



The Denial of Adverse Event Risk Following Immunization and the Loss of Informed Consent - A Perspective

K Paul Stoller*

Fellow, American College of Hyperbaric Medicine, USA

***Corresponding Author:** K Paul Stoller, FACHM, USA.

Received: November 16, 2018; **Published:** December 29, 2018

Abbreviations

HHS: Department of Health and Human Services; CDC: Centers for Disease Control; FDA: Food and Drug Administration; WHO: The World Health Organization; AEFI: Adverse Event Following Immunization; AAP: American Academy of Pediatrics; DTP: Diphtheria-Tetanus-Pertussis; OPV: Oral Polio Vaccine; PIC: Physicians for Informed Consent; VAERS: Vaccine Adverse Event Reporting System; EMA: European Medicines Agency; AAHS: Amorphous Aluminum Hydroxyphosphate Sulfate; NACCHO: National Association of County and Public Health Officials; GSK: GlaxoSmithKline; SV40: Simian Virus 40; MMR: Measles, Mumps and Rubella; I3C?: Indole-3-Carbinol.

"Any preventive, diagnostic and therapeutic medical intervention is only to be carried out with the prior, free and informed consent of the person concerned, based on adequate information...The interests and welfare of the individual should have priority over the sole interest of science or society." 2005 UNESCO Universal Declaration on Bioethics and Human Rights" [1].

Introduction

Vaccines are public health measures that are not evidence-based as portrayed by authorities such as the United States Department of Health and Human Services (HHS) or the Centers for Disease Control (CDC). For example, despite political propaganda to the contrary, the scientific reality is vaccines are not subjected to the same kind of clinical trials as other drugs are. They are classified not as drugs but as biologics allowing them to be routinely approved and mandated with little to no evidence of efficacy or

safety, while at the same time actual evidence of vaccine harm is systematically ignored by vaccine manufacturers and authorities who work together under multiple unethical conflicts of interest. Consequently, vaccines are a grave threat to public health and medical ethics. Furthermore, informed consent in vaccination is deeply endangered today both in medical practice and as an ethical principle in society. Natural immunity is similarly endangered today due to modern vaccination policy. Promoting categorically unsafe vaccines and discouraging the responsible development of natural immunity has become state sponsored policy where the policy itself is what gets protected – not the public.

In the U.S., the Food and Drug Administration (FDA) has stated their policy on this issue clearly, "any possible doubts, whether or not well founded, about the safety of the vaccine 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." This was recorded in the Federal Register (vol 49, No. 107), and made specifically about the polio vaccine.

So, doubts about safety cannot be allowed to exist? An unambiguous policy that has nothing to do with science or public health. Considering how much of the world seems to blindly follow the lead of U.S. health agencies, or is coerced into following them, that FDA policy statement should be very alarming. The trust placed in U.S. agencies ignores that they have been compromised and captured by industry;¹ furthermore, physicians and scientists who criticize this system of rampant corruption² will be increasingly pilloried and attacked as incompetent, dishonest, and a dangerous menace to the public's wellbeing.

¹<http://icandecide.org/white-papers/VaccineSafety-Version-1.0-October-2-2017.pdf>

²https://usrtk.org/wp-content/uploads/2016/10/CDC_SPIDER_Letter-1.pdf

https://www.huffingtonpost.com/carey-gillam/spider-bites-cdc-ethics-c_b_12525012.html

In their 2014 policy paper, Considerations regarding consent vaccinating children and adolescents between 6 and 17 years old, The World Health Organization (WHO) stated, “the physical presence of the child or adolescent, with or without an accompanying parent at the vaccination session, is considered to imply consent”. A child sent to school on the day they are holding a vaccine clinic is now consenting by implication. A parent could refuse to send the child to school on vaccine day, but that assumes they knew about it. However, implied consent is Orwellian doublespeak inconsistent with the UNESCO declaration, and emblematic of an erosion of fundamental rights by the misinformed to protect marketing goals and policies that often have little to no public benefit.

Then in 2017, the WHO revised [2] what they would accept as an Adverse Event Following Immunization (AEFI). Only reactions that have been previously acknowledged in epidemiological studies would now be considered as vaccine-related. Deaths seen in post-marketing surveillance would be identified as coincidental or unclassifiable. These deaths are not classified as vaccine-related if the vaccine had not caused a statistically significant increase in deaths in the Phase III trials. For example, Sri Lanka suspended the use of a pentavalent vaccine after five deaths within four months after its introduction in January 2008, and in 2013, Viet Nam shelved the pentavalent vaccine because it had been associated with 12 deaths. However, in both cases, the WHO teams which investigated the deaths declared they were “unlikely” to be related to the vaccines used.

Puliyel, and Phadke wrote a letter to the editor of the Indian Journal of Medical Ethics expressing their dire concerns as there were 132 cases of children in India being hospitalized after the administration of a pentavalent vaccine between 2012 and 2016. Fifty-four of these children died. When these adverse events were analyzed using the new WHO criteria, not one of the deaths was classified as potentially vaccine-related [3].

“AEFI reporting is said to be for vaccine safety. In view of the above, it is necessary that the AEFI manual be re-evaluated and revised urgently. Safety of children (child safety) rather than safety for vaccines (vaccine safety) needs to be the focus” [3]. In other words, Puliyel and Phadke are saying that reporting on AEFI’s is supposed to be about identifying problems so that if there are safety issues children can be protected from a flawed vaccine. AEFI reporting is not meant to obfuscate safety issues to protect the vaccine from scrutiny. Apparently, Puliyel and Phadke are either naive (“possible doubts, whether or not well founded, about the safety of

the vaccine cannot be allowed to exist”) or they are attempting to inform their colleagues in the most politically polite manner possible that protecting vaccine policy, terminating informed consent, and AEFI denialism has become the global vaccine agenda.

But vaccines save lives, right?

It is worth noting that the American Academy of Pediatrics (AAP) published a summary of vital statistics on the trends in the health of Americans during the 20th Century: “Thus vaccination does not account for the impressive declines in mortality seen in the first half of the (20th) century” [4]. Perhaps, it would be more prudent for the WHO to state that the physical presence of a child on this planet implies consent to clean water, sanitation and a healthy diet, rather than eroding individual and parental rights for invasive medical interventions of questionable value.

The value of vaccines is called into question when unvaccinated and vaccinated populations are compared, which may be why so little is published in this area as the implication of such comparisons could destroy current global vaccine policies. In 2017, a rather unique study was published [5] that examined the introduction of the diphtheria-tetanus-pertussis (DTP) and oral polio vaccine (OPV) in an urban community in Guinea-Bissau (Africa) in the early 1980s. The conclusion of this study stated, “DTP was associated with 5-fold higher mortality than being unvaccinated. No prospective study has shown beneficial survival effects of DTP. Unfortunately, DTP is the most widely used vaccine, and the proportion who receives DTP3 is used globally as an indicator of the performance of national vaccination programs.

“It should be of concern that the effect of routine vaccinations on all-cause mortality was not tested in randomized trials. All currently available evidence suggests that DTP vaccine may kill more children from other causes than it saves from diphtheria, tetanus or pertussis. Though a vaccine protects children against the target disease it may simultaneously increase susceptibility to unrelated infections”.

One might assume the intentions of most vaccine advocates is to help and protect children; however, by design (it seems) there is a pernicious lack of understanding about the risks involved. The indoctrination of today’s medical community that “vaccines save lives” is so ingrained no room is left for the reality that many vaccines are flawed, or that there are serious safety concerns. The malevolent aspects of this level of indoctrination has its own risks that reach far beyond medical malfeasance.

The guiding principle that one simply does not expose a child to any unnecessary risk has apparently been abandoned if they are on the receiving end of a vaccine. Of course, many medical interventions have the risk to cause harm but the risk of that harm may be very small provided effective measures are in place, such as making sure, in the case of vaccines, the child does not have a known medical (physical, genetic or immune) problem that would amplify risk. It is often hard to judge the level of risk that can be tolerated, because the science in this area is not complete. In the case of vaccines, without a previous vaccine reaction in the child in question or one in an immediate family member who shares a common genetic pattern, it really isn't possible to calculate accurate risk. This doesn't mean the risk is not there, it is just it can't be precisely calculated.

