The Denial of Adverse Event Risk Following Immunization and the Loss of Informed Consent - A Perspective (Part 2)

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Correlation Does Not Imply Causality, But…

"Both the epidemics of type 1 diabetes and metabolic syndrome correlate with an increase in immunization."[39]

The consumption of organic food increased at the same time many chronic childhood illnesses increased in the US, 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."**[40]

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.

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.[41] 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"[42] 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 of genetically engineered vaccines.[43] 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 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.[44]

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[45] 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 that physicians temporarily suspend use of Rotarix and switch to RotaTeq,[46] 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 US 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 is "occasionally" finding its way into the vaccine even today.[47] 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.

Gatti and Montanari[48] 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"[49]:

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.[49]

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 vaccines. 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. *(emphasis added)*

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 chickenpox vaccine is an expensive mistake from the point of view of public health[51]:

"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[52]:

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, "Pilot comparative study on the health of vaccinated and unvaccinated 6- to 12- year old U.S. children" was published.[53] 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 seven-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 actually five times greater than developing seizures from getting the measles infection itself.[8]

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."[54]

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.[55]

In the US., 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.[56]

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."*[57]

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

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 and 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 so 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[58] 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 first 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 US, the public is told by the government that 80,000 people die from the flu each year; but they might as well say three million die from the flu because neither is true and a large portion of the population does not even believe the lower number. 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 – that is coercion, and coercion makes informed consent impossible.

From the article "Peptide Vaccines: New Trends for Avoiding the Autoimmune Response"[59]:

…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 one 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 value. (Null value for a risk ratio: The value indicating no difference between the groups.) 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 shortcomings 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 that utilized the Danish Psychiatric Central Research Register was indicted by a US federal grand jury on 13

counts of fraud and nine 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 they allow for manipulation of 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."[60]

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.[61]

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.[62]

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....[63]

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 not 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 times greater (in the US) 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?[64] 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 US government licensed the technology to make the vaccine to Merck and GSK, and thereby profits from its use?

Vaccine policy in the US 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."[65]

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 are 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.[66]

In the US, 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. 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.

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