Comment by Dr. James Lyons-Weiler 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

Dec 15, 2016

We are providing this in response to the CDCs request for public comment.

Summary of our position: The proposed Vaccine Information Statements (VISs) do not provide to individuals sufficient information necessary for them to give fully informed consent, the legal agreement between an individual and a physician, first introduced by the Nuremberg Code, and outlined in the Canterbury decision of 1972, and subsequent rulings, regulations, and laws governing informed consent requirements. (HEALTH LAW: Informed Consent: What Must a Physician Disclose to a Patient? American Medical Association Journal of Ethics, July 2012, Volume 14, Number 7: 563-566.)

The steady erosion of informed consent by Congress and CDC in regards to vaccination reached a low point with the recent passage of 21st Century Cures Act which included unprecedented expansion of informed consent waivers and extension of product liability exemptions (sections 3024, 3091, 3092, 3093.) However, informed consent and other patient rights are still protected under other rules and regulations.

The efficacy and safety of Merck's MMR and MMRV vaccines are currently under intense scrutiny. Former Merck employees and virologists Stephen A. Krahling and Joan A. Wolchowski filed a suit against Merck in 2010, alleging fraud in vaccine testing (see complaint here). Merck delayed the trial for years, but the court has now ordered that discovery be completed by March 2017 (Former Merck Scientists Sue Merck Alleging MMR Vaccine Efficacy Fraud)

Further, CDC senior scientist Dr. William Thompson has filed for whistleblower status, presented 10,000 documents to Congressman Bill Posey, and confessed that the DeStefano et al. (2004) study, deleted positive association results between on-time vaccination w/MMR and autism diagnosis for both African American Male and for Isolated Autism subgroup analyses (Statement of William W. Thompson, Ph.D., Regarding the 2004 Article Examining the Possibility of a Relationship Between MMR Vaccine and Autism). The data removed from the study would support a causal link between the timing of the administration of the MMR vaccine and autism. Jason Chaffetz of the House Oversight Committee has begun investigating (Jason Chaffetz video speaking on CDC & Thompson investigation).

With the integrity, effectiveness, and safety of the MMR/MMR-V currently in question and the subject of much public controversy, revising the VIS's at this time is absolutely critical in order to inform the stakeholders that the effectiveness and safety are currently unknown and under investigation. The drafts presented here for consideration fail to mention this critical information.

Alternatives to vaccination should also be highlighted.

VIS's were introduced in the 1986 National Childhood Vaccine Injury (NCVIA) legislation as a way to safeguard patient's rights to make informed medical decisions, and were, at the time, required to include information on the following 10 items:

> (1) the frequency, severity, and potential long-term effects of the disease to be prevented by the vaccine,
> (2) the symptoms or reactions to the vaccine which, if they occur, should be brought to the immediate attention of the health care provider,
> (3) precautionary measures legal representatives should take to reduce the risk of any major adverse reactions to the vaccine that may occur,
> (4) early warning signs or symptoms to which legal representatives should be alert as possible precursors to such major adverse reactions,
> (5) a description of the manner in which legal representatives should monitor such major adverse reactions, including a form on which reactions can be recorded to assist legal representatives in reporting information to appropriate authorities,
> (6) a specification of when, how, and to whom legal representatives should report any major adverse reaction,
> (7) the contraindications to (and bases for delay of) the administration of the vaccine,
> (8) an identification of the groups, categories, or characteristics of potential recipients of the vaccine who may be at significantly higher risk of major adverse reaction to the vaccine than the general population,
> (9) Summaries of -
> (A) relevant Federal recommendations concerning a complete schedule of childhood immunizations, and
> (B) the availability of the Program, and
> (10) such other relevant information as may be determined by the Secretary.

In 1993, an amendment removed those ten, and replaced them with these four, which are inadequate for anyone to give fully informed consent.

> (1) a concise description of the benefits of the vaccine,
> (2) a concise description of the risks associated with the vaccine,
> (3) a statement of the availability of the National Vaccine Injury Compensation Program, and
> (4) such other relevant information as may be determined by the Secretary.

This change was allowed under the concept of the "learned intermediary" (Holland, 2010).