Today, with our current knowledge base, risk is balanced against the benefit and whether there is a better alternative to accepting the risk. It is reasonable to accept a level of risk if the risk from all the other alternatives, including doing nothing, is even greater. A risk is not acceptable if there is a reasonable alternative that offers the same or greater benefit but avoids the risk. Vaccine enthusiasts routinely assume the risk of the disease is greater than the risk of the vaccine. The reality is quite different. And this goes right to the heart of informed consent, because it involves comparing relative risks of a medical intervention.

For example, it has not been proven that the MMR vaccine is safer than measles. The nonprofit organization Physicians for Informed Consent (PIC) recently reported in *The BMJ* that every year an estimated 5,700 U.S. children (approximately 1 in 640 children) suffer febrile seizures from the first dose of the MMR vaccine - which is five times more than the number of seizures expected from measles [49]. This amounts to 57,000 febrile seizures over the past 10 years due to the MMR vaccine alone. And, as five percent of children with febrile seizures progress to epilepsy, the estimated number of children developing epilepsy due to the MMR vaccine, in the past 10 years, is 2,850. In addition, PIC found that the Vaccine Adverse Event Reporting System (VAERS) receives only about 90 annual reports of seizures following the first dose of MMR—that's only 1.6% of the 5,700 MMR-vaccine seizures that occur each year. PIC contends that VAERS, as a passive surveillance system, does not adequately capture vaccine side effects and that serious side effects, including permanent neurological harm and death from MMR and other vaccines, may similarly be underreported.

Moreover, there are multitudes of medical alternatives to vaccines, whereby patients prevent and heal infectious diseases and

build their natural immunity. Another foundational premise is that good sanitation practices, coupled with well-balanced diet and sensible exercise, encourage a lifestyle conducive to strong natural immunity.

Public health authorities act callously and dismissively toward indicators that help identify children at risk of vaccine injury, either because the authorities care to do so in the first place or for lack of sufficient studies on how to use combined indicators of risk to predict, prior to vaccination; furthermore, the costs involved in screening children are not compatible with priorities or budgets of one-size-fits-all mass vaccination programs. Nevertheless, there are potential tools of science that could provide indicators (biomarkers such as pre-existing Th2/Th1 skew, certain genetic polymorphisms, family history or autoimmunity).

Vaccine mandate proponents (and those who would take away the rights to exemptions) use the tools of speculation and obfuscation to deny evidence of vaccine injury and deaths. This allows vaccine mandate proponents to propagandize the morality of the compulsory vaccine programs, and even to stifle the capability of the medical community to acknowledge and treat vaccine injured children. If it is acknowledged that screening for risk is appropriate, then that risk itself is being acknowledged and that will increase the perception of risk with the public and obviously there will be those (vaccine mandate proponents) who would not want to take the risk, so risk-denialism has emerged as a part of compulsory vaccine programs.

The medical community has allowed a fixation on infectious disease entities alone to truncate our understanding of co-causations of several conditions, such as the role pesticides play, for example, DDT in Acute Flaccid Paralysis/Myelitis or in Burkett's Lymphoma, just to name one environmental problem behind conditions that are considered solely the cause of an infectious agent.

Ponder the huge increase in infant deaths in countries like India when polyvalent vaccines were introduced, but political and economic interests muddle decisions about safety. Indeed, safety is routinely and systematically ignored in the face of these interests. Safety concerns and finding out who might be more at risk from an adverse event does not sell vaccines, and in the U.S. the only way a vaccine manufacturer becomes potentially liable is if they deliberately hide safety problems they learn about their product and were not transparent or forthcoming about those safety issues. Thus, functional safety research has almost completely ended. New vaccines are tested against false placebos (i.e., comparables to other

vaccines) instead of using inert or saline placebos - then children are only followed for a short time (sometimes just a few days). If the child doesn't immediately report adverse events (especially the predetermined adverse events on the list provided by the manufacturer) then the vaccine is considered safe. However, what is taking place goes beyond using placebos that contain the full complement of adjuvants. Protocol V501-018 was the only controlled trial in the target age group of 9-15-year-olds for the Gardasil HPV vaccine and the FDA's June 2006 Clinical Review Table 210 shows that the vaccine formulation in Protocol 018 contained only half the amount of Merck's adjuvant amorphous aluminum hydroxyphosphate sulfate (AAHS) compared to marketed Gardasil. This failure to compare the marketed vaccine, containing 225 mcgs of AAHS, against the carrier solution control, suggests the intent to mislead. It also suggests reckless overexposure of children worldwide who received the marketed vaccine to double the AAHS amount in Protocol 018, helping to explain the high level of reported injuries and deaths worldwide.

A 2017 commentary [6] Puliyeel and Sathyamala describes a shocking dereliction of duty on the part of regulators who were presented with vaccine data carefully tailored to obscure serious risks. Tackling concerns about infant deaths that have occurred following vaccination in several European countries, the authors of the commentary show that GlaxoSmithKline (GSK) neglected to report to regulatory authorities that there was a statistically significant increased risk of sudden infant death in the four days after administration of its hexavalent vaccine—and the European Medicines Agency (the EMA) ignored the omission and accepted GSK's apparently whitewashed data at face value.

In the U.S., the FDA estimates that passive surveillance captures about one percent of vaccine-related adverse events. A study [7] in Africa that compared passive with active surveillance found that passive surveillance "failed to identify half of all AEFIs (adverse events following immunization) that were identified through active surveillance, including all of the serious AEFIs".

Reviewing and reanalyzing GSK's sudden death data, Puliyeel and Sathyamala note a "clustering" of sudden deaths among infants (under age one) in the first three days following vaccination—with 72% of the deaths (42/58) taking place in that time frame and nearly all (93% or 54/58) occurring within 10 days of vaccination. The authors state: "The fact that the rate of death decreases rapidly with the passage of time following immunization suggests that the deaths could be related to vaccination.... If one glosses over the

deaths after vaccination, one can prevent/delay the evaluation of the vaccine's safety profile and this has the potential to result in more, unnecessary deaths, which is difficult to justify ethically".

The WHO and government health agencies are quick to dismiss as a "myth" any possible link between vaccines and sudden infant death syndrome (SIDS) or other unexplained infant deaths—despite a landmark ruling by the U.S. Court of Federal Claims in 2017 (No. 13-611V) that vaccines "caused or substantially contributed" to a 2011 SIDS death. Nevertheless, following Hexavac's withdrawal from the European market, the EU has gone on to grant marketing approval to two other hexavalent vaccines manufactured by Sanofi Pasteur (Hexyon and Vaxelis, in 2013 and 2016, respectively). The EU also gave a scientific thumbs-up for rollout of Sanofi's Hexaxim vaccine in non-EU regions.

Vaccinologists at the CDC give lip-service for need to invest in vaccine safety infrastructure [8] "at a level commensurate with investments in vaccine development," particularly through post-licensure studies that compensate for the "well-known limitations" of prelicensure clinical trials. In what seemed like a lucid moment, these vaccine researchers also state there should be "increasing emphasis...on proving, rather than assuming, that no problems are associated with a vaccine". But actions speak louder than empty words. One action was to ignore CDC whistleblower, Dr. William Thompson, whose confession is hard to ignore: "I have waited a long time to tell my story and I want to tell it truthfully. I have been involved in deceiving millions of taxpayers regarding the potential negative side effects of vaccines. We lied about the scientific findings. The CDC can no longer be trusted to do vaccine safety work. Can't be trusted to be transparent. The CDC can't be trusted to police itself".

William E. Thompson PhD, Senior Scientist, US Centers for Disease Control and Prevention – circa 2014 (as told to Dr. Brian Hooker in the documentary Vaxxed).

Puliyeel and Sathyamala state, that as a result of the EMA's failure to perform due diligence on Infanrix hexa, "numerous children were unnecessarily exposed to the risk of death". They admonish that the "proof" offered by vaccine manufacturers cannot be accepted uncritically and that regulatory agencies must scrutinize pharma-authored/pharma-funded reports rather than simply rubber-stamping them. The problem is in not recognizing the extent to which regulatory agencies have been bled out from the inside by the vaccine industry. For example, in the U.S., the National Associa-

tion of County and Public Health Officials (NACCHO) operates under a written policy to eliminate all exemptions to vaccines “to the greatest degree possible,” other than medical exemptions, which they want to allow only on their terms. The elimination of personal belief exemptions (PBEs) is code for eliminating informed consent. Agencies in collusion with medical boards encourage attacks on those with opposing opinions be that to discredit, silence or discipline them.

