Rebuttal to the comment by Dorit Reiss
By Dr. James Lyons-Weiler, PhD and Bernadette Pajer

Re: Docket Number CDC-2016-0094
Proposed Revised Vaccine Information Materials for MMR (Measles, Mumps, and Rubella and MMRV (Measles, Mumps, Rubella, and Varicella) Vaccines
Federal Register October 18, 2016

While we have provided our remarks on CDC's draft VIS revisions in a separate comment (Comment Tracking Number **1k0-8tlr-fn92**), we are providing this rebuttal in response to the comment of Dorit Reiss with deep concern on the incorrectness of some of her points. Ms. Reiss is a professor at a school of law and as such her comments may be taken as fact by those who do not take the time to verify them. Unfortunately, many of her claims of fact are demonstrably incorrect. Her employer is affiliated with the University of California, which for many endeavors is in partnership with Kaiser Permanente, which in turn is in partnership with Merck, the manufacturer of MMR and MMRV. Ms. Reiss has elsewhere disclosed personal conflicts of interest via family ownership of stock in at least one vaccine-manufacturing company. While these types of affiliations and partnerships are not unusual and are not proof of influence, Ms. Reiss uniformly and very actively takes positions on vaccine law and policy that favor vaccine manufacturers and restrict medical freedom of choice. (http://www.uchastings.edu/faculty/reiss/)

Ms. Reiss's comment can be found here: https://www.regulations.gov/document?D=CDC-2016-0094-0151

(1) Reiss writes:

> "The link to the CDC monitoring of safety and the explanation of VAERS can allow parents who want to understand better how safety is monitored to do so."

Rebuttal: It is widely recognized, and reported by medical experts, scientists, and public health research facilities that the passive surveillance systems known as VAERS fails to capture sufficient representation of the full spectrum of adverse events and injuries from vaccines, and that it therefore provides no useful data for determining cause or frequency of adverse reactions. These reports of insufficiencies are especially frequent when the public cites the numbers of adverse events reported. The Institute of Medicine (IOM) states in their 2004 *Immunization Safety Review: Vaccines and Autism*:

> "Therefore it is **usually not possible** to determine causal associations between vaccines and adverse events from VAERS reports nor can VAERS be used to calculate incidence or prevalence of an adverse reaction (Varricchio et al., 2004)." (emphasis added)

In short, VAERS data, and studies that use VAERS data, cannot provide reliable enough information on risk to provide comfort or understanding to concerned parents.

(2) Reiss suggested changes:

> "If you have gotten any other vaccines in the past 4 weeks. Live vaccines given too close

> together might not work as well." Given the text afterwards, the bold part should probably say "If you have gotten any other live virus vaccines in the past 4 weeks."

Rebuttal: In keeping with the ongoing common practice of failing to provide patients with sufficient information about vaccines and their risks to allow truly informed consent, the general public is often unaware of the details of the vaccines they are given and may not know if a recent vaccination was live or inactivated. Patients should be told to report any recent vaccine given so the administrator and attendant can properly evaluate both type and appropriateness of administering MMR or MMRV.

Also, because studies do not exist which show the safety of every vaccine concomitant or proximal combination, language should be added informing patients when risks of adverse reaction due to concomitant/proximal administration are, in fact, unknown. Doctors and patients can easily be provided access to references to studies for each knowledge claim made by health care professionals about vaccines; therefore, such references (citations) should be provided. The totality of the evidence in support of, and that which does not provide support, for safety and efficacy knowledge claims should be represented in the citations provided. Conflicting evidence from studies representing a variety of levels of evidence, and dissenting opinions or interpretations by scientific professionals should also be included.

(3) Reiss claims:

> "The VIS both mentions "permanent brain damage" and "long term seizures" as "severe and very rare problems following MMR vaccines." However, recent studies do not support a link between MMR and encephalitis or brain damage, and to my knowledge, not to seizures, either. See: http://pediatrics.aappublications.org/content/early/2015/01/01/peds.2014-1822 "

Rebuttal: Ms. Reiss's citation disproves her claim:

> "BACKGROUND AND OBJECTIVES: All measles-containing vaccines are associated with several types of adverse events, including seizure, fever, and immune thrombocytopenia purpura (ITP). Because the measles-mumps-rubella-varicella (MMRV) vaccine compared with the separate measles-mumps-rubella (MMR) and varicella (MMR + V) vaccine **increases a toddler's risk for febrile seizures**, we investigated whether MMRV is riskier than MMR + V and whether either vaccine elevates the risk for additional safety outcomes." (emphasis added)

The study results showed:

> "Compared with MMR + V, MMRV **increased risk of seizure and fever 7 to 10 days after vaccination**." (emphasis added)

This was not a vaccinated verses non-vaccinated study; it was a study that only compared outcomes for those vaccinated with MMRV versus those vaccinated with MMR + V.

