Agenda Comments
Good morning. 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 in U.S. vaccine policies and laws.

This morning we offer comment on the charge to the Process Working Group to enhance interaction with the public. As I have publically commented for about two years now, with regard to how petitions to add to the Vaccine Injury Table are presented to the ACCV, there is a need for increased transparency and interaction with the public. Currently HRSA responds to the petition with a power point presentation of about 15 to 20 minutes and then responds to ACCV commissioner questions. However, there is no similar mechanism in place for parties that have requested the addition to the Table. Again, NVIC strongly supports that members of the public bringing these petitions be allowed the same opportunity to present and respond to the commission as given to HRSA. This addition to the process would allow the ACCV to have the richness of perspective as they consider their recommendations for each petition brought. We are hopeful that NVIC’s outstanding request for such a process is part of the working group’s agenda, as there is nothing in the law to prevent such a process addition.

Additionally, with regard to VIS review, as an organization participating the in collaboration with the CDC on VIS revisions, we encourage the ACCV to support more detailed information be present within the VIS, such as vaccine ingredients related to allergies, encouragement to review the vaccine manufacturer's product insert on the FDA’s website and to make the VIS about informed consent, as it was previous to 1995 amendments to the law. While the law was amended in 1995, there is nothing to prevent the Secretary of Health and CDC from making these additions in the interest of transparency with the public. Currently all information is limited to an arbitrary front and back of one page. We encourage the ACCV to review the law, how it was amended, and what is really needed to inform the public about disease, vaccines and risks and benefits, both known and unknown. More complete information as I am describing today would support the public’s ability to make informed vaccine decisions and the globally recognized human right of being able to exercise informed consent to medical risk-taking procedures, such as vaccination, which as this commission well knows carries the risk for injury and death.

We appreciate the opportunity to comment on today’s agenda.

Public Comment 2 - Good afternoon, I am Theresa Wrangham, NVIC’s Executive Director. Thank you for the opportunity to offer this second public comment today.

During today’s DCIP presentation I believe there was mention of the inclusion of stakeholders in the NPRM process. On behalf of NVIC, I would like to respectfully say that NVIC has historically worked with the ACCV and NVAC, has successfully sponsored members onto these committees, coordinated vaccine-safety workshops with the IOM, as well as having been invited to present parent perspective to the IOM in their reporting process. In recent years NVIC appears to have been excluded from various stakeholder processes in which we have standing. This is of concern to us, given our historic standing and involvement in processes relating to vaccines safety and vaccine injury and death and the fact that our organization worked with Congress to pass the 1986 Act. We welcome and request inclusion in stakeholder processes relating to this commission and what is put before the commission for their consideration, as we represent the concerns of those who have vaccine safety concerns and those who are injured or who die as a result of vaccine adverse events.

As the process working group assesses various improvements and considers recommendations, NVIC requests the commission consider reviewing the 2009 Altarum and 2010 Banyan reports issued to a previous Commission and the 2014 GAO VICP report and consider their findings and recommendations relating to the need for a mechanism to gauge ongoing petitioner satisfaction within the VICP and VICP awards. We base this request in part on the December 2016 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. Currently, there is mechanism to measure satisfaction or adequacy of compensation. This is an outstanding concern voiced by NVIC and is based on the fact that many compensated claims are for conditions that represent the necessity for a life-long continuum of care. The purpose of the VICP was to compensate those injured by vaccines and it is important to be able to understand if the process is working well and if the compensation awarded is adequate to meet the needs of those injured. These basic program metric measures that should be a matter of routine in determining the success of the VICP to compensate the vaccine injured.
In addition to our previous agenda comment, I wanted to clarify that NVIC works in a consultation fashion, not collaboration fashion with the CDC on VIS revisions. NVIC appreciates commissioner comments on provider neutral language and supports provider neutral language in the VIS, as it acknowledges the reality of the variety of professionals that are vaccine providers.

In addition, while the VIS doesn’t provide informed consent, NVIC worked with Congress to put into place informed consent protections within the 1986 Act that resulted in the VIS – meaning the VIS provided information on disease and the risks and benefits of vaccines prior to vaccination. Many of those protections were struck from the law in 1995, to simplify the VIS, at the cost of transparency and information relevant to making educated vaccine decisions. NVIC would again encourage the ACCV to review those changes to the law and the fact that there is nothing preventing reinstatement of previously required information to the VIS, as the Secretary can add information outside of what the law specifies.

NVIC would also state that the purpose of the VIS was to provide information prior to vaccination and the opening statement of why get vaccinated is a marketing line, rather than information about vaccine risks and benefits or information about the disease. NVIC supports more neutral language vs. marketing language. NVIC appreciates information on the disease and notes that prior to the 1995 amendment to the law, disease information was required. It would also be helpful to consumers to understand mortality rates prior to the vaccine’s introduction and how the vaccine has mediated this most severe outcome.

With regard to pregnant women mentioned in the VIS, it would be helpful to note on the VIS which vaccines are licensed for use in this population.

Regarding mention of the VICP on the VIS, as all on the Commission are aware, there is a statute of limitations for vaccine injury compensation and consumers would benefit from a statement appearing on the VIS that contains more specificity on those deadlines.

Of note, Altarum or Banyon report indicate that consumers want more detail, not less, where vaccine injuries are concerned. So again, NVIC would encourage the ACCV to review the findings of these reports and how they may apply to VIS revision work and ACCV’s overall charge.

Finally, NVIC notes that there is funding of vaccine innovation, while there are significant gaps in vaccine safety research, as noted by over 25 years of IOM reports, for vaccines already in use. We ask what efforts to fund quality, independent research to close these gaps is underway? The ACCV has voiced the same concern relating to closing gaps identified by the IOM. NVIC’s concern continues to be that vaccines are being created and mandated faster than the research that assures the public they are safe and/or inform what their associated risks are to support educated vaccine decisions.

In closing, NVIC appreciates the work of the ACCV and the charge undertaken by the process-working group.