Statement of James R. Neuenschwander, M.D.

I am a physician, dually board certified in Emergency and Integrative medicine, who has been in clinical practice for over 30 years. I am not an academic: I sit knee to knee with patients every day. My practice consists primarily of chronically ill adults and children, who make up about 20% of my total practice. Most of these children have neurodevelopmental issues (autism, ADHD, behavioral issues, speech/language delay, etc.) or have immune disorders (allergies, asthma, eczema, recurrent infections, and autoimmunity).

In the past 30 years, I have seen a decline in pediatric health with an accompanying increase in the number and severity of the pediatric patients that I see. Many of the parents of these children believe that it was a vaccine or vaccines that caused their child's condition (whether it be autism, aggression, asthma, autoimmunity, etc.). I was taught, early on in my career, the tenet of "ignore mom (or dad)" at your peril. Yes, parents might be mistaken; but they typically know their children very well. Most of the parents in my practice were believers in the vaccine schedule and the safety of the system that mandated them. It was only after they, themselves, witnessed the injury that they changed their opinion.

I, too, have changed my opinion over the last 30 years based on my personal observations. I have seen febrile seizures and alterations in behavior as a result of a vaccination in the course of my career in Emergency medicine. I have seen unexplained infant deaths in which the parent stated that the child had recently been seen by their pediatrician (and received vaccines). I also know the none of this was ever reported to the Vaccine Adverse Events Reporting System (VAERS) out of ignorance on my part, lack of interest by the hospital, and lack of knowledge of this system by the nursing staff. I also changed my opinion based on the countless histories given to me by the parents of the patients that I see in my office. Sometimes it was obvious—a child received a vaccine and cried continuously for two days and disappeared into autism. Most of the time it was more pernicious—a child received a vaccine and slowly lost eye contact and words; and started stereotypic movements (like flapping and spinning) for which we use the word, "stimming." Some parents have video documentation of their child before and after vaccination showing the regression. With the advent of the Gardasil vaccine, I now have adolescents that can tell me that they developed a headache within 24-48 hours of the vaccine and discoordination within a week followed by fatigue, dizziness/lightheadedness/tachycaria—a syndrome we call postural orthostatic tachycardia syndrome (POTS). Most of these patients were top students and frequently athletic. After vaccine injury, they are reduced to struggling merely to keep up with basic academics. These adolescents have the voice that an infant doesn't.

It has been difficult for me to explain the disconnect I see between what the parents in my practice are telling me and what I have learned from the Centers for Disease Control and Prevention (CDC). The CDC continues to emphasize that vaccines are safe and effective, extensively studied for both, and should be given to all children at standardized dosing

4201 VARSITY DRIVE • SUITE A • ANN ARBOR, MI 48108 • (734) 995-3200 • FAX (734) 995-4254
WWW.BIOENERGYMEDICALCENTER.COM

according to a fairly rigid schedule with nearly no exceptions. They claim that vaccine injuries are exceedingly rare and frequently give numbers like one in a million. Given that about four million children are born in the United States every year and they each receive six rounds of vaccines by the time they are two (when symptoms have usually occurred), I must be seeing every vaccine injured child in the country based on CDC estimates of vaccine injuries.

As we will see, studies on vaccine safety are seriously flawed. No vaccine (with the exception of 340 girls in one Gardasil trial) has ever been subjected to a pre-licensure, inert placebo-controlled trial, which is the gold standard for evaluating medication safety and effectiveness. There have been a few, small studies suggesting that unvaccinated children are much healthier than vaccinated children, but the CDC refuses to do such a study despite having the data at their fingertips--the Vaccine Safety Database (VSD) is a collection of about 10 million patient records from which the CDC is able to study any danger signals that arise from VAERS reports. The current excuse from the CDC is that such a study would be "unethical;" because it would deny a population the benefits of vaccination. The reality is that there are enough unvaccinated children in that database to do a retrospective study, and this could be done in a matter of weeks.