NOTE: In spite of the finding of increased risk of seizure, the conclusion of the study in the

abstract claims:

> "This study did not identify any new safety concerns comparing MMRV with MMR + V or after either the MMRV or the MMR + V vaccine. This study provides reassurance that these outcomes are unlikely after either vaccine."

This conclusion is not supported by the results of the study, as is easily seen, and is in fact so egregiously erroneous, the AAP should demand a revision or retraction of the study. Ms. Reiss has carried forward the misinterpretation without, evidently, a critical examination of the study or its full contents. Here we see a prime example of how public health policy can be made to rely on conclusions claimed but which the results in the study clearly do not support.

IOM disagrees with Ms. Reiss in regards to specific type seizure (febrile) and encephalitis (inclusion body). From IOM's 2012 *Adverse Effects of Vaccines: Evidence and Causality*:

> "Conclusion 4.1: The evidence **convincingly supports** a causal relationship between MMR vaccine and measles inclusion body encephalitis in individuals with demonstrated immunodeficiencies." (emphasis added)

> "Conclusion 4.4: The evidence **convincingly supports** a causal relationship between MMR vaccine and febrile seizures." (emphasis added)

Also of importance, an MMR vaccine fatality resulted in compensation and a new law in New Jersey, permitting parents to waive the second dose of the MMR due to its significant risks:

Case Details

VAERS ID: 133895 (history) **Vaccinated:** 2000-01-25
Age: 5.0 **Onset:** 2000-02-01, **Days after vaccination:** 7
Gender: Female **Submitted:** 2000-02-04, **Days after onset:** 3
Location: New Jersey **Entered:** 2000-02-14, **Days after submission:** 10

Vaccination	Manufacturer	Lot	Dose	Route	Site
DTP: DTP (TRI-IMMUNOL)	LEDERLE LABORATORIES	466022	4		
MMR: MEASLES + MUMPS + RUBELLA (MMR II)	MERCK & CO. INC.	12755	1		
OPV: POLIO VIRUS, ORAL (ORIMUNE)	LEDERLE LABORATORIES	80045	3	PO	

Administered by: Other **Purchased by:** Other
Symptoms: Encephalopathy
SMQs:, Noninfectious encephalitis (broad), Noninfectious encephalopathy/delirium (narrow), Chronic kidney disease (broad)
Write-up: 1 wk post vax, pt devel severe fatal encephalopathy.

Life Threatening? No
Died? Yes
Date died: 2000-02-04
Days after onset: 3
Permanent Disability? No
Recovered? No
ER or Doctor Visit? No
Hospitalized? No
Previous Vaccinations:
Other Medications: Montoux, Parker (mfr), 250611 (Lot) ID/LForearm, 1 previous dose
Current Illness: NONE
Preexisting Conditions: NONE
Diagnostic Lab Data:
CDC Split Type:

> *"After Holly suffered a severe reaction to the vaccine, leaving her convulsing, brain damaged and on life support, her family was told by the doctors that Holly would remain in a vegetative state and would not recover. Holly's parents felt helpless and they reluctantly agreed to have their daughter removed from life support.*

Robin was awarded compensation for Holly's death after it was determined the MMR vaccine caused Holly to suffer acute encephalopathy.

After a long battle and without success, Robin fought to change the National Vaccine Injury Compensation Program. She learned most parents that file a vaccine injury claim get denied compensation.

With support from the governor of New Jersey, Holly's Law was created. This law can save your child from receiving a potentially lethal second dose of the MMR vaccine, required for all children to attend school, except if you have a vaccine exemption filed with the state.

The second MMR vaccine dose, listed on the CDC recommended vaccine schedule, is not actually a booster vaccine; it is recommended or mandated because Merck states two to five percent of children don't obtain levels of protection from the first MMR dose and that all children should get a second dose, to cover those who didn't gain protection from the first one." http://hopefromholly.com/blog/

(4) Reiss states:

"The comment under the listed harms suggests that 'it's impossible to tell whether they are caused by the vaccine.' But most people are likely to read this section, coming right after mild and moderate risks actually associated with the vaccine, as discussing rare risks associated with the vaccine, and the presentation supports such an interpretation. This may make people see the vaccine as having higher risks than the evidence supports. I think the VIS should be changed, to avoid misleading people into believing the vaccine causes brain damage, possibly by simply omitting that line. Alternatively, if you think it must be included, maybe change the title of the section to say: "Rarely reported problems that may not be caused by the vaccine:" Or "Rarely Reported Problems Without Good Evidence of a Link to the Vaccine".