Indoctrinated by the “vaccines are, safe, and the science is settled” groupthink all risks associated with vaccines are now considered acceptable risks— there is no room for discussion or debate (“any possible doubts, whether or not well founded, about the safety of the vaccine cannot be allowed to exist”.) However, even acceptable risk may become unacceptable over time or because circumstances change – such as the changing to a hexavalent vaccine or the health status or clinical condition of a child. Note that the schedule of vaccines for children has never been clinically evaluated for safety either prospectively or retrospectively. Having no science is not settled science, it is non-science, pseudo-science and often fatally fraudulent.

What is unacceptable risk?

Few would argue that having a life-threatening anaphylactic reaction to a previous vaccine might be an almost certain consequence of receiving another vaccine, but should that be held out as the standard that needs to be reached for unacceptable risk? Unacceptable risk is not limited to a history of already being injured by a previously given vaccine. You don’t withhold a white cane from a blind person until they can demonstrate that they might be hit by a bus whilst walking down the street. The fact that they are blind calls for a white cane. In the same way, in the war against disease, you don’t force the genetically infirm, for example, to be part of a public health army any more than you would send soldiers in wheelchairs to the front line.

Proponents of compulsory mass vaccine programs might argue that giving white canes to all the blind is too expensive, or if the blind actually found out walking down the street without a cane could cause them harm, they might not walk down the street at all. Should anyone question how inappropriate it is to withhold white canes from the blind, the authorities will insist it is just “coincidence” that the blind are injured walking around without white canes.

That might seem sadly humorous, but adverse events (AEs) are not to be trivialized: [9] “AEs not only affect patients and their families but also may have devastating effects on health care providers, who may suffer emotional consequences both from preventable AEs and from subsequent malpractice litigation. Affected clinicians may feel guilt, shame, and isolation, and these feelings may be exacerbated by negative reactions from their colleagues. Anticipated or actual punitive consequences can add additional emotional and financial burdens on providers”. Alas, there is legal immunity for healthcare workers in the U.S. for contributing to AEFI. Indeed, there are no punitive consequences. And given there is a lack of understanding about AEFI, there is no remorse either.

Who is responsible for vaccine safety?

A U.S. law was passed in 1986, called the Vaccine Injury Compensation Act (VICA) – this was at a time when there was no coercion to get vaccines and there were only 23 doses of vaccines required, but there were a lot of legal actions taking place against vaccine manufacturers and they insisted on liability protection or they would no longer make vaccines. The law removed all liability from vaccine manufacturers and gave 100% responsibility for determining and evaluating vaccine safety to the Department of Health and Human Services (HHS). Not only was HHS responsible for safety, but it was legally required to report on same to the U.S. Congress every two years. A recent court settlement had HHS admitting they have no reports – 30 years of no reports to Congress even though the law required same.

Eventually, these HHS reports to Congress would likely have attracted a great deal of public attention, and open hearings would have been a likely outcome. The science (or lack thereof) of vaccinology would be center stage and why would HHS want that? Better to ignore the law, hope no one notices, never study vaccine safety, and never try to improve on it? (“possible doubts, whether or not well founded, about the safety of the vaccine cannot be allowed to exist”).

“Vaccine safety is initially assessed in prelicensure clinical trials. However, such trials usually have sample sizes that are insufficient to detect rare adverse events. In addition, vaccine trials are usually carried out in well-defined, homogeneous populations with relatively short follow-up periods, which may limit their generalizability. Post-licensure drug evaluations have relied on passive surveillance systems to monitor adverse events. Such systems are

more practical and less expensive than controlled trials; however, their data are usually inadequate to determine causality" [10].

Send in the vaccines?

Where are the vaccines for some of the world's ongoing plagues? Is it just that there hasn't been enough money thrown at them, or are there just certain diseases that will never allow a vaccine to be efficacious? To facilitate protective immunity against malaria, TB and HIV requires the induction of humoral, antibody-dependent cellular inhibition (ADCI) and effector and memory cell responses that are sustained and vaccine efficacy at or above 75%. The genetic complexity of the pathogens in question exhibit genetic diversity and antigenic variation during the different stages of their life cycles that either exceed our current ability to create a vaccine or are not able to be addressed by any vaccine.

Even the vaccines used today don't necessarily provide protective immunity. The DTaP vaccine, for example, conveys no such protection, as that vaccine only mitigates the impact of the toxin made by the bacteria but is not capable of preventing colonization and transmission of *B. pertussis*. Those aP antibodies are also very ephemeral and may not last more than 3 years [11]. But there are other reasons for concern, "we conclude that aP vaccination interferes with the optimal clearance of *B. paraptussis* and enhances the performance of this pathogen. Our data raise the possibility that widespread aP vaccination can create hosts more susceptible to *B. paraptussis* infection" [12]. Paraptussis does not produce a toxoid so the vaccine has no activity against a toxin that is not even present.

For the acellular pertussis vaccine to work, the *Bordetella pertussis* bacteria must have pertactin (PRN)—a key antigen component of the acellular pertussis vaccine. A study that screened *B. pertussis* strains isolated between 1935 and 2012 for gene insertions that prevent production of PRN found significant increases in PRN-deficient isolates throughout the U.S. [13]. The earliest PRN-deficient strain was isolated in 1994; by 2012, the percentage of PRN-deficient isolates was more than 50%.

The CDC [14] found the *B. pertussis* strains isolated in 2012 from six CDC "Enhanced Pertussis Surveillance Sites indicated that 85% of the isolates were PRN-deficient and vaccinated patients had significantly higher odds than unvaccinated patients of being infected with PRN-deficient strains. Moreover, when patients with up-to-date DTaP vaccinations were compared to unvaccinated patients, the odds of being infected with PRN-deficient strains

increased, suggesting that PRN deficient- bacteria may have a selective advantage in infecting DTaP-vaccinated persons".

In case the nuance of this was missed, the CDC did do a vaccinated vs. unvaccinated comparison (at least for the DTaP). What they found was those children vaccinated with the DTaP were far more likely ("a 2- to 4-fold greater odds") of having PRN-deficient *B. pertussis* than the unvaccinated. to be infected by PRN-deficient pertussis, which seem to now comprise almost 90% of the circulating strains. It means not only does the current vaccine have little to no efficacy but increases the chance of coming down with the very illness it is meant to prevent.

Gill, *et al.* state "This disease is back because we didn't really understand how our immune defenses against whooping cough worked, and did not understand how the vaccines needed to work to prevent it....Instead we layered assumptions upon assumptions, and now find ourselves in the uncomfortable position of admitting that we made some crucial errors. This is definitely not where we thought we'd be in 2017" [15].

So, public health authorities are mandating a vaccine that doesn't work as advertised, and once vaccinated the child is more likely to get the infection. Is that a public health intervention you coerce people to take or destroy the right of informed consent over?

Is it even a vaccine that should be used at all?

Suspending the DTaP and explaining the reason for stopping its use could significantly shake the public's confidence in all vaccines; having said that, to continue to use this harmful vaccine is clearly being done to protect the vaccine program, its policies and its profits. It is clearly not to protect children. Who is going to allow their child to get a vaccine that increases their chance of getting pertussis up to four times greater than if they had never been vaccinated if the parents had that information? I suspect almost no one. It goes without saying that if the public knew the real science then virtually no one would consent - there would just be dissent, which is as it should be as that would be the catalyst for improved and safer vaccines, as well as encouraging modalities the enhance natural immunity.

What are a nations' public health objectives if they aren't about protecting children and the public? In the U.S., public health objectives seem to be to vaccinate as many children as possible with as many vaccines as possible, deny AEFI even exist, and terminate informed consent.

Are safe vaccines even possible?

When compromised government agencies are the providers of vaccine safety information, together with the NGOs they control through funding are the providers of vaccine safety information that makes for a very unsafe situation. The British Medical Journal (BMJ) states these sources are not reliable [16].