We also need to take into consider the concept of "standard of care." The defendant in this case practices integrative medicine and should not be held to the traditional standard of care. Practices standards for integrative medicine dictate that physicians should customize their treatment to the patient in front of them and not adhere blindly to a protocol that is published by some governmental agency or society. These same practice standards dictate that an integrative physician should always be looking for ways to prevent potential health issues and optimize a patient's overall health, not simply focus on one symptom or disease. Everything is interconnected and there is no intervention that does not have potential consequences. As we will see, there are many issues with our vaccine program that have led many of us to question the schedule, the number of vaccines, the blind adherence to that schedule regardless of risk factors, and the complete lack of acknowledgement by the government that there are any problems with our vaccine program or the state of our children's health. Many physicians have seen the damage vaccines can cause and have become concerned over the vaccine schedule. They are afraid to speak out for fear of losing their job, being ridiculed by their colleagues, or being investigated by their medical board.

I. Vaccine Safety

The standard line from the CDC or anyone promoting vaccines is, "Vaccines are safe and effective" and "The science is settled." When evaluating the evidence for how vaccines are tested for safety, we find two approaches. First, there are the pre-licensure trials in which vaccines are supposed to be compared to a placebo to determine the side effects and benefits. Second, there is a post marketing system (using VAERS and the VSD) to identify potential issues that were not discovered in the pre-licensure trials.

With the exception of 340 girls in one Gardasil trial (whom we will discuss in the autoimmunity section), no vaccine has ever undergone an inert placebo-controlled trial. Some vaccines, like the hepatitis vaccine, had no placebo group in their approval trials for children. Other vaccines were compared to old vaccines (that have never undergone an inert placebo-controlled trial either) or to vaccine ingredients, particularly the vaccine adjuvant (an adjuvant is an ingredient designed to invoke an immune response and make the vaccine work—more on this later as well). For example, the "placebo" group with the Gardasil vaccine received an aluminum adjuvant injection. Disregarding the ethics of using an immune reactive material when informed consent implied that the participant would be receiving either the vaccine or a placebo, this is not a true placebo. The aluminum adjuvant is designed to activate the immune system; and, by itself, this adjuvant is associated with immune injury (like fevers, autoimmunity, and particularly autoimmune encephalitis).

Vaccines studies routinely follow patients for short periods of time to determine side effects—six months for Gardasil, six weeks for vaccines like MMR (with a six-month phone follow up), and 3-5 days for vaccines like Hepatitis B. There are no long-term studies to determine outcome for problems that take longer time frames to develop (like neurodevelopmental delay, autoimmunity, infertility, food allergies, etc.). This type of safety science is universal in the industry and would be completely unacceptable if it were applied to medications, which are routinely followed for years prior to approval.

Despite the denials by the CDC, a recent World Health Organization (WHO) summit on vaccine safety revealed the true state of vaccine safety. The most damning statements came from Heidi Larson, the director of the WHO Vaccine Confidence Project. She was reviewing the reasons why there is so much vaccine hesitancy (over 50% of parents by some estimates). She essentially admitted that adequate safety trials have not been done, and the current evidence is inadequate. In her presentation, she stated, "You can't repurpose the same old that's relevant to new problems. So, we need much more investment in safety science." In addition, she admits that physicians are questioning the safety of vaccines—this is not a local phenomenon—it is world-wide.

Our own Maria Guber, director of the Office of Vaccine Research and Review for the FDA admitted that pre-licensure studies may not be powerful enough to see all of the side effects of a vaccine, and that adjuvants approved for adults have different effects on children. The MMR and Hepatitis B vaccines (two and three doses given to 4 million children per year in the United States) were each studied on less than 1000 children prior to licensure. Again, this type of evaluation would never hold water if these were drug trials. How can you find a one in 10,000 side effect (the rate of unexplained infant death in the US) if you study less than 1000 kids?