Rebuttal: Ms. Reiss does not quote the proposed draft correctly. It actually says: "These reactions happen so rarely that is it difficult to tell whether they are caused by the vaccine."

For a full understanding of why it is difficult to ascertain adverse reaction causes in the post-clinical trial phase (meaning, once the vaccine is subjected on the general public and in population groups never tested in the pre-licensure phase), one must understand the flaws and weaknesses in the passive reporting system our nation relies upon to gather after-market data. This FDA article provides a good explanation:

http://www.fda.gov/downloads/Safety/MedWatch/UCM168497.pdf

Add an inadequate reporting system to a no-fault vaccine injury court system, no manufacturer liability and no legal requirement for manufacturers to either attend vaccine court or follow-up with their own studies, and one is left with no choice but to reveal to those attempting to make an informed decision that some reported reactions are "difficult to tell whether they are caused by the vaccine." The presentation order in the current VIS should be updated to better emphasize

this fact of uncertainty, because individuals have a right to know.

Ms. Reiss continues to ignore the reason for the VIS, which is to provide adequate, accurate and unbiased information for fully informed consent. The VIS proposed language should be expanded and revised to fully explain that **adequate studies have not been done, and therefore safety has not yet been determined**. A truly informative VIS would state that worldwide, millions of parents have reported remarkably similar serious adverse events following administration of MMR, including high fever, high-pitched screaming lasting hours or days, head-banging, developmental regression, diarrhea, constipation, intestinal disorders, sensory issues, and more. No comprehensive study has ever been done to examine these parental reported adverse responses, but Dr. Lyons-Weiler has completed a comprehensive review of the scientific literature and found that the scientific evidence exists to show specific molecular mechanisms of autism and symptoms of autism from vaccines and other environmental exposures. Specific, identified molecular mechanisms provide a level of evidence toward causality that is considered, for drugs, much higher than mere correlation studies. He presents these findings, citing over 1,000 studies on autism, in "*The Environmental and Genetic Causes of Autism*" (Skyhorse, NY, 2016).

(5) Reiss states:

> "Because some people are still concerned about an alleged link to autism, in spite of the evidence, it would be a good idea for the VIS to address it directly, and explain that "Studies done by different teams all around the world examined whether there is a link between MMR and autism. No such link has been found: children who get MMR have the same rates of autism as children who do not."

Rebuttal: Ms. Reiss's opinion is not eligible for inclusion on a VIS. Since no vaccinated verses non-vaccinated studies have been done, such a statement cannot possibly be made. And we refer the CDC again to "*The Environmental and Genetic Causes of Autism*" (Skyhorse, NY, 2016), which include a list of studies in which links between vaccines and autism have, in fact, been found. The VIS content must not cherry-pick the scientific literature. Ms. Reiss's reference to "different teams all around the world" could be indicating studies which the IOM examined in their Adverse Effects of Vaccines: Evidence and Causality (2012) report. While it is often said that mountains of evidence exist showing no link between autism and MMR, the truth is that after considering the worldwide body of published material, IOM selected just 22 studies that were worthy of even examining, and upon close examination they then found that 17 of the 22 were unable to contribute to the weight of evidence because they were either too flawed or they lacked adequate comparison populations or sufficient data. Of the 5 remaining studies, IOM noted they did not know the status of the integrity of one study because Poul Thorsen, a lead researcher, has been indicted on 22 federal felony counts and is on the most-wanted list of the Department of Health and Human Services (DHHS). Meta-analysis studies polluted by these limited, flawed and potentially fraudulent studies are thereby misleading.

Other studies that failed to find association, such as Madsen et al. and Verstraeten et al. are under scrutiny for being the result of leviathan attempts to make original association findings go away by repeatedly analyzing the results with different approaches until one was found that had no significant association between vaccines and autism (personal communication, William

Thompson, CDC Scientist to Brian Hooker, and Verstraeten, T. "It just won't go away" email to Robert Davis and Frank DeStefano, Dec 17, 1999). Please also see *SafeMinds Investigative Research Report: Fewer Antigens argument by CDC and media misleads parents*.

