

**NVIC Written Public Comments**  
**Advisory Commission on Childhood Vaccines – December 3, 2020**  
**Theresa Wrangham, NVIC Executive Director**

I am Theresa Wrangham and the Executive Director for the National Vaccine Information Center. NVIC's 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. As I mentioned earlier, our co-founders worked with Congress to draft and pass the National Childhood Vaccine Injury Compensation Act of 1986.

In listening to the presentations during this ACCV meeting, I am appreciative that ACCV has provided a forum for discussion of all viewpoints. Particularly at a time when we see censorship of any discussion of vaccines that steps outside a one-size-fits-all pro-vaccine scenario.

Briefly, I wanted to provide some historical context based on some of the presentations today. With regard to the NPRM position of removing automatic addition of vaccines that are routinely recommended by the CDC for children to the federal Vaccine Injury Table. The law is quite clear that at a minimum, the Secretary must add these vaccines to the table no later than 2 years after they are recommended by the CDC, per Sec. 300aa-14 - Vaccine Injury Table.

Though I am not an attorney, it seems clear that the bottom line is that additions to the table are mandated. I believe that the reason two years was crafted into the law links back to my presentation with regard to the research mandate. It was the hope of the community that we represent and our co-founders as we helped craft the law, that as vaccines were developed and recommended an investment in research to identify mechanisms of injury was also made to expedite vaccine injury compensation. Instead, because that investment has not been made and the research mandate fails to be fulfilled, vaccines are added to the table without commiserate injuries being added to the Table. Again, this contributes to the program becoming a lengthy and adversarial process. However, the Secretary cannot prevent addition of vaccines to the table without a change to the 1986 Act.

With regard to vax/unvax studies, the IOM stated clearly that the schedule had not been systematically reviewed as a whole, and also issued a report on access issues to VSD data by independent researchers to replicate and confirm research findings produced by government using the VSD. Replication of findings is the gold standard and necessary. Public trust issues were also cited by the IOM in that same report. There is also question about whether or not the VSD is statistically powered to conduct such a study.

NVIC has for almost 40 years supported the creation of an independent agency to monitor vaccine safety and oversee vaccine safety research and a large, prospective study to compare the long term health outcomes of highly vaccinated children and unvaccinated children.

Should a vax/unvax study be undertaken, such a study must be conducted by independent researchers, as all agencies under DHHS are inherently conflicted in conducting such a study given their involvement in the vaccine enterprise starting at patenting right through, approval and direction on their use, distribution and then determining who gets compensated for what injury. There is no independent safety and monitoring of the US vaccine system, and these inherent conflicts of interest that allow a "fox to guard the hen house" scenario, as demonstrated in the latest NPRM and contributes to vaccine hesitancy.s

While ACCV cannot put forth funding of such a study, they can and should fulfill their legal obligation to make research recommendations as provided in the 1986 Act. The creation of a research workgroup to explore what research is needed to fulfill the 1986 Act research mandate and invite members of the public to assist in assessing such a charge to help frame recommendations and report findings back to the ACCV for their consideration could be formed. Given that the research mandate is an ongoing mandate, an ongoing workgroup led by ACCV commissioners and populated by other members of the public with various expertise similar to how the National Vaccine Advisory Committee and Advisory Committee on Immunization Practices for workgroups to explore questions for their committees would assist in upholding the spirit and intent of research informing and providing information to expand the vaccine injury table and expedite compensation to those injured by vaccines. Commissioner Pahud question about the role of the ACCV in this sense is provided for under the 1986 Act and the Secretary also has an obligation to fulfill the ongoing research mandate. ACCV research recommendations play an important role in documenting how to close existing gaps highlight by the IOM reports and were part of the spirit and intent of the 1986 Act that continues to live on in statute today.

ACCV can also, per the 1986 Act, recommend other avenues to raise awareness around the existence of the VICP, as current efforts continue to fall short, as noted in federal reports. Per the 1986 Act, the ACCV can also survey what federal, state and local government processes have been put into place to better capture vaccine adverse events, which is much needed, given the passivity of VAERS and its capturing only a fraction of vaccine adverse events.

Under the law, the ACCV can also petition to add injuries to the table independent of current NPRM efforts. With regard to a change in administration

The clarification of language on the VIS is much needed and appreciated and we note that organizational consults required under the 1986 Act have not been conducted for two years now, though consults continue with the ACCV in a timely manner.

With regard to the lack of commissioners filling positions within the ACCV. NVIC has offered nominations, and we assume other nominations have also been submitted by other individuals and organizations. It is unknown why or what the status is for some of these nominations. However, open positions may not necessarily be due to the lack of applications to fill these positions, but rather a lack of action to move forward with the applications already received.

With regard to COVID-19 vaccine and the letter from the National Vaccine Advisory Committee to assure confidence. We note that engagement of the vaccine safety and informed consent concerned has been excluded in their confidence building efforts, and they were also excluded from similar engagement in the review of the draft five year plan. The plan focuses on vaccine innovation and development, with no equal investment in vaccine safety science and does not support the human right of informed consent, which includes refusal of medical interventions. We would also note, there doesn't appear to be involvement of the ACCV within NVAC efforts to build confidence or the plan, though vaccine injury is a concern of the vaccine hesitant. The AHRQ published for the plan is also subject to the same conflicts of interest I mentioned earlier and is not a substitute for the role the National Academies of Science has played in reviewing the literature for safety and uses a different methodology than used by the Academy and NVIC submitted comments to that effect with regard to the Plan and the AHRQ review of literature.

Again, thank you for the thoughtful deliberation of concerns around the NPRM. It is disappointing that the Secretary is exercising authority in what appears to be an abusive manner, rather than call on the ACCV to examine the evidence in a thoughtful and deliberative manner and then give full consideration to an informed recommendations prior to exercising his authority to enter into the rule-making process.

I hope the ACCV will review their function and abilities within the 1986 Act move forward more effectively in fulfilling their role as envisioned within the 1986 Act. There are long standing concerns from the community NVIC's represents, the vaccine injured, safety and informed consent concerned community, that could be addressed by the commission.

Thank you for the opportunity to provide comments.