II. Vaccine Injury

The VAERs system was established to monitor post-licensure vaccine injuries and was supposed to serve as an early warning system to the CDC so they could follow up with further evaluation of that signal using the VSD. A study funded by the HHS to determine whether VAERs data

could be automated, showed that less than 1% of all vaccine events are ever reported.(Bernstein, 2010) This system has been an abject failure. We can get an idea of vaccine injury by evaluating pre-licensure trials. The most recent of these was a trial funded by Glaxo Smith Kline (GSK) to get approval of their MMR vaccine in the US. This trial, in usual fashion, did not use an inert placebo or even a delayed treatment group (completely ethical since there is a 4-6 month time window to administer the MMR): they used the current MMR2 vaccine from Merck as their control group. Because the side effects were the same, they declared the vaccine to be safe.(Klein et al., 2019) When evaluating their safety data (Supplementary table 6, which was published in a separate document), you find that 50% of parents reported an unsolicited (meaning something other than arm soreness, shoulder disfunction, or fever) reaction. 6% of parents reported a grade 3 unsolicited adverse event (these are the most serious reactions) and 10% of these otherwise healthy 12 month olds ended up in an emergency room. All of this was within six weeks of the vaccine. In addition, a six month follow up revealed that about 3.5%of these kids had a new, chronic medical condition (primarily eczema, which is an immune disorder) after the vaccine. This was considered safe because the current, MMR2, vaccine had the exact same rates. Without a real placebo group, how do we know if these outcomes were random or related to the vaccine (most of us who practice in the real world know that 10% of healthy 12 month old babies don't end up in the ER every 6 weeks or develop a new chronic medical condition in 6 months). This does not address the question, "do vaccines make our children healthier?" It merely shows the injuries caused by the MMR vaccine.

In the case of the Gardasil vaccine, we actually have an inert placebo group in the pre-licensure trials. 340 girls received a saline placebo. They are reported in the package insert when discussing local reactions to the injection (tables 1-4).(Merck, 2006 (with updates)) There are three columns: Gardasil vaccine, aluminum adjuvant (AHSS) control group, and saline control group. The biggest complaint with the Gardasil vaccine has been its propensity to cause autoimmunity. When Merck reports the rates of adverse events, particularly the rate of autoimmune disorders (tables 5-9), that third column disappears as the data of the 340 saline placebo arm patients is folded into the to the over 9000 girls who received the AHSS arm of the study, thereby obscuring the fact that the AE outcome was dramatically worse in the subjects who received the vaccine or AHSS, versus the girls who received a true inert placebo, (which is really what a placebo is or should be) . The resulting autoimmune rate of about 2.5% in six months following the vaccine was considered acceptable, because it was the same in both groups. A recent FOIA request to the FDA confirmed that none of the 340 saline placebo girls developed an autoimmune disorder in that time period. AHSS appears to have caused 2.5% of healthy teenage Danish girls to develop an autoimmune disorder within six months of receiving the vaccine. We have no idea what the real numbers are—almost all of the placebo groups received the vaccine after six months.

When I, as a practicing clinician, see something in my office that I cannot explain, I start researching. In the case of vaccine injuries, what I have found is a vehement denial of vaccine injuries by the CDC despite documentation of vaccine injuries by the manufacturers. Since vaccine manufacturers cannot be sued for any injury that a vaccine causes (unless they commit

fraud and knowingly hide that injury), they report all of these. Review of the trials that were used to approve these vaccines reveal the same type of adverse event reporting that I have described above. There is no doubt that vaccines can cause injury and do so at a much higher rate than one in a million.

The question of vaccine safety has been put to the Institute of Medicine (IOM, now known as the Health and Medicine Division of the National Academies of Sciences, Engineering, and Medicine) a number of times; and with each report, there is a rebuke as to the lack of safety studies with vaccines and the complete lack of any study of the safety of the entire vaccine schedule.(Hinshaw, 2013; Stratton, 2012) The 2012 examined the evidence behind vaccine/injury pairs and found that there was inadequate evidence for the majority of them. The 2013 study evaluated evidence for the safety of the entire vaccine schedule and found there was none. Given that the CDC is responsible for the safety of the vaccine program and they appear to be unwilling to do the studies, it is understandable why many of us in the medical community have begun to doubt the safety of our current vaccine schedule.