The IOM committee in this report also points to 'secondary autism' as possibly caused by vaccines. Moreoever, The Office of the Special Masters has in fact repeatedly found that vaccines may cause encephalopathy leading to autism; this "indirect causality" should be included in the VISs for any vaccine that OSM has made awards (See Holland M, Conte L, Krakow R and Colin L, (2011) Unanswered Questions From The Vaccine Injury Compensation Program: A Review of Compensated Cases of Vaccine- Induced Brain Injury 28 Pace Environmental Law Review pages 480-543.)

(6) Reiss suggests:

> ". . . the latest sibling study (Jain A, et al. (2015) Autism occurrence by MMR vaccine status among US children with older siblings with and without autism. JAMA 313(15):1534–1540.)

Rebuttal: This study was a retrospective cohort study of a commercial health plan's administrative claims database, and it did not compare fully non-vaccinated to vaccinated siblings. Many factors confound findings in the Jain et al. (2015) study, including "healthy user bias" and the fact that younger siblings may be less likely to be vaccinated compared to older siblings *because* the older siblings regressed into autism after vaccination, and, as a result, their parents eschewed vaccination for their children thereafter. Also, individuals who are not genetically or environmentally predisposed to vaccine injury will have far lower rates of reported injury even with higher rates of vaccination. And those with a history of neurological, developmental, or health issues may have higher rates of injury even with lower rates of vaccination. The MMR is not the only vaccine with adverse reactions that can lead to a diagnosis of autism. Studies such as this one do not illuminate vulnerable populations nor prove one way or another the impact of vaccination on autism rates (http://vaccinepapers.org/category/vaccine-autism-studies/). Also, negative results of association at the population level do not rule out causality for any individual.

(7) Reiss also suggests:

> " . . . the Australian meta review (Luke E. Taylor, et al., Vaccines are not associated with autism: an evidence-based meta-analysis of case-control and cohort studies., 32 VACCINE 3623(2014) may be a good substitute."

Rebuttal: The author of this meta-review sorted through the entire body of published work on the relationship between vaccines and autism, just as the IOM did in 2012, and found just 10 studies that met his parameters. Five of these studies (Andrews, Hviid, Madsen, Verstraeten, Price) were analyzed in another review published the same year and found, as the review title states, "Methodological Issues and Evidence of Malfeasance in Research Purporting to Show Thimerosal in Vaccines Is Safe."

Hooker, et al https://www.ncbi.nlm.nih.gov/pubmed/24995277

In regards to the Hviid study, in 2004, the IOM Adverse Event report, "The committee identified a few limitations of the study, including its time-series design and the generalizability of the study's findings to the U.S. situation, especially with regard to the different dosing schedule used in Denmark and the relative genetic homogeneity of the Danish population."

Per the Verstraeten study, IOM found, "Limitations include the study's ability to answer whether thimerosal in vaccines causes autism **because the study tests a dose-response gradient, not exposure versus non-exposure**." (emphasis added)

Per the Madsen study, IOM found, "However, despite the reanalysis the authors stated that autism incidence after 1995 may have been exaggerated due to the change in including outpatient cases into the Danish Psychiatric Central Register. **This limits the study's contribution to causality.**" And in their 2012 Report, IOM noted, "One of the authors of this article, P. Thorsen, was indicted for embezzlement on April 13, 2011. **The implications for the integrity of the study are unknown at this time**" (emphasis added)

Also in IOMs 2012 report, "DeStefano et al., 2004; Richler et al., 2006; Schultz et al., 2008; Taylor et al., 2002; Uchiyama et al., 2007) had **very serious methodological limitations** that precluded their inclusion in this assessment [IOMs 2012 report]. Taylor et al. (2002) inadequately described the data analysis used to compare autism compounded by serious bowel problems or regression (cases) with autism free of such problems (controls). DeStefano et al. (2004) and Uchiyama et al. (2007) did not provide sufficient data on whether autism onset or diagnosis preceded or followed MMR vaccination."

Dr. William Thompson, one of the researchers on the DeStefano et al study, mentioned above, came forward in 2014 as a whistleblower on this study, stating results that did, in fact show a causal link between the timing of the administration of the MMR and autism were removed prior to presentation of the results to the IOM.

IOM in 2012 determined per the Mrozek-Budzyn et al., "This study was rated as having **serious limitations** because it did not provide information on medical conditions among the controls and relied on medical record abstraction for immunization dates and autism diagnosis dates." (emphasis added).

