NVIC Written Public Comments Advisory Commission on Childhood Vaccines – September 1, 2022 Theresa Wrangham, NVIC Executive Director

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. As I mentioned in earlier meetings, our co-founders worked with Congress to draft and pass the National Childhood Vaccine Injury Compensation Act of 1986 which gave rise to this Commission.

Briefly, I would again state that the ACCV would benefit from exercising a higher level of scrutiny on studies and reports provided to them using agency databases such as the Vaccine Safety Safety Link. As the committee was advised in their June meeting, the Institute of Medicine, the lead provider of evidence to the ACCV for vaccine injury table changes, reported in 2005 that the VSD's data-sharing program required significant improvements to assure transparency, and independent replication of findings that are necessary to the scientific process and the maintaining the public's trust.

As former committee member Karen Kain pointed out in June's meeting, it is unknown for example, what improvements have been enacted by the CDC with regard to the IOM VSD data-sharing program recommendations. For example, today's autism findings in relation to MMR is a VSD study. Has that dataset been made available to independent researchers to replicate or pose alternate hypotheses outside of federal agencies and VSD partners? Again, this is simply a part of the scientific process and yet the public has no understanding if the VSD and similar datasets are subject to the norms of the scientific process.

NVIC encourages the ACCV to use their 2006 guiding principles on research considerations as they consider statements made during meetings relating to research findings, such as independent researcher access to federal datasets to replicate findings and/or the ability to make alternative findings and hypotheses and funding sources.

These concerns also apply to using the VSD for comparative health outcomes in vaccinated and unvaccinated populations to expand vaccine safety understandings of the mechanisms of injury and safety of the federally recommended schedule recommended by the IOM and CDC.

Additionally, the VICP would also benefit from seeking to close research gaps highlighted by over two decades of IOM vaccine safety reports and making research recommendations as is their charge. The Government Accountability Office (GAO) has issued more than one report on the lack of expansion of the vaccine injury table as contributing to the backlog that is a constant discussion point during ACCV meetings. Expansion of the injury table by addressing these acknowledged gaps highlighted in the IOM causality tables would also address program backlogs of concern.

Thank you for the opportunity to provide comment.