Advisory Commission on Childhood Vaccines
NVIC Public Comment – Theresa Wrangham, Executive Director
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My name is Theresa Wrangham and I am the Executive Director for the National Vaccine Information Center, the mission of which is to prevent vaccine injury and death through public education and to defend the informed consent ethic in vaccination practices. I appreciate the opportunity to comment today.

While NVIC supports extending the statute of limitations, we reiterate that the original intent of the law in was that the VICP would not be the sole remedy and would allow consumers that were not satisfied with VICP decisions recourse. This recourse was designed in part to act as a mechanism of accountability for vaccine manufacturers. As such, NVIC does not support extending the statute of limitations at the expense of the VICP becoming an exclusive remedy. We would ask that as the ACCV follows up with the Secretary that their recommendation for extending the statute of limitations retain the original intent of the law. We would also encourage the Commission to consider additional strategies to raise awareness to lower these types of dismissals such as media advisories and press releases on the activities and meetings of the Commission similar to what is done for the ACIP.

With regard to the VIS revisions, we note that the VIS is much shorter today and the information is limited. Including statements about the fact that death may occur as a result of vaccination is not optional and must appear on all VIS'. Consumers are entitled to understand that vaccines are not risk free and must have accurate information to make informed decisions, even when that means that they may decline or delay one or more vaccines. This is the promise of informed consent. Under the law the VIS is to provide clear and accurate information to consumers on risks and benefits of vaccines. Adequate length to provide this information should be revisited, as the current length limits this information.

NVIC took part in the parent organization consultation held by the CDC. During that time one participant suggested that provider materials should emphasis that the VIS should be given well in advance of vaccination and NVIC supports that premise, as consumers are usually given this information just before vaccination without adequate time to review the information. It was also suggested that at the top of the VIS that a statement about the VIS being only one of many resources of information be included. Given the brevity of the VIS today, this statement would be helpful to the consumer and ties into Section 7. In general, we would encourage the ACCV to assure that all VIS' acknowledge the following:

- A return to a more informative tone by changing the Section 1 title from "Why get vaccinated?" back to "What is XYZ disease?" As noted by Mr. Krause, the current Section 1 title is persuasive in tone. Information about the vaccine is addressed in other sections of the VIS and starting with "Why get vaccinated?" is a policy stance.
- Acknowledgement that vaccines do not always work – this must be said clearly. The current failure of the pertussis vaccine to protect children today is a good example of why this statement must be clear. The general public is not aware of this failure and media reports continue to demonize the unvaccinated as being responsible for these current outbreaks when the opposite has been acknowledged by the CDC. The reality is that there is no vaccine provider that can tell a consumer if the vaccine they receive today will protect or harm them.
- Risks stated in the VIS should also reflect injuries in the current Vaccine Injury Table and their associated timeframe.
- Globally there is also a need in VIS language to acknowledge susceptibility and unknown risks that the Institute of Medicine has repeatedly noted in their reviews of vaccines and their risks. The IOM has provided clear language in their 2012 report, which states:

"Vaccinations—like all medical procedures—are neither 100 percent free of risk nor 100 percent effective. Vaccines, in rare cases, can cause illness. Most children who experience an adverse reaction to immunization have a preexisting susceptibility. Some predispositions may be detectable prior to vaccination; others, at least with current technology and practice, are not." (IOM, 2012, p. 82)

- Consumers should also have the benefit of a clear understanding of the disease, its symptoms, transmission, treatment and the frequency and severity of the disease and its complications. Statements on pre-vaccine era disease incidence should also include information on whether or not the disease trend was already in decline prior to the advent of vaccines and the reason for decline to better inform the consumer of the impact of vaccines on the disease.
- With regard to effectively communicating with consumers, we would suggest using absolute terms in relation to risk and benefit statements.
- Clear information is also needed on vaccine safety deficits with regard to the schedule as a whole as noted by the IOM. Language stating that this vaccine is safe to give with others may not reflect the IOM's findings.
- The law requires reporting of reactions by vaccine providers by stating "***Each health care provider and vaccine manufacturer shall report to the Secretary***". This is accomplished via the creation of VAERS. Provider materials should encourage providers to report beyond legal requirements, if they believe they are seeing a vaccine reaction. The legal requirement to report reactions was a point of contention during the consultation meeting and legal reporting requirements that pertain to providers should be reflected in VIS language.
- There are many resources from which to obtain information on vaccines, one being the manufacturer product insert. This information should appear in Section 7, and also be referred to throughout the VIS because many consumers are unfamiliar with the product insert and the information it contains. Referencing the insert would also help with challenges in addressing wording on allergies as it pertains to vaccine ingredients, adverse events, contraindications and precautionary information relevant to the vaccine.
- The statute of limitations on the eligibility for vaccine injury compensation should appear on all VIS'. A short statement that may be used could be: If you believe you have been injured by a vaccine, you can file for compensation with the Vaccine Injury Compensation Program. *To be eligible for compensation, claims must be filed within 36 months from the date of the vaccine being administered to you.*
- Where vaccines are recommended for pregnant women, information on off label use and FDA pregnancy category information should be included for transparency.

These suggested global template changes in how information is presented allows the consumer to more accurately weigh the risk and benefit of vaccines as well as differentiate between the disease and vaccine reaction symptoms and adverse events.

In closing, we would reiterate that the priorities that govern whether or not the ACCV meets in person need to be closely evaluated. Parents today are under increasing pressure to vaccinate and with increased vaccine uptake comes increases in vaccine injury and death. The charge of the ACCV is no less important than that of the NVAC or ACIP, which consistently meet in person. We would agree with the chair - what is more important than addressing injuries and deaths that occur as a result of federally recommended vaccines? To limit the meetings of the ACCV minimizes their role and those they represent – the vaccine injured. Those who are injured or die as a result of vaccination are real people; they have faces and names and their voices must be given equal weight, priority and concern within federal advisory committee decisions relating to vaccine policy recommendations.