

The Institute for Pure and Appied Knowledge 2912 Kilcairn Lane Allison Park, PA 15101 (412) 728 8743

Jan 18, 2017

Dear Medical Community Leader:

I am enclosing a copy of my latest book, "The Environmental and Genetic Causes of Autism", published six months ago by Skyhorse Press, a project for which I read over 2,000 research studies on autism. I am sending it in the hope that you might help bring about much-needed reforms in training the next generation of physicians. I hope you will take some time and look over the results and conclusions from the literature I have canvassed. While writing Causes", I offer you the following highlights, which do not represent by any means the entirety of the science reviewed in the book:

- (1) Contrary to testimony given to Congress by Rr Adm. Schuchat of the US Centers for Disease Control, studies do indeed exist that demonstrate association between vaccines and autism. Those studies are reviewed on page 217 of "Causes". These are not trivial studies and should no longer be ignored.
- (2) A growing number of studies have found an increase in the risk of autism after the MMR if Paracematol (Acetaminophen, e.g., Tylenol[™]) is administered to ease the fever. These include:
 - Schultz ST, Klonoff-Cohen HS, Wingard DL, Akshoomoff NA, Macera CA, Ji M. 2008 Acetaminophen (paracetamol) use, measles-mumps-rubella vaccination, and autistic disorder: the results of a parent survey. *Autism.* 12(3):293-307. doi: 10.1177/1362361307089518.
 - Bauer AZ, Kriebel D. Prenatal and perinatal analgesic exposure and autism: an ecological link. *Environ Health.* 12:41. doi: 10.1186/1476-069X-12-41.
 - Claudia B. Avella-Garcia, Jordi Julvez, Joan Fortuny, Cristina Rebordosa, Raquel García-Esteban, Isolina Riaño Galán, Adonina Tardónf, Clara L. 2016. Rodríguez-Bernal, Carmen Iñiguez, Ainara Andiarena, Loreto Santa-Marina, Jordi Sunyer. Acetaminophen Use in Pregnancy and Neurodevelopment: Attention Function and Autism Spectrum Symptoms. *International Journal of Epidemiology* DOI: 10.1093/ije/dyv
 - Saeedan AS et al., 2018. Effect of early natal supplementation of paracetamol on attenuation of exotoxin/endotoxin induced pyrexia and precipitation of autistic like features in albino rats. *Inflammopharmacology.* doi: 10.1007/s10787-017-0440-2.

In 2010, Shoffner et al., (2010) found that 71% of kids with regressive autism had an episode of fever > 101°F In 33% of these cases, the fever occurred right after vaccination – and none showed regression unless fever had occurred:

 Shoffner J, Hyams L, Langley GN, Cossette S, Mylacraine L, Dale J, Ollis L, Kuoch S, Bennett K, Aliberti A, Hyland K. 2010. Fever plus mitochondrial disease could be risk factors for autistic regression. J Child Neurol. 25(4):429-34. doi: 10.1177/0883073809342128.

These studies, and many other, tell me and many others that we clearly need to develop rapid biomarker for screening and develop a culture within medical practice that inform patients of their individual risk.

- (3) There are four plausible mechanisms of vaccine-induced encephalopathy-mediated autism (VIEMA). These include (a) chronic microglial activation, (b) mitochondrial damage, (c) protein disorder, and (d) vaccine-induced autoimmunity. The evidence of for each of these mechanisms are reviewed.
- (4) In my book "Cures vs. Profits", I reviewed vaccines in a chapter and I found that the evidence that CDC misled the public, the IOM, the FDA, and Congress to be overwhelming. As one example, positive association results were fraudulently removed from the Destefano et al. (2004) study of the rates on-time vs. delayed MMR vaccination. I am enclosing a copy of statements provided by Dr. William Thompson, who was put on administrative leave after taking his concerns about presenting these results to the Institutes of Medicine to Dr. Julie Gerberding, who at the time was the Director of the CDC. After leaving CDC, Dr. Gerberding accepted a position at Merck, Inc. to head up their vaccine division.
- (5) A pattern exists in the studies most commonly cited by CDC as demonstrating no effect of vaccines on autism. First, they are nearly all severely underpowered. In 2012, the Institute of Medicine rejected 17/22 studies put forward for consideration by CDC, leaving four studies (one study was published twice). We have performed power calculation on these studies and have found that these studies could not have detected a positive association between vaccines and autism if one did, in fact, exist. (This inference is non-circular as no effect size from the studies were used in the power calculations). This small handful of studies determined the IOM's conclusion of no association. A manuscript is being prepared with these results. Second, the studies conducted by CDC nearly all initially found association, but then after overcorrecting for assumed confounders, the analyses were conducted in manner that made the association insignificant. However, these studies did not report interaction terms, and suffer from other serious irregularities to objective statistical model selection. When they could not make an association go away, they simply removed the results, as in the case of Destefano et al. (2004).

