

**NVIC Public Comment**  
**Advisory Commission on Childhood Vaccines – March 3, 2016**  
**Theresa Wrangham, NVIC Executive Director**

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 vaccine policies and laws.

Our concerns today relate to the potential reclassification of pregnant women as a complex population vs. vulnerable population for ethical reasons. What exactly will the definition of a complex population? There was little information on this concept. In addition, there is even less information on adverse effects on unborn children when vaccines are given during pregnancy and the majority of this information is observational.

Additionally, there appears to be a lack of harmonization between efforts of the maternal working groups within the National Vaccine Advisory Committee and the ACCV's maternal working group and a duplication of efforts where injury compensation is concerned. The ACCV has spent considerable time on this matter and should be the lead committee making injury recommendations to DHHS. In relation to the National Adult Immunization Plan, there is no language to supporting the ongoing vaccine safety research mandate within the law to close IOM acknowledged gaps and while there is great focus on new vaccines and vaccine innovation. The bottom line is that there is a lack of balance within this plan that does not harmonize with concerns normally expressed by the ACCV relating to vaccine injury.

With regard to the VIS discussion, there continues to be a marketing of vaccines within the general language of the VIS and more specifically a lack of background on the disease, its incidences and severity as a matter of informed consent information to be given to the consumer. These documents were meant to disclose the risks and benefits of vaccines and were once much longer and more informative, though there is no statutory limitation on length. I respectfully remind the ACCV that the Altarum report on VICP petitioner satisfaction noted that parents wanted more information up front on risks of vaccination and the VICP program. Today's VIS is very brief and does little to balance this information against the necessity of also disclosing background information about the disease so that risks and benefits of the vaccine are put into an appropriate context for consumers.

There also seems to be a push to put information into the provider guidelines and wait for consumers to ask questions. As an organization of standing who receives many phone calls from the injured and those who have questions about vaccination, many consumers do not know what questions to ask, and when they do ask their healthcare provider, they are threatened with being kicked out of the medical practice and/or their questions are not welcome. In short, the VIS is not living up to what the spirit and intent of what the law originally required and amendments to the law have not supported informed decision-making by consumers. NVIC respectfully requests that the ACCV consider revisiting VIS content and statutory requirements as well as possible recommendations that would promote informed decision-making that doesn't rely upon vaccine provider dialog, given the current hostility parents face when they do ask questions of their providers about vaccines.

In closing, NVIC would appreciate the ACCV's consideration of the requests NVIC made during the ACCV's meeting, which were provided in writing to members. We appreciate the opportunity to provide public comment.