In the Fall of 2018, the BMJ published: Pandemrix vaccine: why was the public not told of early warning signs? [17]. This article discussed the unearthed GSK internal reports suggesting problems with the vaccine's safety. Editor Doshi asks what this means for the future of transparency during public health emergencies, because we are dealing with a situation where truth and safety are not part of operation. However, a public health emergency is taking place now because a virtually unregulated, well-financed industry colludes with the very agencies, organizations, and academic institutions the public relies on to help protect them from disease.

When is a poison not a poison?

Using aluminum as an example, in the U.S., children receive over 50 injections and over 200 antigens in those injections. If you count pregnancy vaccines of Tdap and flu, that would be 4 more doses. The total amount of aluminum injected is over 10,000 mcg, but how safe is this?

The American Academy of Pediatrics (AAP) published a policy in 1996 called Aluminum Toxicity in Infants and Children (18) leaving little doubt that aluminum is a neurotoxin even at very small amounts.

Mold, *et al.* [19] looked at the brains of 10 donors who had autism and demonstrated they contain some of the highest levels of aluminum ever recorded in human brain, and the aluminum was found in the brain's immune cells, the microglia and the cells which provide support and protection for the neurons, the glia. How does a 15-year-old have as much aluminum in his brain as someone who is many decades older who has died of familial Alzheimer's disease? What does this mean for today's generation of children who receive 5,000 mcg of aluminum in vaccines by the age of 18 months and up to 5,250 additional mcg if all recommended boosters, HPV and meningitis vaccines are administered? Shaw would argue it is destroying their brains [20].

"Aluminum has long been identified as a neurotoxic metal, affecting memory, cognition and psychomotor control, altering neu-

rotransmission and synaptic activity, damaging the blood-brain barrier (BBB), exerting pro-oxidant effects, activating microglia and neuroinflammation, depressing the cerebral glucose metabolism and mitochondrial functions, interfering with transcriptional activity, and promoting beta-amyloid and neurofilament aggregation" [21].

The danger of using aluminum-based adjuvants was further described by in Asin, *et al.* [22] in 2018: "Al-based adjuvants induce persistent, sterile, subcutaneous granulomas with macrophage-driven translocation of Al to regional lymph nodes. Local translocation of Al may induce further accumulation in distant tissues and be related to the appearance of system".

At the end of 2018, the same researchers published a study [23] a study describing behavioral changes in sheep after having received repetitive injections of Al-containing products, explaining some of the clinical signs observed in ovine ASIA syndrome (Autoimmune/Inflammatory syndrome induced by Adjuvants). Vaccinated lambs received the same aluminum adjuvant that is used in human vaccines and then began aggressively biting the wool from other sheep, pacing restlessly and overeating. The research effort was made to understand a new disease that had decimated Spanish industry between 2008 and 2010 following a government-mandated bluetongue vaccine campaign.

Obviously, if several toxins are in the mix together the risk of a toxic synergy taking place being far greater than the additive effects of each toxin, but if no effort is made to study what that synergy is there is no appreciation of how toxic a brew is created. It is pataphysics to believe the toxic metals in vaccines are safe.

Common sense alone should stop anyone from injecting the most toxic non-radioactive element into the human body. Nevertheless, in August of 2018, the CDC Immunization Safety Office posted a "fact" sheet that maintains that "Thimerosal in vaccines is not harmful to children," in spite of abundant evidence [24] to the contrary. The fact sheet parades their collection of CDC controlled thimerosal-related studies ("conducted by CDC or with CDC's involvement") that it has used for years to hush-up Thimerosal detractors.

Thimerosal is 49.55% percent ethylmercury by weight and is an organic mercury compound with toxicity comparable to methylmercury [25] but ethylmercury is far more toxic to and persistent in the brain, where it has a propensity to accumulate as inorganic

mercury [26], with an estimated half-life of as long as twenty-seven years [27].

All eight studies included in the CDC fact sheet involve lead or co-authors accused of fraud or known to have been involved in behind-closed-doors data manipulation or weighed down by serious conflicts of interest.

“Thimerosal was not scrutinized as part of U.S. pharmaceutical products until the 1980s, when the U.S. Food and Drug Administration finally recognized its demonstrated ineffectiveness and toxicity in topical pharmaceutical products and began to eliminate it from these. Ironically, while Thimerosal was being eliminated from topicals, it was becoming more and more ubiquitous in the recommended immunization schedule for infants and pregnant women. Furthermore, Thimerosal continues to be administered, as part of mandated immunizations and other pharmaceutical products, in the United States and globally. The ubiquitous and largely unchecked place of Thimerosal in pharmaceuticals, therefore, represents a medical crisis” [28].

Manufacturers use Thimerosal in some single-dose and multi-dose vaccines to impede bacterial growth during the manufacturing process even when it is not being used as a preservative. The CDC states that “when Thimerosal is used this way, it is removed later in the process” and only “trace amounts” remain (no more than one microgram per dose), which is extremely misleading given the known toxicity of mercury and some vaccines have as much as 25 mcg of mercury, but the FDA will obfuscate and state that is the same amount in a can of tuna fish, so nothing to be concerned about. Except this just brings to the fore the toxic load from eating fish, it does not placate concerns about mercury being injected into infants rather than orally ingested – indeed most of the mercury in fish is not bioavailable because it is ingested orally [29]. The FDA does promote the faux-science that comes out of other.

Grandjean and Landrigan observed that the developing human brain is uniquely vulnerable to mercury and other neurotoxins, often “at much lower exposure levels than had previously been thought to be safe” [30]. The authors also noted that developmental neurotoxicity occurs at far lower exposure levels than “the concentrations that affect adult brain function”. Others have argued that there is no safe level of organic mercury [31].

One study showed that Thimerosal diminished the viability of

human cells in the lab at a concentration one-fiftieth that of methylmercury [32]. Vaccine injury deniers will state that ethylmercury disappears from the bloodstream more quickly than methylmercury as if that means anything if you don’t know where it goes after that, but we do know - it migrates quickly to organs and stays there [33].

‘No worries’ the vaccine enthusiasts say, for the WHO’s Global Advisory Committee on Vaccine Safety states that “no additional studies of the safety of [Thimerosal] in vaccines are warranted”. Don’t expect the WHO to state the reality: “The ubiquitous and largely unchecked place of Thimerosal in pharmaceuticals, therefore, represents a medical crisis” [34].

Correlation does not imply causality, but...

“Both the epidemics of type 1 diabetes and metabolic syndrome correlate with an increase in immunization” [35].

The consumption of organic food increased at the same time many chronic childhood illnesses increased in the U.S., and no one would argue that organic produce has caused that increase, but when there are known poisons applied to the population at the same time as the plethora of chronic childhood illnesses increases, logic would call out the poisons in question before pointing the finger at organic fruits and vegetables.

When vaccines were found contaminated with glass fragments made by one manufacturer the FDA just accepted that the contamination would pose no risk because the manufacturer said so, and the FDA ignored it. Curiously, they are not ignoring the issue of retroviral contamination of vaccines and have launched an investigation into this danger that is not disclosed to those who will get vaccinated. So, from the FDA website: “These latent, or ‘quiet,’ viruses pose a potential threat, since they might become active under vaccine manufacturing conditions”.

That is an interesting admission that the FDA doesn’t actually know what level of threat these quiet viruses pose, given they did absolutely nothing when well over 98 million people were given the cancer-causing Simian Virus 40 (SV40) via the polio vaccine. A thorough review of the iatrogenic transmission of pathogenic agents via vaccine is beyond the scope here but the facts are readily available to those willing to observe what the FDA did in the case of the rotavirus vaccines.

³<https://www.fda.gov/biologicsbloodvaccines/scienceresearch/biologicsresearchareas/ucm127327.htm>

Two new genetically engineered oral rotavirus vaccines entered the vaccine marketplace in 2006 and 2008, respectively: RotaTeq, a pentavalent (five-strain) bovine-human reassortant rotavirus vaccine made by Merck, and Rotarix, a live-attenuated single-human-strain rotavirus vaccine manufactured by GlaxoSmithKline (GSK). Although pre-licensure trials found no evidence of an association between the two vaccines and intussusception, post-licensure monitoring later indicated a statistically significant increased risk of intussusception events for all rotavirus vaccines [36]. The FDA merely instructed Merck, in 2013, and GSK, in 2014, to update their labeling and prescribing information to include brief statements about increased intussusception risks but otherwise allowed the two vaccines to remain on the market.

