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.

NVIC’s thoughts and prayers with the victims of hurricane Irma and we appreciate Ms. Toomey’s presence here today and are grateful that her family is safe and hope that she will be able to return home soon.

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. This is important because today’s meeting book does not contain the presentations from DOJ and the DICP and authors of these presentations sometimes make last minutes changes that are not reflected in the meeting book. Posting both the meeting book and finalized presentations will assure transparency with the public.

With regard to the NPRM around coverage of maternal vaccines and public input, NVIC would like to point out that making sure that public input is real and listened to is an important part of retaining public trust in the VICP and supports ACCV efforts for public input. Finally, as Ms. Toomey noted, people don’t care about what happens to others, but what happens to themselves and their children as a result of vaccination and that vaccine injury risks are 100% for those injured. Additionally, vaccine injury cannot be predicted in advance of vaccination, thus are subject to the informed consent ethic. ACCV was created in the backdrop of government acknowledging that vaccine injury is real and worthy of compensation. As a result, NVIC renews again its request that 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.

Relating to VAERS 2.0 paperless reporting, during the meeting of the National Vaccine Advisory Committee in December of 2015, CDC officials reported that about 70 percent of VAERS reports are handwritten and submitted by mail or fax, while 30 percent are online submissions. The system receives about 30,000 reports annually and it is estimated that only between one to 10 percent of vaccine adverse events are reported to VAERS.

Underreporting of vaccine reactions in the U.S. is a widely acknowledged weakness of VAERS. It is also known that little has been done by federal health officials to increase vaccine provider reporting to VAERS since the passage of the National Childhood Vaccine Injury Act in 1986, which requires the reporting of vaccine adverse events. Aside from the fact that CDC’s own data demonstrates that most would prefer to submit their report by means other than online, the proposed shift to a completely “paperless” system is likely to result in even more underreporting of vaccine adverse events and penalize those who are not computer literate, and those with limited or no access to the internet. Thus, NVIC encourages the ISO to provide information to the ACCV regarding how the potential negative effects of a paperless system will be monitored and negated.

Finally, 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.

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