[Holland, Mary S., Reconsidering Compulsory Childhood Vaccination (September 15, 2010). New York University School of Law Public Law Research Paper No. 10-64. Available at SSRN: https://ssrn.com/abstract=1677565 or http://dx.doi.org/10.2139/ssrn.1677565]

Doctors were implicitly entrusted to keep up-to-date with vaccine inserts, the latest information on vaccine risks and contraindications, and to relay this information to their patients. However,

the NCVIA protects doctors from liability, and a "regulatory vacuum" therefore exists, as Justice Sotomayor called the 2011 Bruesewitz, et al decision which relieved vaccine makers of liability even for vaccine flaws that result in serious and avoidable negative impacts on human health, leading to an increasing separation between those who administrate vaccines and the science concerning them. Patients, however, retain the right to give or refuse informed consent, which makes the information provided by CDC in the VIS more important than ever before.

Vaccine designs and medical implementation have not kept pace with scientific advancements and insights in the fields of immunology, neurology, or genetics. Today, in their busy practices in which mere minutes are allotted to each patient, doctors rely heavily on the guidelines provide by the CDC, medical associations, and pharmaceutical companies, which increasingly exaggerate benefits, minimalize risks, ignore critical studies, and disseminate information that potentially increases the risk of vaccine injury. For example, a publication on HPV vaccine found a 15-fold increase in the incidence of Spondylosis (a degeneration of spinal tissue) in vaccinated individuals, and yet neither the abstract, nor the CDC VIS, nor the vaccine insert sheet reported that risk of Spondylosis was that high. The omission of the such details from the abstracts of vaccine "safety" studies belies bias in interpretation, which contributes to denial of informed consent. (Magnify Table 3. Klein NP et al., 2012. Safety of quadrivalent human papillomavirus vaccine administered routinely to females. Arch Pediatr Adolesc Med 166:1140-1148.)

The regulatory vacuum has led to rampant, perhaps willful, ignorance, as evidenced by such documents as the AAP's "Countering Vaccine Hesitancy" guide, with unsupported statements such as:

> *"The opposition to the presence of aluminum as an adjuvant in some vaccines can be addressed by providing evidence for both the necessity of the aluminum for a vigorous immune response and* ***the lack of evidence for its toxicity****."*

We encourage AAP, Congress, and CDC to read the literature on aluminum neurotoxicity:

https://www.ncbi.nlm.nih.gov/pubmed/?term=aluminum+neurotoxicity

Ignorance of the actual risks involved has also led to publication of an article by an academic individual in the New England Journal of Medicine contemplating the usefulness and best ways to **coerce** patients into accepting vaccines (Colgrove, 2016):

"Both persuasion and ***coercion*** *are necessary, and neither is sufficient. Laws serve as a critical safety net as well as a powerful symbolic statement of proimmunization social norms."*

[Colgrove J Vaccine Refusal Revisited - The Limits of Public Health Persuasion and Coercion. N Engl J Med. 2016 Oct 6;375(14):1316-1317.]

Coercion of patients into medical practices and experimentation has NOT been the accepted societal norm since the practices of Dr. Mengele, the Nazi doctor who tricked children into horrible medical experiments, came to light after World War II.

The widespread misinformation on the reality of vaccine risks has also led some to contemplate revocation of first amendment freedom of speech rights on vaccine safety. This untenable position was confronted by Prof. Mary Holland of NYU:

[Holland, M. 2015. Legally Censoring Speech on Vaccines and Autism: A Response. www.jurist.org/forum/2015/12/mary-holland-vaccines-autism.php]

The fact that such practices have been unabashedly recommended in the pages of medical and legal journals in the US in 2015/2016 says much about how widespread the ignorance of the real risks of vaccination have become, and reveals the risks of indemnifying vaccine manufacturers and medical doctors from liability. **Coercion, and attempts to use the law to silence the minority viewpoint are the tools of tyrants, and have no place in our society.**

These tactics place millions of Americans at risk of neurodevelopmental conditions and neurological degradation each year. Medical doctors who proclaim that one cannot "blame the vaccines" are dangerously misinformed, or, in some cases, have considerable financial conflicts of interest. If misinformed, there is no excuse (pediatricians are referred to https://www.ncbi.nlm.nih.gov/pubmed and to http://envgencauses.com). For example, there are many studies showing ample evidence of the toxicity of aluminum adjuvants; it is inconceivable that AAP was ignorant of them when they published their hesitancy-guide in August of 2016.