Meanwhile, the governmental safety systems, oft purported to be rigorous, that ushered the two rotavirus vaccines to market failed to detect an additional and highly concerning problem, which an academic research team “unexpectedly” [37] identified in 2010. While conducting “a novel, highly sensitive analysis not routinely used for adventitious agent screening,” ...the researchers discovered that RotaTeq and Rotarix were contaminated with DNA from two porcine circoviruses—type 1 (in Rotarix) and both type 1 and 2 (in RotaTeq). Both GSK and Merck later confirmed these findings. The porcine circovirus 2 pathogen is associated with severe wasting and immunodeficiency in pigs.

Although the dangers from these viruses are unknown, horizontal gene transfer—the direct uptake and incorporation of genetic material from unrelated species is a clear risk (38) of genetically engineered vaccines. Unlike chemical pollutants, nucleic acids are infectious and can invade cells and genomes, multiplying, mutating and recombining indefinitely. Potential hazards of horizontal gene transfer include generation of new disease-causing viruses and bacteria (or reactivation of dormant viruses); spread of drug and antibiotic resistance genes among viral and bacterial pathogens; and random insertion into genomes of cells resulting in cancer.

Of great concern, outside of regulatory circles, is research [39] demonstrating that the pathogenic potential of Porcine Circovirus-2 to cause an AIDS-like disease in pigs is unleashed when there is simultaneous vaccine-induced immune system activation.

At a 2010 meeting convened by the FDA to discuss this contamination, a GSK executive went so far as to concede, “evolving technologies can lead to new findings that were not known at the time of licensure”. The contamination of vaccine with viruses that

can potentially cause cancer decades after vaccination, as the SV40 virus seems to have done, is downplayed as a “manufacturing quality issue” and swept under the rug. The space under that proverbial rug is crowded with one vaccine controversy after another, from the vaccine trials for the so-called Spanish flu epidemic (1918) that seems to have been the result of a botched military vaccine experiment that went on to cost over 100 million lives, the notorious Cutter incident that left many crippled, and some dead, as a result of vaccine-induced polio (1955), and the transmission of the cancerous SV40 virus to almost 100 million, just to name three. Nonetheless, the GSK researchers [40] expressed little worry, having framed the presence of the viral DNA in their vaccine as a simple manufacturing issue rather than a safety risk.

Are unforeseen outcomes inevitable?

Shortly after the GSK discovery, FDA recommended [41] that physicians temporarily suspend use of Rotarix and switch to RotaTeq, but when Merck’s vaccine was found to contain similar contaminants, FDA reversed course and allowed continued use of both. Instead of calling for new safety studies and completing a new risk-benefit analysis (taking into consideration that mortality from rotavirus disease in the U.S. is very low), the FDA once again reassured the public that the benefits of rotavirus vaccination outweighed any “hypothetical” health risks of viral contamination. The agency’s sole follow-up action was to rubber-stamp updates to the Merck and GSK package inserts to “reflect the presence of Porcine Circovirus Type-1 and -2 DNA in the vaccine[s]”.

SV40 [42] is “occasionally” finding its way into the vaccine even today. Why is this being tolerated? How can the benefits outweigh the risks when, in addition to the proven risks, the scientific evidence reveals multitudes of under-appreciated risks? There is persuasive evidence that SV40 is present in human ependymomas, choroid plexus tumors, bone tumors, and mesotheliomas. A 2002 Institute of Medicine report cited strong biological evidence that SV40 can transform normal cells into malignant cells. Whether the porcine circovirus contamination that afflicts the two current—and highly engineered—rotavirus vaccines will turn out to have insidious long-term health effects remains an unanswered question.

When Gatti and Montanari [43] revealed, for the first time that vaccines had more than aluminum salts adjuvants, Polysorbate-80, and other inorganic chemicals in them, they also harbored stainless steel, tungsten, copper, mercury and rare elements that probably shouldn’t be injected directly into the human body, but what do regulators do with this information?

Gatti was about to testify in a parliament enquiry on vaccine damages when her lab was raided by police and all their research materials confiscated. They had crossed the line by finding nano-contamination in random vaccines, Gatti and Montanari revealed, for the first time, what no one knew – information that could potentially make the public question the safety of vaccines. That kind of revelation is just not “allowed to exist”. Take this one step farther and those who question vaccine safety are not “allowed to exist”.

But assume, for the sake of argument, that vaccines are generally safe, they still will have unintended consequences. From the article, “Vaccination can drive an increase in frequencies of antibiotic resistance among nonvaccine serotypes of *Streptococcus pneumoniae*” [44].

“The bacterial pathogen *Streptococcus pneumoniae* is a major public health concern, being responsible for more than 1.5 million deaths annually through pneumonia, meningitis, and septicemia. Available vaccines target only a subset of serotypes, so vaccination is often accompanied by a rise in the frequency of nonvaccine serotypes. Epidemiological studies suggest that such a change in serotype frequencies is often coupled with an increase of antibiotic resistance among nonvaccine serotypes...we find that vaccination can result in a rapid increase in the frequency of preexisting resistant variants of nonvaccine serotypes due to the removal of competition from vaccine serotypes”.

The Pneumococcal vaccine is not the only vaccine that has the potential to increase strains not covered in the vaccine that are much more problematic than the strain covered by the vaccine (for example the HPV and Hib). If this were about science and in the interest of public safety, then the use of the vaccine would be suspended until this issue was sorted out.

In 2006, researchers wrote in the *Journal of Toxicology and Environmental Health* [45] “Genetically modified (GM) viruses and genetically engineered virus-vector vaccines possess significant unpredictability and a number of inherent harmful potential hazards... Horizontal transfer of genes... is well established. New hybrid virus progenies resulting from genetic recombination between genetically engineered vaccine viruses and their naturally occurring relatives may possess totally unpredictable characteristics with regard to host preferences and disease-causing potentials.

“There is inadequate knowledge to define either the probability of unintended events or the consequences of genetic modifications”.

Though this was 12 years ago, little has changed even as the technology has advanced. Today pharma has several different types of GM vaccines in production and in development. But what happens when foreign DNA is inserted into the human body is an evolving mystery. Will it trigger undesirable changes in human cells or tissues? Will it combine or exchange genetic material with human DNA? Will it transfer to future generations? No one knows if no one is looking.

Vaccine policy is not about public health

The Chicken Pox vaccine is an expensive mistake from the point of view of public health [46].

“Universal varicella vaccination has failed to provide long-term protection from VZV disease”. The immunity the vaccine provides “is temporary and of unknown duration—shifting chickenpox to a more vulnerable adult population which, as Dr. Jane Seward cautioned in 2007, carries 20 times more risk of death and 10–15 times more risk of hospitalization compared to chickenpox in children”. This is an interesting statement given that it is often stated that vaccination rarely leads to serious adverse events. But here the adverse events are not in the vaccinated but in an older population that didn’t get the vaccine.

Infants who receive several vaccines concurrently, as recommended by CDC, are significantly more likely to be hospitalized or die when compared with infants who receive fewer vaccines simultaneously. Goldman and Miller showed that reported adverse effects were more likely to lead to hospitalization or death in younger infants [47].

“Our findings show a positive correlation between the number of vaccine doses administered and the percentage of hospitalizations and deaths. Since vaccines are given to millions of infants annually, it is imperative that health authorities have scientific data from synergistic toxicity studies on all combinations of vaccines that infants might receive. Finding ways to increase vaccine safety should be the highest priority”.

In 2017, this was published: Pilot comparative study on the health of vaccinated and unvaccinated 6- to 12- year old U.S. children [48]. The study reported no reductions in the incidence of measles, mumps, rubella, influenza, or rotavirus among vaccinated children. But it did find that there is a 7-fold increase in the odds of having a neurodevelopmental disorder if a child is vaccinated. And as highlighted above, the incidence of seizures after the MMR is ac-

tually 5x greater than developing seizures from getting the measles infection itself [49].

The Institute of Medicine (IOM) lamented in 2012 that “for the majority of cases (135 vaccine-adverse event pairs), the evidence was inadequate to accept or reject a causal relationship” [50].