The Uno et al study was far too under-powered (Cases n=189 were diagnosed with ASD, controls n=224) for a condition that effects 1-2% of the population and that has a diffuse genetic risk. The IOM found that the population also lacked genetic population diversity.

https://www.ncbi.nlm.nih.gov/pubmed/22521285

Smeeth et al. is also too under-powered to provide a useful conclusion, and we refer you to this published criticism: http://www.bmj.com/rapid-response/2011/10/30/criticisms-confounding-smeeth-et-al.

Statements in the VISs should not be included, excluded, or modified based on faulty or fraudulent studies.

(8) Reiss states:

> "The VIS correctly says that the live virus vaccines are contraindicated in pregnancy. It might, however, be helpful for readers if you mentioned that the risk in pregnancy is, at this point, theoretical, and that there is no recommendation to terminate a pregnancy if MMR or MMRV were administered by accident."

Rebuttal: We agree there is not and should not be a recommendation to terminate a pregnancy based on the accidental administration of MMR or MMRV. Since vaccines are an uncontrolled, experiment-wide clinical trial that provide data for post-market (retrospective) surveillance studies, any recommendation to terminate a pregnancy would violate rules and regulations safeguarding the rights of the unborn during clinical trials. We disagree with stating that the risk of adverse reaction for the mother or child or both are theoretical. It is more accurate to state that no studies have been done on the *fetal* safety of administering ANY VACCINE to pregnant women as it is universally accepted that such studies would be unethical. The FDA has not licensed any vaccines for use for protecting fetuses because studies showing safety and efficacy have not been done.

The practice of vaccinating pregnant women is an ongoing, poorly managed, ad-hoc trial study, without fully informed consent. *Accurate* surveillance of spontaneous abortion, fetal demise, birth outcomes, or long-term health effects on children are not being done. As Merck states in their product insert: "M-M-R II has not been evaluated for carcinogenic or mutagenic potential, or potential to impair fertility." And the vaccine is a "Pregnancy Category C product. Animal reproduction studies have not been conducted with M-M-R II. It is also not known whether M-M-R II can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity." The VIS should be updated to include this information.

(9) Reiss states:

> "In addition to the changes applicable to both VIS, I would recommend you consider a number of changes to the MMRV VIS alone: Both VIS correctly mention that mumps can, rarely, cause death. But the VIS for MMRV does not make such a statement for varicella. Since varicella can also cause death, for consistency and completeness of information, the MMRV VIS should mention that."

Rebuttal: Agreed. The VIS should state that prior to the introduction of the varicella vaccine, the annual US fatalities due to varicella were approximately 105.

Fully informed consent requires providing US death and severe injury rates just prior to the introduction of the MMR and V vaccines, as those rates partially reflect the benefit:risk trade-off of accepting a vaccine, but they don't fully reflect how today's medical knowledge would likely lower the rates of morbidity and mortality even further. Unfortunately, tragically, because of the inadequacies of VAERS as mentioned above, an accurate table of severe injury and death data due to vaccination cannot be similarly prepared for comparison.

CDC acknowledges that improved water, sanitation, and living conditions in the US were responsible for much of the decline of fatalities due to communicable disease (conditions which

still need to be addressed in developing nations) prior to the introduction of most vaccines; they have provided this information in their own data. Improvements in medical care of infectious disease should also be given consideration. For all vaccine-preventable diseases, the population-wide chance of catching and dying of the disease was less than .01% (per CDC data) immediately prior to the introduction of their corresponding vaccines. On a population level, the risk of serious reaction/fatality was for measles 1 in 500,000, for mumps 1 in 2 million, for rubella 1 in 1 million. Everyone else fully recovered and acquired lifetime immunity that passively protected the very young and the very old.

While attention and research should be given to those population groups included in that .01% that experience disease complications/fatalities, it doesn't make sense to pressure the other 99.99% to accept the risks of vaccines. Providing historical data helps individuals understand relative risk; when that occurs, they then can realize that coercive pressure tactics, such as being told one must be responsible to the community and get a vaccine to prevent many deaths, or being told the only reason deaths are so low is because everyone is being vaccinated, are not valid arguments. Attributing reduction in deaths to any disease to vaccines alone not only exaggerates the role vaccines have played in the reduction of mortality rates, such attribution fails to reveal that continued improvement to living and medical conditions, good hygiene and sanitation, and maintaining individual immune health, are tools proven to be even more effective than vaccination against disease. Any data about the number of deaths due to a disease prior to a vaccine's introduction should be accompanied by current risk of catching the disease, current risk of death from the disease, alternatives to avoiding the disease, and currently known disease treatments, as well as the risks posed by the vaccine, and the benefits of a healthy individual at the appropriate stage of life being exposed to the wild disease, and developing lifetime immunity.

