NVIC Written Public Comments
Advisory Commission on Childhood Vaccines – May 18, 2020
Theresa Wrangham, NVIC Executive Director

First Comment – Invited for Beginning of the Meeting

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. Our co-founders worked with Congress to draft and pass the National Childhood Vaccine Injury Compensation Act of 1986. That work by parents of vaccine injured children resulted in the creation of the VICP and an ongoing vaccine safety research mandate to assure Americans that the safest vaccines were in use, should they choose to vaccinate. Our co-founders undertook the arduous task of working with Congress on this federal law by invitation due to our standing as being representatives of the vaccine injured and informed consent movement. Our co-founders came to the table, not because they were anti-vaccine, but because they recognized that the regression in health they had seen in their children post DPT vaccination was similar to the stories shared by parents and in the NBC Emmy award winning documentary DPT: Vaccine Roulette, which aired in 1982.

This documentary also interviewed doctors, public health officials and researchers on both sides of the debate on whether or not the benefits of the vaccine outweighed the risks, noted that serious vaccine adverse events, including brain damage, had been documented in the medical literature for 40 years. It also noted, that pertussis had declined significantly prior to the vaccine's introduction, and the likelihood of widespread pertussis vaccine failure would become a reality. However, the one of the most stunning admissions made in this documentary was by Dr. John Robbins of the FDA's Bureau of Biologics that licenses vaccines for use in America. After many stories by parents on not being advised of vaccine risks prior to vaccinating their children, Dr. Robbins was asked, why when serious adverse events had been documented for decades were doctors not advising parents of this vaccine's risk, his response was, and I quote,

> ***"I think if you as a parent brought your child to a doctor for a DTP shot and the doctor said to you initially that "I have to tell you that some children who get this vaccine get brain damaged" there's no question what your reaction would be. As a responsible parent your response would be I wish not to take this vaccine."***

And there is the rub. A key component of informed consent is to have access to accurate information on the risks of condition the treatment that seeks to mediate the condition, as well as the risks and benefits of treatment. It also requires voluntary consent without coercion or threat of sanction and is globally recognized as a human right.

Instead of coming out against vaccines, the key safety provisions our co-founders secured in the 1986 Act were

> "(1) the frequency, severity, and potential long-term effects of the disease to be prevented by the vaccine, to be prevented by the vaccine;
> "(2) the symptoms or reactions to the vaccine which, if they occur, should be brought to the immediate attention of the health care provider,
> "(3) precautionary measures legal representatives should take to reduce the risk of any major adverse reactions to the vaccine that may occur,
> "(4) early warning signs or symptoms to which legal representatives should be alert as possible precursors to such major adverse reactions,
> "(5) a description of the manner in which legal representatives should monitor such major adverse reactions, including a form on which reactions can be recorded to assist legal representatives in reporting information to appropriate authorities,
> "(6) a specification of when, how, and to whom legal representatives should report any major vaccine adverse reaction,
> "(7) the contraindications to (and bases for delay of) the administration of the vaccine,
> "(8) an identification of the groups, categories, or characteristics of potential recipients of the vaccine who may be at significantly higher risk of major adverse reaction to the vaccine than the general population,
> "(9) a summary of—
> "(A) relevant Federal recommendations concerning a complete schedule of childhood immunizations, and
> "(B) the availability of the Vaccine Injury Compensation Program, and
> "(10) such other relevant information as may be determined by the Secretary."

The Act also required that doctors record changes in their patient after vaccination, whether thought to be vaccine related or not, in the permanent medical record and to report these events to the federal vaccine adverse event reporting system, also created by the Act.

That risk informing requirement was gutted from the Act in 1995. The protection provided by the Act for injured to be able to sue vaccine makers, if unhappy with the decisions out of the VICP was taken away by the Supreme Court in 2011 and in essence vaccine makers cannot be liable for vaccine injury and death, acknowledged as real by the Act. Reports by the Altarum Group (2009) over 20 years after the Act's passage indicate that doctors still have an agenda and do not want to discuss vaccine risks with parents, though that same report shows that parents want to know and would likely still vaccinate their children.

In the years since the passage of the Act, DHHS has systematically narrowed the vaccine injury table to a point where it no longer meets the spirit and intent of the law to compensate the vaccine injured expeditiously and generously and to always give them the benefit of doubt. DHHS has also failed in their federal duty to make widely known the existence of VAERS and the VICP to the public, which results in underreporting of vaccine adverse events and vaccine injury compensation. Research demonstrating that vaccine reporting could be greatly improved through Electronic Support for Public Health (ESP) remains unpursued and a missed opportunity to increase VAERS ability to detect vaccine safety signals.

The Act's requirement that vaccines in use have the fewest side effect possible to reduce vaccine injury and death has been largely been ignored while the childhood vaccine schedule has almost tripled in size since the Act's passage. Reports by the Institute of Medicine reports on vaccine adverse events consistently state that for the vast majority of events there is a lack of quality science or an absence of science that prevents them from making causality conclusions, and thus prevents the vaccine injury table and the compensation program from keeping pace with understanding the mechanisms of vaccine injury and death and compensating those harmed, which makes the following statement in the draft NPRM as offensive and wholly inaccurate:

> ***"…the proposed rule will also limit the ability of those opposed to vaccinations to misleadingly suggest that vaccines are less safe than they truly are."***

The inconvenient and unescapable truth is that DHHS has never attempted to implement the intent of this law or acted to close significant vaccine safety research deficits highlights by the Institute of Medicine reports, and our government lacks the political will to do so.

This latest NPRM to remove vaccine injuries from the table is one in a long line of action by DHHS to gut the Act's original spirit and intent of compensating those harmed by vaccines. The mischaracterization of those who voice legitimate vaccine safety concerns as anti-vaccine serves only to increase hostilities, pit parent against parent, and remove informed consent rights to refuse vaccines. The end goal is that the vaccine injured are acceptable collateral damage for the greater good.

I have monitored this advisory committee for over 15 years and this current attempt to narrow the vaccine injury table without presentation of evidence by DHHS and thoughtful and unhurried discussion by ACCV to remove injuries from the table is unprecedented.

The remainder of NVIC's concerns are highlighted in our written comment to the ACCV.

Summary of Second Comment – End of the Meeting

Ms. Wrangham agreed with Mr. Milmoe's statements today with regard to the actual intent of the law not being met and liability mechanisms relating to injury is reflective of NVIC's history with the law and the filing of an amicus brief to the U.S. Supreme Court for Bruesewitz v. Wyeth. NVIC expressed deep concern that DHHS neglected to present any evidence to the ACCV in support of the removal of SIRVA and syncope from the federal vaccine injury table, contrary to previous routine established by DHHS and ACCV in this regard and that a presentation of evidence is necessary, particularly given that many physicians and members of the public commenting during the meeting are against the removal of these injuries from the table based on their professional and personal experiences and that there appears to be evidence to support that vaccines can cause SIRVA injuries. These comments from the public underscores the need for DHHS to present evidence to the ACCV in order for the ACCV to make a recommendation to the Secretary on whether or not to remove SIRVA and syncope from the vaccine injury table. NVIC renewed its request that when petitions to change the vaccine injury table are considered by the ACCV that the ACCV include in their process equal time in the presentation of evidence from the public to that given to federal agencies.