

**Advisory Commission on Childhood Vaccines**  
**NVIC Public Comment – Theresa Wrangham, Executive Director**  
**June 5, 2014**

My name is Theresa Wrangham and I am the Executive Director for the National Vaccine Information Center, the mission of which is to prevent vaccine injury and death through public education and to defend the informed consent ethic in vaccination laws and policies. I appreciate the opportunity to comment today.

I would like to thank the committee for their careful consideration of language clarifications to the Vaccine Injury Table recommendations made by the Commission in March 2012. NVIC is requesting a copy of those recommendations as they relate to this topic, and the presentations and the emails distributed to the Commission yesterday that do not appear to be on the website for public access. We appreciate consideration of this request.

We would reiterate that people are individuals and genetic predispositions and susceptibilities are risk factors that do not necessary manifest into medical conditions during one's lifetime. Simply put these risk factors do not predestine individuals to an associated medical condition.

The ability of environmental factors to trigger or exacerbate underlying conditions must be considered individually and where vaccines have been found to trigger or exacerbate these predispositions, susceptibilities and conditions for claims filed within the VICP, compensation must be granted. In addition, the IOM has clearly voiced the limitations of epidemiology in relation to susceptibility by stating that -

*“Most children who experience an adverse reaction to immunization have a preexisting susceptibility. Some predispositions may be detectable prior to vaccination; others, at least with current technology and practice, are not.”* (IOM, 2012, p. 82)

We would also note that the statement made during the meeting with regard to herd immunity and vaccines is not accurate. The CDC acknowledges that herd immunity is “a situation in which, through vaccination or prior illness, a sufficient portion of the population is immune to an infectious disease,”

With regard to VIS revisions, consumers are entitled to understand that vaccines are not risk free. Consumers must have accurate information to make informed decisions, even when that means that they may decline or delay one or more vaccines. Parents and individuals are the decision-makers in vaccination – not vaccine providers.

A vaccine provider's role under federal law and the informed consent ethic is to inform on vaccine risks and benefits so that the decision-maker – the consumer – can make an informed and voluntary decisions that include accepting, delaying or declining one or more vaccines.

The federal law requires that the VIS to provide clear and accurate information to consumers on vaccine risks and benefits must clearly state that vaccines carry with them three clear risks – the risk that the vaccine will fail to protect against the disease; the risk of injury; and the risk of death and these risks must be clearly communicated to the public. Additionally, we again note the following relating to the VIS:

- The VIS is much shorter today than in the past and is consequently much more limited in conveying risk and benefit information. The law doesn't require that providers go over the VIS with parents or that parents read it and this could contribute to it not being read, saved or thrown away. However, this possibility is not a valid reason to limit the information provided in the VIS.
- The opening statement on the VIS “Why get vaccinated?” is not appropriate. This is *not* a statement that should be a part of the VIS because this is an informational piece and as

pointed out by today's meeting is not a sell piece. This statement should revert back to "What is XYZ disease?" along with disease trend pre- and post vaccine to speak to efficacy, disease incidence, frequency of complications and severity.

- The VIS should include conditions/injuries that appear on the Vaccine Injury Table as vaccine injuries that are possible.
- Information on statute of limitations on injury compensation is necessary – nuanced or not – and needs to be included on the VIS. The reality is the majority of consumers don't know who the ACCV is or that the VICP exists. But, that doesn't negate the right of consumers to know there is a time clock ticking from the minute a vaccine is administered to receive compensation and is even more necessary given that this information is largely unknown by the public.
- Unknown risks in the form of vaccine safety research deficits noted by the IOM should be included in the VIS forms globally. The gaps in research are not widely known by the general public and they have a right to understand unknown and known risks. To only include known risks misleads the public to believe that all the information on risks is known and disclosed when this is clearly not the case.
- A list of vaccine ingredients should be included for consumers to be able to verbalize if they have had an allergic reaction to a vaccine ingredient, as well as directing consumers to the vaccine manufacturer product insert for this information.

NVIC is a participant in the federal process governing the updating and revision to the VIS. With regard to the ACCV's part in that process, we would encourage the ACCV's consideration of our other comments regarding global changes that would benefit consumers who receive the VIS made during March's meeting.

I thank the process workgroup for their consideration of the vaccine injury compensation report improvements that I submitted and look forward to clarifying my statements in that regard.

In closing, we would reiterate that the priorities that govern whether or not the ACCV meets in person need to be closely evaluated. Parents today are under increasing pressure to vaccinate and with increased vaccine uptake comes increases in vaccine injury and death. The charge of the ACCV is no less important than that of the NVAC or ACIP, which consistently meet in person. This commission should meet in person for every scheduled meeting as is done for the NVAC and ACIP