(10) Reiss states:

> "The VIS mentions people who have relatives with seizure disorders or autoimmune disorders under the heading "Some people should not get this vaccine." This will suggest to readers that people in these situations should not get the vaccine, and that is problematic. After all, the CDC's "Conditions Commonly Misperceived as Contraindications to Vaccination" document mentions family history to seizures as something which is not an issue for getting DTaP –admittedly, a different vaccine. But this is neither a precaution nor a contraindication to either vaccine, and to my knowledge is not supported."

Rebuttal:
It has long been recognized that individuals with unresolved neurological disorders and with aberrant immunological conditions should eschew vaccines. All VISs should include "unresolved neurological disorders" as an exclusionary criterion. CDC also lists "Known severe immunodeficiency" as a contraindication for both MMR and V vaccines in their Pink Book (http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/a/contraindications.pdf), and since CDC, IOM, and the vaccine makers acknowledge MMR/MMRV can cause seizures, due diligence would require including both "known severe immunodeficiency" and "familial history of seizure" as contraindicated for these vaccines on the VIS.

(11) Reiss states:

> "It can, however, lead to people refusing to vaccinate and protect children without good cause, and can be used to claim – incorrectly – the vaccines are dangerous for people with such a family history. In California, for example, it has been raised as a potential justification for a medical exemption from school vaccination requirement – with no good support. Including this language in the VIS can reinforce these beliefs. For these reasons, I recommend removing it."

Rebuttal:
Again, Ms. Reiss fails to recognize the reason for a VIS which is to provide adequate information for an *individual* to make an informed decision.

As shown above, seizure disorders and autoimmune disorders can be indicators of higher risk of vaccine adverse reaction, and the decision should be left to the individual. No drug is one-size-fits-all. Genetic, health, and environmental exposures affect an individual's reaction to vaccination, and these conditions are not static. Vaccines are potent immune stimulants and contain multiple ingredients that must be (according to the rules, regulations and laws governing informed consent) considered in relation to each individual, each and every time any vaccination is considered.

The VISs should also provide sufficient warning that intake of the vaccine, due to specific components, may violate the creed of persons of certain beliefs; in deference to individual rights to religious freedoms, they should include warnings when they contain non-kosher animal components (e.g., pig serum) as well as whether they were manufactured using cells of aborted fetuses, so individuals can properly weigh their religious vs. societal obligations when considering vaccine use.

"Residual human DNA (single and double stranded) levels from the human fetal cell lines used to manufacture Meruvax® (Rubella, Merck & Co. Inc.) [and] the rubella component of MMRII®" (see: http://www.academicjournals.org/journal/JPHE/article-full-text/C98151247042)

IN CONCLUSION, the VIS statements provided by CDC are currently often the only information an individual sees before agreeing to a vaccination. Due to regulatory capture and the "regulatory vacuum" created by the 1986 NCVIA and amendments, and the 2011 Bruesewitz decision, physicians and other vaccine administrators cannot be counted on to be "learned intermediaries." Therefore, the VIS statements for MMR and MMRV must be substantially strengthened and lengthened, so they may better aid doctors in their attempts to fulfill the legal requirements and obligations of allowing fully informed consent to be met.

James Lyons-Weiler, PhD
Bernadette Pajer

Dr. Lyons-Weiler is a research scientist, with a PhD in Ecology, Evolution and Conservation Biology from the University of Nevada, and the author of three books *Ebola: An Evolving Story, Cures vs. Profits:Successes in Translational Research,* and *The Environmental and Genetic Causes of Autism.* He is the CEO and Director of the Institute for Pure and Applied Knowledge, former Director of the Bioinformatics Core, and Assistant Professor both at the University of Pittsburgh (Departments of Pathology and Biomedical Informatics) and at the University of Massachusetts (Department of Biological Sciences). He has taught courses in study design, genetics, bioinformatics, and in the analysis of large, complex biological data sets in the clinical setting. He has designed and directed the analysis of data from over 100 biomedical studies, and has developed algorithms for the integrative analysis of data from genetic, genomic, proteomic and clinical sources that insure objective interpretation of data from randomized clinical trials.

Bernadette Pajer is a citizen journalist, novelist, and informed-consent advocate.