

**NVIC Written Summary of Oral Public Comments
Advisory Commission on Childhood Vaccines September 6, 2019
Theresa Wrangham, NVIC Executive Director**

Good afternoon. My name is Theresa Wrangham and I am the Executive Director for the National Vaccine Information Center. Our mission is to prevent vaccine injury and death through public education and to defend the informed consent ethic in U.S. vaccine policies and laws.

In listening to presentations today, it is unclear if the publications presented at the end of the CDC's presentation were all epidemiological studies.

NVIC also shares commission concerns about how few children are in the VICP system and subsequently compensated. We encourage the Commission to look at shifts in provision, qualifications and aids definitions within the vaccine injury table that may result in the exclusion of these child vaccine injuries and what can be done to insure that the original focus of compensating childhood vaccine injuries is met.

There also continues to be a lack of awareness of the compensation program that contributes injuries not being compensated that could perhaps be undertaken by the workgroup and what can be done to raise awareness outside of relying on healthcare professionals. Review of previously commissioned reports on this topic would likely benefit program awareness discussions, as well as how this concern as well as making sure the VIS and reporting to VAERS is addressed in the Adult Immunization Plan and National Vaccine Plan.

Again, ongoing mechanisms to assess the adequacy of compensation awards and level of information consumers would like on vaccine injury noted by the Banyan and Altarum reports may also be of benefit to review, as well as how vaccine safety research deficits that contribute to petition backlogs will be resolved. These deficits likely contribute to the majority of VICP claims being litigated as off table claims.

As the ACCV understands that vaccines have real risks and cause injury and death, support by the Commission of informed consent and the need for voluntary choice, particularly given the continued attacks vaccine exemption laws is encouraged by NVIC.

Lastly, with regard to the VIS, it is notable that the law was amended in 1993 to exclude information that is important to the decision-making process. However, this information may still be included and would assist in informed decision-making and supports more detailed information based on feedback we have received from the public over the 37 years of our existence.

NVIC is also a part of the consultation call and has expressed these concerns, along with concern relating to stating clearly the risk for vaccine strain infection for live virus vaccine and says rash. Also, because that GBS is on the vaccine injury table for influenza vaccine as an outcome and it should be reflected on the vaccine information statement (VIS). Lastly with regard to the VIS, overall, due to the lack of information on the VIS, there should be information on how to access the vaccine manufacturer product insert, particularly where allergies are concerned, as well as clear statements on the statute of limitations relating to the VICP. The statute of limitations has been discussed and I believe at one point there was different language indicating that there was a deadline was in the VIS. NVIC offered alternative wording that is not anymore lengthy than what currently appears in the draft today that would work here.

Thank you.