NVIC Public Comment
Advisory Commission on Childhood Vaccines – June 3, 2016
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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 vaccine policies and laws.

This morning we would like to provide comment on the Petition to Add Injuries for Seasonal Flu Vaccine to VIT agenda item. The presentation that will be made by the Division of Injury Compensation's Medical Officer will tell you there is an absence of medical research to support adding many of the items in the petition to the Vaccine Injury Table (VIT).

NVIC would like to remind the commission that the 1986 law that created the ACCV states that the Secretary of DHHS is required to

1. *"promote the development of childhood vaccines that result in fewer and less serious adverse reactions than those on the market on Dec. 22, 1987, and promote the refinement of such vaccines;"* and
2. *"to make or assure improvements in, and otherwise use the authorities of the Secretary with respect to, the licensing, manufacturing, processing, testing, labeling, warning, use instructions, distribution, storage, administration, field surveillance, adverse reaction reporting, and recall of reactogenic lots or batches, of vaccines, and research on vaccines, in order to reduce the risks of adverse reactions to vaccines."*

The ACCV has long discussed the need for Congress to appropriate funds to close vaccine safety research gaps identified by the Institute of Medicine since the inception of the VICP. The fact that there is a lack of literature to support these additions to the table should surprise no one, because there is a lack of funding for quality research to close these gaps.

In reviewing the presentation to be made by the DICP today to the commission we note that the addition of information on how many claims have been settled by the program for the injuries noted by the petition as well as the evidence base for those decisions may assist the commission in its deliberations is absent.

For example, there have been awards for vaccine induced Multiple Sclerosis in association with influenza vaccine in cases like Williams v HHS in 2016, Swigert v HHS in 2015, Pederson v HHS in 2014 and Froelick v HHS in 2013. These successful petitioners must have had to present enough evidence to show a "presumption" of causation in the absence of a more biologically plausible explanation for the injury in order to receive compensation, though there was an absence in the medical literature to support their claim. What was that evidence and expert testimony?

During the commission's deliberations to add GBS in association with influenza vaccine to the table the presentations made by DICP included information on the number of claims awarded for that condition, due to the absence of data from the medical literature. In that case a policy decision was made to add GBS to the table, though the medical literature could not conclusively support its addition.

NVIC would suggest that since many petitions for the addition of injuries to the table will likely face many of the same gaps in research that today's petition faces, that DICP's presentation include evidence from the award process to assist the commission's decision-making process.

Part II

We echo concerns express relating to the increase in compensated claims and the lack of impact to the trust fund. During December's ACCV meeting DOJ reported 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 potential for awards to not be sufficient compensation, NVIC requests that ongoing petitioner satisfaction be revisited.

To date, there is no mechanism in place that we are aware of to assess satisfaction by petitioners or adequacy of compensation delivered by the program since the issuance of the Altarum report of 2009. While improvements in the speed of settlement and number of claims settled since that report are good news, it is not enough to see claims settled quickly or in great numbers without an understanding what the drivers are for numbers reported by DOJ and DICP, as demonstrated by the Altarum report.

NVIC renews its request from December that the ACCV review findings from the 2009 Altarum, 2010 Banyan and 2014 GAO reports on the VICP and issue a report on the progress made or what is needed to improve satisfaction and awareness of the VICP. A review and report by the ACCV on these reports could also include an analysis of the impact to

the VICP of vaccine safety deficits reported by the IOM to the litigative process and how closing vaccine safety research gaps recognized by the IOM would improve the process.

As we have stated in our previous public comments, the law has changed over the years and as has its interpretation in general, and the VICP program more specifically has become increasingly adversarial for petitioners. Vaccine injury represents financial and emotional burdens that are often publicly minimized in the media and by governmental agencies. As this committee knows all too well, vaccines carry with them the risk for injury and death. It does not matter how small that risk is and the fact is the IOM points to many additional unknown risks that require investigation. Because there is risk, there must be choice and vaccines cannot be exempt from the informed consent and precautionary principles.

Today, the attacks on non-medical vaccine exemptions are being encouraged by federal and state agencies. This creates an environment where vaccine risks are not being equally shared and any loss of non-medical vaccine exemptions have the effect of further minimizing those injured or who die as a result of vaccine adverse events as acceptable collateral damage.

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 without sanction and free from governmental coercion and interference.

It is unclear to me that such an opportunity exist for the public to make clear their concerns and what supports those concerns as additions to the table are considered. NVIC also renews its request that when a petition by the public is made for additions to the Table, that there be a process which includes an opportunity for the individual or organization making the request to also present information supporting their petition for addition.

In closing, we appreciate the opportunity to provide public comment.