III. Vaccine induced autoimmunity

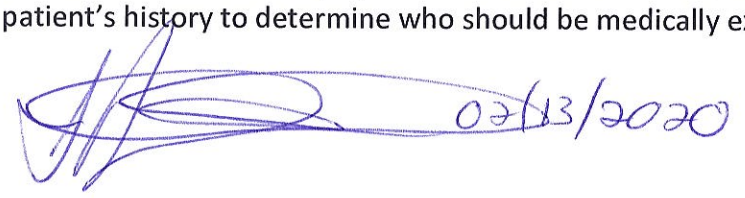
This issue lies at the crux of most requests for medical exemptions for vaccines. We know from the above MMR and Gardasil studies, that certain vaccines appear to cause autoimmune disorders in some populations. There is a syndrome known as Autoimmune Syndrome Induced by Adjuvants (ASIA) to explain this link between vaccines and autoimmunity. Autoimmune syndromes are a result of an underlying genetic tendency along with an environmental insult. This theory has been backed by a number of prominent immunologists and has been the topic of two editions of the journal Lupus. A recent review of 300 patients with ASIA revealed that the average time between vaccination/adjuvant exposure and the onset of symptoms was about 16 months (range=3 days to 5 years)—far beyond the reach of any of the pre-licensure trials.(Watad et al., 2018)

The link between vaccine adjuvants and autoimmunity is essential to understand, because many childhood neurodevelopmental disorders have some sort of immune based chronic encephalitis at their source. This is particularly true of autism spectrum disorder (ASD). A recent autopsy study from a Harvard group showed that 70% of autism brains in the study demonstrated evidence for autoimmune encephalitis.(DiStasio, Nagakura, Nadler, & Anderson, 2019) Despite repeated denials over the lack of link between vaccines and autism, the 2012 IOM report on the subject rejected the connection between MMR and autism (based on seriously flawed population studies), discarded one study linking DPT and autism (because it used data from VAERs), and could not find evidence one way or the other for all of the other vaccines. We have since had a true vaxxed versus unvaxxed study suggesting that autism rates were four-fold higher in vaccinated kids (and unvaccinated kids, in general, were much healthier than their vaccinated peers).(Mawson, 2017) This data is supported by another, yet unpublished study as well. We also have data from a secret meeting on the links between Hepatitis B vaccine and autism that showed a link (Simpsonwood/Verstraeten data)

If there is a family history for autoimmunity or immunodeficiency, wouldn't it follow that perhaps these individuals would be at more risk for developing a significant adverse event as a result of a vaccine? We know that genetics can explain why some individuals do not respond to certain vaccines, like the MMR: this concept is not disputed.(Ovsyannikova, Salk, Larrabee, Pankratz, & Poland, 2015) It would follow that certain genetic polymorphisms (SNPs) would be linked to vaccine injury. In integrative medicine, use of genomics to guide clinical decision making has become much more popular (and accepted) to the point where it is becoming standard of care.