Since writing "Causes", I have also been conducting, with colleagues, research on matches between peptides found in pathogens in vaccines in search of potential molecular mimics that could explain why autistics and their mothers tend to have antibodies against brain proteins. To our surprise, we have discovered that vaccines are not routinely screened for epitopes that match human proteins. Thus, autoimmunity induced by vaccines would seem to be guaranteed for some individuals, especially from adjuvanted vaccines.

We have also been studying pediatric dosing of aluminum from vaccines on the CDC schedule. Contrary to intuition, our analysis shows that infants receive far too much aluminum from vaccines when the doses are properly studied as mcg/kg/day. We have a manuscript under review that we hope we will be able to share with you. The CFR/FDA limit of exposure of aluminum from parenteral sources is 4-5 mcg/kg/day. On Day 1, infants receiving the HepB vaccines receive 250 mcg. A 7.5 lb (3.3 kg) male infant thus receives 75.75 mcg/kg/day. Thus, the HepB vaccine is violation of Federal Regulation 21CFR201 on exposure for body weight per unit time. Our manuscript on this topic is undergoing peer review.

Available scientific knowledge does not point exclusively to vaccines. The book includes many studies that point to high individual risk associated with specific industrial and agricultural-sourced toxins. The Environmental Toxin Liability Sampling theory is based a total load of toxins that are less tolerable, in general, by individuals who, for inherited (rare) or de novo (more common) have a susceptibility due to errant detoxification abilities. I point to the work of Scott Faber and his team especially on the different response of autistics to total exposures to environmental toxins (they did not study vaccines; *Nature Scientific Reports* 6:26185 doi:10.1038/srep26185). Thimerosal and aluminum make matters worse for these kids as they damage cells' ability to detoxify - both disrupt proper endoplasmic reticulum functions). Thimerosal specifically inhibits ERAP1, disrupting the MHC adaptive immune protein production. This is likely why people who receive Thimerosal-containing flu vaccines end up with increased rates of other upper respiratory infections. Aluminum causes distortions of the endoplasmic reticulum – the cell's detoxification channels (e.g., Rivzi et al., 2014). This disables cells' ability to properly conduct the Unfolded Protein Response.

It is my sincere hope you take these messages under consideration in the training of the next generation of pediatricians, both nurses and doctors, and in your interactions with professionals in your School of Medicine and your Graduate School of Public Health. While vaccines can provide key protection against diseases, they are formulated in a manner that also disregards the effects of their excipient on individual and public health. There is a single-mindedness about vaccines the excludes risk awareness, and see discussion of risk and safety as a threat, rather than a warning signal. The warning signal has been sounded, but, like so many other disasters, the signal has not been heeded. This need not be so. I have ideas on how artificial immunization could be approached, and am working with public interest groups to petition the government for \$1 Billion in extramural funding for Neurodevelopment Research Reform. These include, among others, safety screening programs (biomarkers) as well as encouraging technological innovations in artificial immunity that compete on the platform of safety. Our aim is the bring immunization into the realm of personalized medicine. This effort is critically important, and I urge you to call your Congressional Representatives and NIH Program Officers to have them demand change in biomedical research priorities that looks past the many weak, underpowered, and biased correlation studies on vaccine safety and into a future where both our children's health and their minds are protected. For details on seven major research programs that over 600 American citizens will be asking for, please contact me at jim@ipaknowledge.org.

For more information additional non-canonical perspectives, see jameslyonsweiler.com

I hope you will join the growing number of Americans who will no longer engage in the culture of ridicule, derision, spite, refusal of access to medical care for those who are Vaccine Risk Aware, and help us work toward a future of artificial immunization that is made much safer for all.

Sincerely, James Lyons-Weiler, PhD Allison Park, PA 15101 Jan 16, 2018 http://ipaknowledge.org