NVIC Public Comment
Advisory Commission on Childhood Vaccines – March 2, 2023
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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.

I would like to state concern that we do not have a member of the commission chairing the commission – this is highly unusual and not provided for in any way that I am aware of within the law. Clarity on this point would be appreciated, along with why this commission continues to have so many vacancies.

Many thanks to all the presenters today for their presentations. They were helpful.

The presentations on Dengue seem to indicate that we can expect an addition to the VICP at some point in the future. Our concern would be the timeframe that vaccine-induced hospitalization occurs and any potential interaction with the statute of limitations on filing a VICP claim. Additionally, vaccine adverse events reported in these presentations would seem to indicate a vaccine placebo was used instead of an inert placebo, which will dampen safety signals. Additional information on what kind of placebo was used would likely be more informative to the public and commission to better understand the risk for vaccine adverse events. Lastly, information on how the frequency and severity of vaccine-enhanced disease and natural enhanced disease will be monitored and distinctions made, since the approved vaccine is given after the first infection and the known risk for enhanced disease with a secondary infection.

The RSV presentation for children mentioned that ACIP had made no recommendation for the monoclonal antibody, and we are wondering why they would – monoclonal antibodies are not vaccines. Why this information is being presented at ACIP and ACCV seems questionable, given that the purview of these committees are vaccine-related.

Additionally, to Commissioner Boyles request on how to amend the vaccine injury table, NVIC would encourage the commission to review research gaps highlighted by over two decades of IOM vaccine safety reports presented to the ACCV and form a subcommittee to look into how research is being conducted and what research is needed. These reports are a good starting point. 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. NVIC would also encourage the ACCV to discover if the recommendations by the Institute of Medicine relating to data sharing program in the CDC's Vaccine Safety Datalink and barriers for independent researchers' access to this data to replicate or pose different hypotheses for CDC findings have been resolved.

Thank you for the opportunity to provide a public comment.