limited subjects; it's not known how diverse populations and subgroups will react to a vaccine, or a combination of vaccines, until use begins in the general population. Aftermarket reporting of adverse events by physicians, individuals, and parents are absolutely critical.

Aftermarket reporting begins with parents phoning their child's pediatrician, saying *something's not right*, or rushing into the ER, saying, *my child was recently vaccinated, and now . . .*

For too long, the subject and science of vaccine risk has been silenced for fear of impacting vaccination rates. We now have the ability to identify some of those who are susceptible to vaccine injury. It is no longer justifiable to continue to focus solely on the protection of those who are vulnerable to a complication and bad outcome from disease at the expense of those who are vulnerable to vaccine injury.

We, the members of InformedChoiceWA, sincerely hope those who read this will continue to explore issues of safety, individual risk, the "regulatory vacuum," and the need for current science to be incorporated into vaccine design, administration, and policies.

A personalized approach to vaccination is the only ethical policy.

And always, fully informed medical choice must be given and respected.