Conclusions

My evaluation of this case shows a physician seeking to minimize the possible damage that can be caused by vaccine through using the tools that are available to an integrative physician, including the use of genomics. The cases that are mentioned are of patients who have family history for autoimmunity or immune dysfunction. These are the patients where you would expect to have some type of genomic variation that would increase risk for injury. The defendant is well aware of all of the literature that I have discussed and knows the connections between aluminum adjuvants and autoimmunity, between autoimmune encephalitis and autism, and immune over-activation and multiple chronic diseases (like asthma, eczema, and allergies). The defendant is also aware of the research (and has the experience) suggesting that unvaccinated children are much healthier than their vaccinated peers. Our job, as integrative physicians, is to care for the patient in front of us in a way that we feel is best based on current evidence in our field—and not based on some blanket recommendation from a committee that has never seen this patient or is willing to admit that vaccine injuries occur. Individuals like this should not be brought before medical boards to be threatened. They should be lauded for their meticulous care of their patients in an attempt to prevent a medical disaster. This is clearly an attempt to warn other physicians not to write medical exemptions, and it has been very effective. An advocacy group, during the passage of SB276 called multiple offices in California posing as a parent with a child who was moving to California from a state that had other exemptions and who had anaphylaxis as a result of vaccination (a CDC approved reason for medical exemption). This group could not find one practice that was willing to write that exemption. This type of practice by fear of the medical board will only accomplish one thing—harm to the patient. It is time to understand that all medical interventions have risks, including vaccines; and those patients that have a medical, family, or genetic history that singles them out as have much higher risk, should never be forced to undergo that intervention. It is also time to understand that physicians should be able to use their individual knowledge of a patient's history to determine who should be medically exempted from these procedures.



Bernstein, L. K. (2010). Electronic support for public health—Vaccine Adverse Event Reporting System (ESP:VAERS). Retrieved from

https://digital.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf

DiStasio, M. M., Nagakura, I., Nadler, M. J., & Anderson, M. P. (2019). T lymphocytes and cytotoxic astrocyte blebs correlate across autism brains. *Ann Neurol, 86*(6), 885-898. doi:10.1002/ana.25610

Hinshaw, A. A., TJ; Berg, A; Buka, SL; Charo, RA; Fairbrother, G; Fuentes-Afflick, E; Gospe, SM; Greenberger, PA; Heitjan, DF; Leland, AC; Rohani, P; Ross, LF; Thomas, PA (2013). *The Childhood Immunization Schedule and Safety: Stakeholder Concerns, Scientific Evidence, and Future Studies*. Washington (DC): National Academies Press.

Klein, N. P., Abu-Elyazeed, R., Povey, M., Macias Parra, M., Diez-Domingo, J., Ahonen, A., . . . Henry, O. (2019). Immunogenicity and Safety of a Measles-Mumps-Rubella Vaccine Administered as a First Dose to Children Aged 12 to 15 Months: A Phase III, Randomized, Noninferiority, Lot-to-Lot Consistency Study. *J Pediatric Infect Dis Soc*. doi:10.1093/jpids/piz010

Mawson, A. B., A; Jacob, B; Ray, BD. (2017). Preterm birth, vaccination and neurodevelopmental disorders: a cross-sectional study of 6 to 12 year old vaccinated and unvaccinated children. *Journal of Translational Science, 3*(3), 1-8. doi:10.15761/JTS.1000187

Merck. (2006 (with updates)). Gardasil prescribing information. Retrieved from https://www.fda.gov/files/vaccines,%20blood%20&%20biologics/published/Package-Insert---Gardasil.pdf

Ovsyannikova, I. G., Salk, H. M., Larrabee, B. R., Pankratz, V. S., & Poland, G. A. (2015). Single nucleotide polymorphisms/haplotypes associated with multiple rubella-specific immune response outcomes post-MMR immunization in healthy children. *Immunogenetics, 67*(10), 547-561. doi:10.1007/s00251-015-0864-z

Stratton. (2012). *Adverse Effects of Vaccines: Evidence and Causality* (K. Stratton Ed.). Washington (DC): National Academies Press.

Watad, A., Quaresma, M., Bragazzi, N. L., Cervera, R., Tervaert, J. W. C., Amital, H., & Shoenfeld, Y. (2018). The autoimmune/inflammatory syndrome induced by adjuvants (ASIA)/Shoenfeld's syndrome: descriptive analysis of 300 patients from the international ASIA syndrome registry. *Clin Rheumatol, 37*(2), 483-493. doi:10.1007/s10067-017-3748-9