The Institute of Medicine (now National Academy of Medicine) has issued three disturbing reports on the evidence for suspected and/or reported vaccine adverse events. For 80% of the suspected vaccine adverse conditions investigated, there wasn’t enough research evidence to accept or reject vaccine causation. Of the reviews with sufficient evidence, 72% found that the vaccine did likely cause the injury.

In 2013, the IOM studied the entire Childhood Immunization Schedule and stated: “No studies have compared the differences in health outcomes... between entirely unimmunized populations of children and fully immunized children... Furthermore, studies designed to examine the long-term effects of the cumulative number of vaccines or other aspects of the immunization schedule have not been conducted”.

In the U.S., the Vaccine Injury Compensation Program has paid out approximately \$4 billion in compensation to victims of vaccine injury. The children and adults who have been compensated for injuries have never been studied to determine why they were injured, in an effort to make vaccines safer for everyone. Preventing vaccine injuries should be tackled as zealously as we tackle preventing infectious diseases, but by ignoring or denying adverse events from vaccines and using vaccines as the primary intervention to combat infectious diseases we are neither preventing injury from vaccine or combating infectious disease.

Genomics seems to give us the best-educated estimate of the potential of risk for any given individual of having an AEFI.

“The long-term goal is to identify genetic features that could be determined before vaccination, allowing practitioners to modulate the vaccination plan according to risk. This type of practice—the goal of personalized predictive medicine—appears to be closer in terms of feasibility than ever, given the pace of genetic testing.

“It is highly likely that widespread genetic testing will become a common feature of vaccine testing protocols. In fact, a testing sequence using genome wide arrays for genetic polymorphisms

followed by transcriptional and proteomic arrays at multiple time points in association with sophisticated laboratory immunological assays and carefully graded clinical scores will likely become the norm. The guiding biological concept for interpretation of such massive sets of disparate types of data will be that all of the data should ‘tell the same story.’ We can foresee a time soon when these data will not be interpreted individually; rather, integrated analytical tools will emerge to coordinate the use of genomic, proteomic, and clinical data from clinical trials. The potential for false discovery of associations is high, but new methods are emerging that will reduce such random associations” [51].

Risk cannot be precisely calculated from genetic association; nevertheless, it is still evidence that can be used today to determine the presence of risk even though the level of risk cannot yet be determined, but you have to ask the right questions.

“Is there a general association between vaccination and a specific adverse outcome?” Is this the right question to ask or should the right question be: “Who among those who otherwise might be vaccinated has highest specific risk of any adverse outcome?” or “how can we identify such individuals and protect them from vaccine injury?”

“This susceptibility to vaccine-induced autoimmunity is probably determined also by genetic predisposition... the dilemma of whom and when to vaccinate remains unresolved”.

The above quote is from the article: Vaccination and autoimmune diseases: is prevention of adverse health effects on the horizon? [52].

There is clearly a disconnect between science and policy. If the science says you don’t, for example, give the Dengue Fever vaccine to anyone who has not already been infected, then you don’t give the vaccine to the previously uninfected. For when you do then those vaccinated get infected serious AEFI will occur, but that would require only giving the vaccine to dengue seropositive children – that may not be profitable for pharma. This choice would necessitate doing dengue virus serology on drawn blood. Is that a problem? It is if there is no rapid and reliable test or there is no budget for testing. The appropriate response is not, “testing for seropositive children is not standard of care,” or “we don’t have access to reliable testing, so we are going to just give the vaccine anyway,” or “We have this vaccine let’s just use it and see what happens in post-market surveillance”.

As highlighted above, there are responsible alternatives to vaccines that can enhance the body's own immunity and heal infectious diseases. But pharma's one-size-fits-all profit motive discourages knowledge and practice of such alternatives. Indeed, even pharmaceutical alternatives that compete with vaccines are denigrated. For example, the off-patent drug Nitazoxanide [53] has activity against dengue and could be available to many given it is often sold for pennies in certain countries. Who is going to invest in the research on this drug that is off-patent and for a disease that is not prevalent in 1st World countries, where it might be sold for a price that would allow the drug company to recoup the cost of getting the drug approved for that use?

Informed consent is not some archaic ethos reserved for unenforceable global declarations, but for vaccine stakeholders there is a fear of informed consent becoming informed dissent. We must respect medical ethics above pharma. If that means vaccine uptake is poor then so be it, because you don't place children in unnecessary harm's way. It is not appropriate to misinform the public and say the chance of a serious untoward reaction is one in a million, when that is not a truth. AEFI denialism may eventually destroy the public's trust in physicians; and moreover, pharma's presently favored adjuvant-laden vaccine schedule may find itself no more respected than the practice of bloodletting.

In the U.S., the public is told by the government that 80,000 people die from the flu each year, but they might as well say 3 million die from the flu, because neither is true and a large portion of the population does not even believe the lower number, but despite the financial incentives given to health care providers for making sure as many are vaccinated as possible, scaring people is the only way you can sell a vaccine that may have as little as 10% relative efficacy. It raises questions about what is driving the obsession with vaccinations that have little to no benefit given there are alternatives to dealing with the flu beyond a vaccine? Be that as it may, health care providers and institutions that get financial incentives for promoting a specific intervention are probably not the appropriate source of information for true consent. Informed consent isn't even possible when vaccination is a condition of employment or school entry – and coercion makes informed consent impossible.

From the article, Peptide Vaccines: New Trends for Avoiding the Autoimmune. Response [54] "the rate of adverse complications in association with the combined measles, mumps and rubella

(MMR) vaccine, has been found to occur in approximately 17,500 individuals per million vaccinated persons. The complications reported in consequence of the MMR vaccine administration include a diabetes type I syndrome, thrombocytopenia, arthritis and various CNS disorders such as acute disseminated encephalomyelitis and/or transverse myelitis." The real incidence of adverse events from the MMR are 1 in 57 not 1 in a million.

Epidemiological Obfuscation

Many epidemiological vaccine safety studies make the basic error of declaring "lack of association" because the confidence interval of the odds ratio does not span the null value⁴. These conclusions are simply wrong, in fact, epidemiological safety studies are not only the easiest to manipulate (and they have been by excluding certain population here or diluting down a certain population there, so to speak), they have significant short comings because they are utilized routinely by pharma and authorities (working together with conflicts of interest) to count what they want to count rather than answer important safety questions.

For example, there are 16 epidemiological studies most often cited by scientists, public health officials and members of the media when trying to refute any evidence of an association between vaccinations and autism. The flaws in these studies have been pointed out by government officials, other researchers, medical review panels and even the authors of the studies themselves. Taken together, the limitations of these studies make it impossible to conclude there is no association. In other words, from a risk assessment angle these studies are meaningless and provide no assurance of safety.

In addition, Poul Thorsen, a prominent researcher responsible for a series of epidemiological studies which utilized the Danish Psychiatric Central Research Register was indicted by a U.S. federal grand jury on 13 counts of fraud and 9 counts of money laundering based on a scheme to steal grant money the CDC had awarded to governmental agencies in Denmark for autism research.

The reason it is so easy to manipulate epidemiological studies is that epidemiology counts numbers without a lot of context—biosemiotics is not part of epidemiology. You can count the number of people having intercourse, but without an understanding of what intercourse does biologically, you can't casually associate intercourse with pregnancy. So, epidemiological studies allow for a lot of interpretation, but the truth is that it allows for manipulation of

⁴Null Value for a Risk Ratio: The value indicating no difference between the groups.

statistics to reveal just about whatever someone wants those statistics to reveal, as long as that someone doesn't have an expert in epidemiology looking over their shoulder. The CDC has had the ability to flood the medical literature with garbage epidemiological studies that help them push policy not public health.

Right now, there is an explosion of allergies to milk, peanuts, eggs to name three – it is a big mystery until you realize that vaccines contain bovine casein, eggs, porcine gelatin and peanut oil. They also contain glyphosate – the herbicide. “This combination of atopic children and food protein injection along with adjuvants, contributes to millions developing life-threatening food allergies” [55].

