NVIC Written Public Comments
Advisory Commission on Childhood Vaccines – June 2, 2022
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The National Vaccine Information Center'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.

From a historical perspective, NVIC has served on and been monitoring this committee since its inception, and I believe that the Commission would benefit from looking at the total trends in adult vs. childhood petitions and changes in the table that may have influenced trends, as I believe initially the number of child petitions and awards were higher than what is reflected in trends from 2010 forward. Additionally, concerning resources and backlogs, reports by the Government Accountability Office (known as the GAO) note the lack of expansion for the vaccine injury table and its impact to VICP backlogs and the adversarial nature of the program, as have many public and written comments by NVIC. The lack of research recommendations by the ACCV, and the unfulfillment of the 1986's Act's requirement for ongoing safety research to define the vaccine injury table creates a more adversarial and backlogged program.

The 1986 Act intended to expand the vaccine injury table via the research mandate and IOM findings to create a generous and expeditious no-fault compensation program. The IOM is charged with determining causality and has been prevented from doing so due to lack of quality science or absence of science for the ACCV making recommendations to expand vaccine injury table. These deficits are not being addressed and the table is not being expanded as intended by the 1986 Act. Just as resources are needed to address the backlog, the long-term success of the program and the public's confidence in it depends on the research mandate within the 1986 Act being fulfilled, and the table expanded. Vaccine safety research must also follow the recommendations of the IOM's 2005 report that recommended VSD core data be available to independent researchers outside of the CDC and its partners to be proved true and/or to pursue alternate hypotheses. Reports from the Institute of Medicine and CDC have stated that the VSD is an excellent source for conducting total health outcome comparisons between vaccinated and unvaccinated populations; however, have studies conducted to date by federal agencies and their partners been proven by outside researchers, and has the VSD been opened to researchers to do so? This is a matter of good scientific process and transparency which will increase the public's trust, which is at an all-time low. Americans deserve this transparency and a compensation program that meets the law's original intent.

We note that under federal law, the National Vaccine Program is charged with not only establishing optimal prevention of human infectious diseases through vaccination but also is charged to achieve optimal prevention against adverse reactions to vaccines. To this end, ACCV is charged with making research recommendations to the ACCV to fulfill the 1986's Act research mandate. It would benefit the ACCV as new Commissioners are onboarded to understand what activities the NVP has undertaken in this regard.

With regard to the December 2021 minutes, I believe the Federal Advisory Committee Act requires that certified minutes reflect what happened in any meeting. Where in error, it would seem logical to correct minutes without so lengthy a discussion. The meeting is recorded, and votes and more can be verified when questions similar to Ms. Kain's are brought to the attention of the ACCV. Regarding ACCV open positions, it would benefit the candidates under consideration to receive status reports on their nomination, as one of NVIC's nominations was submitted before Ms. Kain's appointment with no understanding of whether additional information is needed or if the candidate remains under consideration. NVIC has had a history of service to this Commission, and our monitoring of the Commission since its inception has never seen so many or such lengthy vacancies as we have seen in the last five years.

Relating to research data presented to ACCV by agencies, this data would benefit from being presented in a manner similar to the guidelines the ACCV uses to consider changes to the vaccine injury table. For example, is the data the result of a peer-reviewed study or a closed database such as the vaccine safety data link; was the research funded by industry; was it a case series or a systematic review; what are the study limitations and implications for research and policy? This type of information would assist the Commission in its research recommendation process, and the current state and quality of the science presented to them.