NVIC Public Comment
Advisory Commission on Childhood Vaccines – Sept 7-8, 2023
Theresa Wrangham, NVIC Executive Director

Sept. 7

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. NVIC's cofounders worked with Congress to draft and pass the National Childhood Vaccine Injury Act of 1986 that created this commission.

I would like to welcome new commissioners and appreciate their willingness to volunteer their time and their thoughtful questions. With regard to today's presentations, I would like to draw attention to three points.

First, the approval by the ACIP of nirsevimab for use in infants, while within the ACIP's charter to make recommendations on, it should be noted that nirsevimab is not a vaccine. It is a monoclonal antibody that the FDA approved as a drug, not a vaccine. CDC's counsel advised the ACIP it could be treated like a vaccine due to a lack of definition within federal statutes on vaccines and is likely to become a part of the VICP, opening the door for extending a new level of liability shields for vaccine makers and administrators should it be added to the VICP.

Secondly, the ISO safety reports on VSD studies conducted should be taken with a grain of salt, until independent researchers can access VSD data for confirmation or opposing hypotheses. The Institute of Medicine report on the VSD data-sharing program in 2005 noted legitimate public trust issues because the VSD's data-sharing program didn't meet traditional data-sharing standards. More specifically, VSD datasets could not be subjected to the scientific method by independent researchers for audit, a broader reanalysis, a corroboration study, and an investigation of a new hypothesis by independent external researchers in part to fulfill 42 U.S.C. §§ 300aa-27 – Mandate for safer childhood vaccines. It is unclear to this day what improvements, if any, have been made ensure that VSD studies are subjected to the rigors of the scientific method.

Lastly, with regard to the Denmark study on aluminum, I believe that Denmark's childhood schedule recommends far fewer vaccines than does the CDC childhood vaccine schedule, and is therefore not likely to be an apples to apples comparison and its differing conclusion should note that limitation if compared to the U.S. schedule in such a manner.

Thank you for the opportunity to provide a public comment.

Sept. 8

My name is Theresa Wrangham, and I am the executive director of 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.

Good morning to everyone and thank you for the opportunity to comment on today's agenda. With regard to data presented influenza and brachial neuritis, it is hoped that the data will provide information consistent with the ACCV's guiding principles for recommending changes to the vaccine injury table passed by the ACCV in March of 2006. Specifically, the guidelines prioritize the type of data and its quality for the consideration of the ACCV. It is hoped that the data presented to the ACCV today will provide information in this respect to allow the ACCV to weigh the data properly.

Thank you for the opportunity to provide a public comment.

Public comment session.

Theresa Wrangham again, for National Vaccine Information Center. Thank you for the opportunity to provide public comment and for the informative presentations today.

We note that the Influenza overview lacked context with respect to vaccine effectiveness over the seasons overlayed with mortality and morbidity. This is important data, as the CDC's has estimated vaccine effectiveness on their website for seasons since 2004 and has ranged from 10 to 60 percent.

While virus match is important to a vaccine's effectiveness, the frequency and severity of flu complications should be included for vaccinated and unvaccinated in presentations. Data presented notes the very young and elders are most impacted by flu and that the vaccines most benefit those in ages in between those groups. This suggests that this middle group is also less likely to be impacted by flu even if they were not vaccinated. The fact that vaccines are not as effective in elders who are at higher risk for complications raises additional questions about routine vaccination and the need for fuller data presentations on comparisons of effectiveness in vaccinated and unvaccinated populations. With such relatively low vaccine effectiveness over time and populations the vaccine are most effective in, the transmissibility statements are also put into question in terms of protecting others by vaccinating.

A fuller presentation teasing out these areas would be of benefit to better understand vaccine effectiveness and who most benefits from the vaccine, as data gaps in today's presentation suggest routine vaccination for everyone may not be the most effective approach. This additional information would be of benefit to the public and the commission in understanding the risks and benefits of the vaccine and their associated costs. The ACCV's guiding principles on the consideration of data relating to the vaccine injury table also support this fuller type of presentation. Prior to the addition of SIRVA to the vaccine injury table, influenza vaccine injuries in adults were the leading injuries compensated by the VICP and continue within SIRVA-related vaccine injuries today, if I have understood the data presented yesterday correctly.

The presentation of the ACCV's guidelines during the brachial neuritis was refreshing, however, neglected to include the additional factors that the ACCV should consider with regard to the source of evidence, bias and methodological limitations and confounders when considering the quality of the evidence presented when considering changes to the vaccine injury table. Other factors that may be in need of further consideration by the ACCV as they consider data is study funding from industry and the potential bias in study outcomes. The brachial neuritis presentation was also informative on the limitations of the data that has transpired since the 2012 IOM report.

NVIC's continues to ask the question – what is being done to close the vaccine safety research gaps identified in over two decades of reports by the IOM? Commissioner Boyle also raised good points on the need for deeper investigation of cases of brachial neuritis to understand if there is a mechanism of vaccine injury. While the VICP is not a research program, the ACCV's charge is to make recommendations to improve the program and research recommendations based on gaps noted by the IOM – as research impacts the construct of the Vaccine Injury Table. The IOM states that inadequate evidence is defined as the absence of evidence, or a lack of high-quality evidence to determine causality. As such, these findings represent vaccine safety research gaps that impact the VICP and development of a credible vaccine injury table to expeditiously compensate the vaccine injured – as was the intent of the 1986 Act in the development of the table.

Possible next steps by the ACCV could be to undertake providing the public with a report giving an overview of IOM reports that found evidence to be inadequate conditions investigated with what DHHS and Congress has done to close these vaccine safety research gaps, and depending on those finding provide recommendations to the Secretary and advise the Secretary in implementing the Secretary's responsibilities under Section 2127 of the PHS Act regarding the need for childhood vaccination products that result in fewer or no significant adverse reactions as it relates to these vaccine safety research gaps.

As I noted yesterday, the IOM report from 2005 on Public Trust and the VSD data-sharing program and its application to other DHHS programs in use in a similar fashion to express vaccine safety and their transparency would also warrant inclusion in such a report and recommendations to improve scientific rigor in the data presented to ACCV on vaccine safety and potential additions to the Vaccine Injury Table. While the VSD is being used for vaccine safety research, those datasets must be made available to independent researchers as noted by the IOM to maintain the public's trust and ensure that this science is subject to the scientific method. Such an effort is within the ACCV's charge and is also in alignment with the 1986 Act's mandate for ongoing vaccine safety research and safer childhood vaccines.

Of great concern is the fact that over time the IOM reports have documented the widening of these vaccine safety research gaps with the continued expansion of vaccine schedules. The schedules are expanding beyond what is known about vaccine injury mechanisms and greater emphasis and resources on safety science must be invested, similar to resources invested to innovate for new vaccines. It is not enough to identify inadequate evidence – these gaps must be closed as a matter of trust with the public.

In closing, now that the commission has filled many of its vacancies, it would appear to be time for the commission to elect a chair and vice chair from within the commission in alignment with the ACCV's charter.