“No state party shall, even in time of emergency threatening the life of the nation, derogate from the Covenant’s guarantees of the right to life; freedom from... medical or scientific experimentation without free consent... and freedom of thought, conscience and religion. These rights are not derogable under any conditions even for the asserted purpose of preserving the life of the nation” [56].

Medical ethicists have long maintained that a patient who has been coerced to consent to injection of biotechnology or a medical procedure, due to fear of losing access to basic necessities (i.e., food, medical care, education) should not be presumed to have provided lawful informed consent to the injection or medical procedure [57].

“As with all forms of medical therapy, informed consent must precede vaccination administration. In the informed consent discussion, health care professionals must discuss information central to the decision-making process for vaccination, including the indications, risks, and benefits of the vaccine and available alternatives, as well as possible consequences from nonvaccination... In addition, healthcare professionals should respect patients’ informed refusal of vaccinations. For some patients, receiving vaccines conflicts with personal or cultural beliefs. For others, the perceived uncertainty of scientific research on vaccine safety hinders their acceptance of clinical recommendations for vaccination” [58].

The above policy is that of the American College of Obstetricians and Gynecologists (2013), but the duplicity in policies like this is that most of the members are neither informed and only rely on the CDC for information. One is not supposed to give a vaccine without informed consent, but can informed consent be obtained

when the physician does not have the appropriate information? An OB/GYN physician would most likely be giving an HPV vaccine. Would said physician know that HPV is only associated with cervical cancer, but direct causality has never been proven? That there is no evidence that the vaccine can prevent invasive cancer let alone avoid death by this cancer, or that the clinical trial mortality was 64 x greater (in the U.S.) than getting the disease the vaccine maybe/might prevent? Would an OB/GYN physician know women who have adequate vitamin D levels probably won't get cervical dysplasia? Or that dysplasia might be treated nutritionally with Indole-3-carbinol (I3C)? That the benign drug Isoprinosine could potentially treat this cancer? [59]. That the clinical trial was run using only half the aluminum adjuvant as the marketed vaccine, and then compared against those who received a faux-placebo that also contained aluminum?

How does one obtain informed consent if one is not informed other than what is printed on a sanitized Vaccine Information Sheet from the CDC? Why would a clearly experimental vaccine be made mandatory? Might it have something to do with the fact the U.S. Government licensed the technology to make the vaccine to Merck and GSK, and thereby profits from its use?

Vaccine policy in the U.S. is inextricably linked to commercial interests leading to unconstrained government self-dealing in arrangements whereby the HHS can transfer technology to pharmaceutical partners, simultaneously both approve and protect their partners’ technology licenses while also taking a cut of the profits. That is an interesting conflict of interest that, at best, does not get disclosed to the medical community, and at worst this is a situation where the agency in charge of safety is protecting their business partners and granting them a license to cause whatever harm results and with no accountability.

How are impartial vaccine safety recommendations even the least bit possible when the government assumes the vaccine is safer than the disease, approves the vaccine, makes the market for it, shields the vaccine from liability with its recommendations and then cashes in on the profits? This is a form of racketeering.

Conclusion

“that bloodletting survived for so long is not an intellectual anomaly—it resulted from the dynamic interaction of social, economic, and intellectual pressures, a process that continues to determine medical practice” [60].

Electricity for refrigerating food, plumbing for toilets and pipes bringing potable water, are the interventions that have improved health the most for most of humanity that has had access to them. There is no evidence that vaccines improved on what plumbers, civil engineers and electricians have done for public health. Given a choice between funding a vaccine or a toilet, the priority (based on evidence) is to fund the toilet. On the other hand, it should be abundantly clear that vaccines are no magic bullet; nevertheless, they are bullets, and often fired without any appreciation for the target, the consequences of hitting the target or even how the gun operates that fired the bullet.

“Vaccines may have a place in our medical arsenal, but they are not the silver bullet they’re portrayed to be. Year after year the pharmaceutical industry, looking for lucrative new profit centers, churns out new vaccines. They use pseudo-science to convince the public that these products are safe and effective, and they use public shaming to convince the citizenry that non-compliance is a public health threat”⁵.

In the U.S., the Pharmaceutical industry is the largest campaign donor to politicians and the largest advertiser in all forms of media, but even that level on influence should still yield to safeguards on human rights and bioethics. For when a medical intervention becomes shielded from liability and is then mandated by governments who are often in an unholy partnership with the corporations responsible for that intervention then we are all in peril. When coercion becomes part of the equation, a crime against humanity is being perpetrated. The intellectual and social suppression of views, research and information inconvenient to vaccine stakeholders and proponents is no different today than it was for those who opposed the practice of bloodletting and dosing patients with mercury. The difference today are the economic factors, for it is projected that by 2020, global vaccine revenues exceed \$60 billion dollars, so with that amount of money in play vaccine and public health policies have been made to support the desires of a criminal cabal where informed consent is perhaps the only remaining firewall.

While phlebotomy therapy is now restricted to two or three specific conditions, obviously the obsession with dosing humans with mercury (Thimerosal) has not been retired and is almost the exclusive province of the vaccine industry. As standard-of-care, bloodletting went on for hundreds of years past when physicians

began using statistics and pointing out the practice was not efficacious. With hundreds of new vaccines in the pipeline, the human race may not survive a few hundred years more of vaccines as currently employed. Thus, vaccine risk awareness and informed consent are the real protectors of public health at this critical time in history.

Bibliography

1. Andorno R. “Global bioethics at UNESCO: in defence of the Universal Declaration on Bioethics and Human Rights”. *Journal of Medical Ethics* 33.3 (2007): 150-154.
2. World Health Organization. “Causality assessment of adverse event following immunization (AEFI): user manual for the revised WHO classification”. WHO/HIS/EMP/QSS (2013).
3. Puliye J and Phadke A “Deaths following pentavalent vaccine and the revised AEFI Classification”. *Indian Journal of Medical Ethics* 2 (2017).
4. Guyer B., et al. “Annual summary of vital statistics: trends in the health of Americans during the 20th century”. *Pediatrics* 106.6 (2000): 1307-1317.
5. Mogensen SW, et al. “The Introduction of Diphtheria-Tetanus-Pertussis and Oral Polio Vaccine Among Young Infants in an Urban African Community: A Natural Experiment”. *E Bio Medicine* 17 (2017): 192-198.
6. Puliye J, et al. “Infanrix hexa and sudden death: a review of the periodic safety update reports submitted to the European Medicines Agency”. *Indian Journal of Medical Ethics* 3.1 (2018).
7. Morbidity and Mortality Weekly Report 66.12 (2017): 343-344.
8. Chen RT, et al. “Combination Vaccines: Postlicensure Safety Evaluation”. *Clinical Infectious Diseases* 33.4 (2001): S327-S333.
9. Disclosure of Adverse Events in Pediatrics: Committee on medical liability and risk management, council on quality improvement and patient safety. *Pediatrics* 138 (2016).
10. Baum C and Anello C “The spontaneous reporting system in the United States”. In: Strom BL, ed. *Pharmacoepidemiology* New York, NY: Churchill Livingstone (1989): 107-118.
11. Schwartz KL, et al. “Effectiveness of pertussis vaccination and duration of immunity”. *CMAJ* 1 188.16 (2016): E399-E406.