More often, doctors are simply unaware of these issues. With doctors denied ready access to the totality of the information on vaccine risks in the VISs, including those of MMR, they cannot, by definition, truly be "learned intermediaries." They are being directed to mislead, and simultaneously misinformed by the very agencies they should be able to trust most. They are not provided with sufficient indicators of risk of autoimmune-mediated neurological damage from vaccines, for example, there is no information provided on the findings that familial rheumatoid arthritis may be a risk factor for autism from vaccines. By exclusion of the full body of knowledge available from the VISs, doctors are denied the ability to provide information required for truly informed consent, and patients are denied the ability to obtain that information from the supposed "learned intermediaries".

The average American, and often doctors themselves, are unaware of the history of the erosion of informed consent rights regarding vaccination. The general public assumes that the same rules apply to vaccines that apply to other drugs. They assume vaccines are held to the same standard of safety, and that doctors have been fully educated on vaccine risk, contraindications, individual susceptibility to injury, and the latest science regarding vaccines, ingredients, and administration. The doctors often assume this, too. Everyone who is not paying attention assumes they are truly being told all they need to know give and receive fully informed consent. This state of ignorance must end.

The FDA states, "Post-marketing surveillance is a necessary component of vaccine safety monitoring" and because vaccine pre-clinical trials are relatively small and controlled, "previously unstudied components of a patient's social or medical history may be risk factors which could impact the outcome of vaccination and contribute to the development of adverse

events" (Post-marketing surveillance for adverse events after vaccination: the national Vaccine Adverse Event Reporting System).

Most of the studies conducted on vaccine safety rely on post-marketing surveillance using weak "association studies" with data from passively collected data sources (such as VAERS). Patients are not informed that they, or their children are, in fact, participating in a large, shoddily-run, non-randomized retrospective clinical trial. This practice is widespread, and violates provisions of the National Research Act [Title II, Public Law 93-348], Regulations for the Protection of Human Subjects of Biomedical and Behavioral Research [45 CFR 46] and revisions of various regulations, rules, and laws ([21 CFR 50, [21 CFR 56], [45 CFR 46 Subpart D], [10 CFR 745]. Pregnant women and fetuses are afforded special protections by [45 CFR 46 Subpart B], and children are afforded additional protections by [45 CFR 46 Subpart D]. Yet the rights of pregnant women and fetuses are violated with each and every vaccine administered to them because not only is there a paucity of pre-licensing clinical trials, no vaccine is actually licensed for use to protect fetuses, and pregnant women are not told any of this as they are pressured to get vaccinated. (FDA: Vaccines For Use in Pregnancy)

Of note, in the Common Federal Policy for the Protection of Human Subjects ("Common Rule") [10 CFR 745] Sec 745.103(b)(3), none of these rights were revoked by any subsequent legislation, including [21 CFR 50.24], which allows the relaxation of requirements for informed consent during emergencies. In fact the Common Rule re-asserted safeguards both for informed consent, and for special protections against coercion:

§46.116 General requirements for informed consent.

Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. ***An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.*** *The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.*

"When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects."

Unfortunately, some medical doctors have been using vaccine exemption forms in which parents are asked to sign and acknowledge that they are placing their child at risk if they decline to vaccinate. Clearly such actors are denying the participants of this massive uncontrolled clinical trial their rights to informed consent both for medical procedures and for participating, without

coercion, in a human subjects clinical study. This type, and all other forms of coercion to participate in clinical trials must stop. This is especially so when the current ongoing clinical trial has no known safety profile given the history of the fraudulent and biased nature of the conduct and interpretation of vaccine safety studies.

Comprehensive, accurate and forthright VISs are more necessary than ever as they are often the only information an individual and the vaccine administrator sees. They should include statements that bring them into FDA and HHS compliance with respect to clinical trials regulations, and they should point medical doctors to the appropriate regulations regarding enrollment of their patients in clinical trials (§46.116 and 21 CFR §50.3(r)). The proposed changes as shown in the draft VISs remove and/or weaken critical information. Looking from a fully informed lens, it appears CDC has chosen to put their "war on disease" ahead of any individual's particular risk for adverse reaction to their chosen weapons, and ahead of the right to fully informed consent.

We need VISs that are consistent with our nation's constitution, and our tradition of being leaders of the *free* world. CDC has become blind to vaccination's collateral damage: those who are injured, those who may be injured due to individual risk, informed consent, and medical freedoms. We therefore recommend that the CDC return to including in the VISs the original 10 items as listed above, and to rethink the balance of ethics in their approach to convincing the public to use vaccines.

Sincerely,

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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 Biology). 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.