## NVIC Public Comment Advisory Commission on Childhood Vaccines – September 20, 2016 Theresa Wrangham, NVIC Executive Director

Good afternoon. 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.

We thank the commission for the opportunity to provide comment. We also thank VICP staff for posting the meeting book for today's meeting in the ACCV's website. NVIC, along with other citizens, has requested the meeting books for all meetings of the ACCV be posted to the ACCV's website, along with finalized presentations, as what is presented and what appears in the meeting book can differ. It is important that both the meeting book and the finalized presentations that were presented to the commission be posted to reflect the fullness of information given to the committee. These items are also items that are to be made available to the public under the Federal Advisory Committee Act. We appreciate efforts to update the website with this information and the fulfillment of public requests that have been emailed to the VICP liaison.

In listening to the process working group's recommendation today, we would note that while claims are up and caseloads have increased that so have gaps in what we know or don't know about vaccine injury.

As the recommendation for an increase in special masters to handle the increase in vaccine injury compensation petitions has been put forward by the process working group, NVIC would ask the commission to make recommendations for the funding of independent research to close vaccine safety research deficits identified by the IOM. Such a recommendation would assist in the expedient compensation of claims in that there is potential for the vaccine injury table's expansion, and other findings based on previous findings of the IOM when appropriate quality research was available for their review.

Additionally, such a recommendation should not identify the trust fund as a research funding mechanism, as that fund was specifically created to compensation the vaccine injured. NVIC would respectfully ask that any recommendation by the ACCV relating to addressing IOM acknowledged vaccine safety research deficits make funding recommendations outside of the trust fund.

Finally, the ACCV has long expressed concern relating to vaccine safety research gaps identified by the Institute of Medicine. NVIC notes, that according to previous reports given by the DOJ and DICP, the majority of claims submitted to the VICP are for off the table claims. The closure of vaccine safety research deficits with quality science would assist in making more claims less adversarial and settled as on the table claims and be less burdensome to petitioners.

NVIC also renews our request for the commission to consider recommendations on a mechanism that would gauge ongoing petitioner satisfaction with the VICP. We base this request in part on December's ACCV meeting and the DOJ's report on a case where a successful VICP petitioner felt their injury award was inadequate and requested the award amount to be revisited. Given the number of awards made by the VICP and the potential for awards to not be sufficient, NVIC requests that ongoing petitioner satisfaction be revisited and that the committee additional review other findings of this nature that appear in the Altarum report of 2009, the 2010 Banyan report and 2014 GAO reports.

We renew our request that the ACCV issue a statement that reaffirms that that the use of vaccines carries the risk for injury and death, and that because there is risk the ACCV supports the human and informed consent right of every individual and parent to make voluntary vaccine decisions for themselves and their children.

NVIC's renews this request due to the recent statements made by the American Academy of Pediatrics stating that only medical exemptions should be allowed. The commission is a witness to the fact that vaccines can and do cause injury and death. This fact is recorded in the medical literature. The IOM has stated that individual susceptibilities and predispositions are likely to play a role in vaccine injury and death and there are many vaccine safety deficits that remain unaddressed.

Because vaccines are pharmaceutical products that carry the undeniable risk for injury and death, the ability of individuals to decide what risk they are comfortable taking, must have primacy. NVIC get reports daily of physicians kicking individuals and families out of their practices for exercising their human and informed consent right to delay or decline one or more vaccines. In essence, families are being refused well-care and being punished for exercising their right to decide what is best for themselves and their children. There are no doctors, vaccine providers or health officials that can predict prior to vaccination who will be harmed or die as a result of a vaccine adverse event.

We ask the ACCV to support the informed consent ethic, which is recognized globally as a human right, and issue a report on the need for public health to recognize not only the gaps identified by the IOM in their mass vaccination agendas, but the ethical need to implement flexible vaccine exemptions in all public health programs that will allow

individuals to exercise their informed consent rights and not be punished with the withholding of medical care, education and employment.

Again, we thank the commission for the opportunity to provide public comment today.