⁵<https://thehill.com/blogs/congress-blog/healthcare/295562-if-only-half-of-america-is-properly-vaccinated-where-are-the>

12. Long GH. "Acellular pertussis vaccination facilitates Bordetella parapertussis infection in a rodent model of bordetellosis". *Proceedings of the Royal Society* 277.1690 (2010): 2017-2025.
13. Pawloski LC., et al. "Prevalence and molecular characterization of pertactin-deficient Bordetella pertussis in the United States". *Clinical Vaccine Immunology* 21.2 (2014): 119-125.
14. Martin SW., et al. "Pertactin-Negative Bordetella pertussis Strains: Evidence for a Possible Selective Advantage". *Clinical Infectious Diseases* 60.2 (2015):223-227.
15. Gill C., et al. "The relationship between mucosal immunity, nasopharyngeal carriage, asymptomatic transmission and the resurgence of Bordetella pertussis". *F1000Research* (2017): 1568.
16. Doshi P. "The unofficial vaccine educators: are CDC funded non-profits sufficiently independent?". *BMJ* 359 (2017): j5104.
17. Doshi P. "Pandemrix vaccine: why was the public not told of early warning signs?". *BMJ* 362 (2018): k3948.
18. Pediatrics, *Pediatrics* 97.3 (1996): 413-416.
19. Mold M. et al. "Aluminium in brain tissue in autism". *Journal of Trace Elements Medicine and Biology* 46 (2018): 76-82.
20. Shaw CA. "Aluminum as a CNS and Immune System Toxin Across the Life Span". *Neurotoxicity of Aluminum* (2018): 53-83.
21. Gherardi R., et al. "Biopersistence and brain translocation of aluminum adjuvants of vaccines". *Front Neurology* (2015).
22. Asin J. et al. "Granulomas Following Subcutaneous Injection with Aluminum Adjuvant-Containing Products in Sheep". *Veterinary Pathology* (2018).
23. Asin J. et al. "Cognition and behavior in sheep repetitively inoculated with aluminum adjuvant-containing vaccines or aluminum adjuvant only". *Pharmacological Research*.
24. Hooker B., et al. "Methodological Issues and Evidence of Malfeasance in Research Purporting to Show Thimerosal in Vaccines Is Safe". *BioMed Research International* (2014).
25. Risher JF and Tucker P. "Alkyl mercury-induced toxicity: multiple mechanisms of action". *Reviews of Environmental Contamination and Toxicology* 240 (2017): 105-149.
26. Burbacher TM., et al. "Comparison of blood and brain mercury levels in infant monkeys exposed to methylmercury or vaccines containing thimerosal". *Environmental Health Perspectives* 113 (2005): 1015-1021.
27. Rooney JP. "The retention time of inorganic mercury in the brain - a systematic review of the evidence". *Toxicology and Applied Pharmacology* 274 (2014): 425-435.
28. Geier D., et al. "A review of Thimerosal (Merthiolate) and its ethylmercury breakdown product: specific historical considerations regarding safety and effectiveness". *Journal of Toxicology and Environmental Health* 10 (2007): 575-96.
29. Bradley M. et al. "A Review of Mercury Bioavailability in Humans and Fish". *International Journal of Environmental Research and Public Health* 14.2 (2017): 169.
30. Grandjean P and Landrigan PJ. "Neuro behavioural effects of developmental toxicity". *Lancet Neurology* 13 (2014): 330-338.
31. Rice DC. "The U.S. EPA reference dose for methylmercury: sources of uncertainty". *Environment Research* 95 (2004): 406-413.
32. Guzzi G., et al. "Effect of thimerosal, methylmercury, and mercuric chloride in Jurkat T Cell Line". *Interdiscip Toxicology* 5 (2012): 159-161.
33. Harry G., et al. "Mercury concentrations in brain and kidney following ethylmercury, methylmercury, and Thimerosal administration to neonatal mice". *Toxicology Letter* 154.3 (2004): 183-189.
34. Geier D., et al. "A review of Thimerosal (Merthiolate) and its ethylmercury breakdown product: specific historical considerations regarding safety and effectiveness". *Journal of Toxicology and Environmental Health* 10 (2007): 575-596.
35. Classen JB. "Review of evidence that epidemics of type 1 diabetes and type 2 diabetes/metabolic syndrome are polar opposite responses to iatrogenic inflammation". *Current Diabetes Review* 8 (2012): 413-418.
36. Kassim P and Eslick GD. "Risk of intussusception following rotavirus vaccination: An evidence based meta-analysis of cohort and case-control studies". *Vaccine* 35.33 (2017): 4276-4286.
37. Dubin G., et al "Investigation of a regulatory agency enquiry into potential porcine circovirus type 1 contamination of the human rotavirus vaccine, Rotarix: approach and outcome". *Human Vaccines and Immunotherapeutics* 9 (2013): 2398-4208.
38. Chan VSW. "Use of Genetically Modified Viruses and Genetically Engineered Virus-vector Vaccines: Environmental Effects". *Journal of Toxicology and Environmental Health, Part A* 69 (2006): 1971-1977.

39. Rakowka SK, *et al.* "Activation of the Immune System is the Pivotal Event in the Production of Wasting Disease in Pigs Infected with Porcine Circovirus-2 (PCV-2)". *Veterinary Pathology* 38 (2001): 31-42.
40. Han HH, *et al.* "Serologic response to porcine circovirus type 1 (PCV1) in infants vaccinated with the human rotavirus vaccine, Rotarix™: A retrospective laboratory analysis". *Human Vaccines and Immunotherapeutics* 213 (2017): 237-244.
41. Kuehn BM. "FDA: Benefits of Rotavirus Vaccination Outweigh Potential Contamination Risk". *JAMA* 304 (2010): 30-31.
42. Rizzo P, *et al.* "Unique Strains of SV40 in Commercial Poliovaccines from 1955 Not Readily Identifiable with Current Testing for SV40 Infection". *Cancer Research* 59 (1999): 6103-6108.
43. Gatti AM and Montanari S. "New Quality-Control Investigations on Vaccines: Micro- and Nanocontamination". *International Journal of Vaccines and Vaccination* 4 (2016): 72.
44. Obolski U, *et al.* "Vaccination can drive an increase in frequencies of antibiotic resistance among nonvaccine serotypes of *Streptococcus pneumoniae*". *PNAS* 115 (2018): 3102-3107.
45. Chan VS. "Use of genetically modified viruses and genetically engineered virus-vector vaccines: environmental effect". *Toxicology Environment Health* 69(2006): 1971-1977.
46. Goldman GS and King PG. "Review of the United States universal varicella vaccination program: Herpes zoster incidence rates, cost-effectiveness, and vaccine efficacy based primarily on the Antelope Valley Varicella Active Surveillance Project data". *Vaccine* 31(13), 1680-1694.
47. Goldman G and Miller N. "Relative trends in hospitalizations and mortality among infants by the number of vaccine doses and age, based on the Vaccine Adverse Event Reporting System (VAERS), 1990-2010". *Human and Experimental Toxicology* 31 (2012): 1012-1021.
48. Mawson AR, *et al.* "Pilot comparative study on the health of vaccinated and unvaccinated 6- to 12-year-old U.S. children". *Translational Science* (2017).
49. Miller S. *BMJ* 359 (2017): j5104.
50. Stratton K, *et al.* "Adverse Effects of Vaccines : Evidence and Causality". *Injury* (2011): 0-24.
51. Crowe JE. "Genetic Predisposition for Adverse Events after Vaccination". *The Journal of Infectious Diseases* 196 (2007): 176-177.
52. Vadala M. *et al.* "Vaccination and autoimmune diseases: is prevention of adverse health effects on the horizon?". *EPMA* 8 (2017): 295-311.
53. Rossingol JF. "Nitazoxanide: a first-in-class broad-spectrum antiviral agent". *Antiviral Research* 110 (2014): 94-103.
54. Rajčáni J and Szathmary S. "Peptide Vaccines: New Trends for Avoiding the Autoimmune Response". *The Open Infectious Diseases Journal* 10 (2018): 47-62.
55. Arumugham V. "Evidence that Food Proteins in Vaccines Cause the Development of Food Allergies and Its Implications for Vaccine Policy". *Journal of Developing Drugs* 4 (2015): 4.
56. The Siracusa Principles on the limitation and derogation provisions in the International Covenant on Civil and Political Rights. UN Doc E/CN.4/1984/4 (1984).
57. Bi S and Klusty T. "Forced Sterilizations of HIV Positive Women: A Global Ethics and Policy Failure". *AMA Journal Ethics* 17 (2015): 952.
58. Ethical issues with vaccination for the obstetrician-gynecologist. Committee Opinion No. 564. American College of Obstetricians and Gynecologists". *Obstetrics and Gynecology* 1211 (2013): 144-150.
59. Kadrova A, *et al.* "Isoprinosine in treatment of cervical intraepithelial neoplasia (CIN I-III) and cervical cancer (CC) in situ affected patients with human papillomavirus (HPV) 000308". *International Journal of Gynecological Cancer* 15 (2005): 136-137.
60. Kerridge IH and Lowe M. "Bloodletting: The story of a therapeutic technique". *The Medical Journal of Australia* 163 (1995): 631-633.

Volume 2 Issue 1 January 2019

© All rights are reserved by K Paul Stoller.