

NVIC Public Comment
National Vaccine Advisory Committee Meeting – June 11, 2014
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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 vaccine policies and laws.

Yesterday the committee heard the Association of Immunization Managers' (AIM) position opposing legislative attempts to add personal belief exemption in states where this exemption is not available and AIM's support for making this exemption harder to obtain in states where personal belief exemption is available. There were also presentations made which attempted to ethically justify and encourage vaccine mandates for health care workers that do not offer non-medical exemptions. We note that many labor unions, OSHA and NVIC opposed such mandates in 2012 for similar recommendations made by the NVAC.

We remind this committee that, vaccines, like all pharmaceutical products, carry with them the risk for injury and death and there is no vaccine provider that can predict if a vaccine will protect and not harm an individual. Because vaccines are not risk free, individuals choosing to be vaccinated are federally required to receive benefit and risk information prior to vaccination. That information is given in the form of the CDC's Vaccine Information Statement (VIS), which was secured in federal law by NVIC's co-founders. However, there is no legal requirement for a vaccine provider to explain the VIS or obtain a signature from a vaccinated individual stating it has been read or understood.

Inherent within the informed consent ethic is the receipt of accurate risk and benefit information about a condition and its treatment options with the ability of individuals to voluntarily decide to accept, delay or decline a treatment or medical procedure. Ethical arguments, positions and strategies that attempt to justify the removal of non-medical exemptions or make them harder to obtain violate the informed consent ethic and erroneously frame vaccine injuries and deaths as rare, acceptable and necessary sacrifices for the good of public health. Some of the positions are clearly discriminatory and coercive because they require education above federal requirements for those choosing to vaccinate.

NVIC opposes policies, positions and strategies that obstruct access to non-medical exemptions because they support discriminatory and coercive actions that infringe upon basic human rights and fail to uphold both the precautionary and informed consent principles. They also fail to recognize acknowledged vaccine safety research gaps, and biodiversity and susceptibility statements in reports issued by Institute of Medicine.

We also take this opportunity to express concern that IOM statements also appear to be absent in the vaccine hesitancy group's work thus far and note that many parents who delay or decline one or more vaccines cite legitimate safety concerns that are echoed by the IOM. We are encouraged that this working group plans to hear from parents. NVIC's supporters range from the vaccinated to the unvaccinated and we have over three decades of experience in representing parents who are hesitant and are able to provide insight to the working group.

During this meeting, the NVAC also discussed vaccine innovation and development. The NVAC's charge includes the prevention of vaccine adverse events and we encourage discussion addressing acknowledged gaps in vaccine safety research and the urgent need for independent research to close those gaps.

Presentations made on HPV neglected to highlight the CDC's report to Congress, which stated that the majority of HPV infections resolve on their own without consequence. This fact may contribute the low value providers place on the vaccine noted in today's presentations. As HPV communication strategies are implemented, these efforts must be balanced and include information about the disease to enable the public's access to accurate information during the decision-making process, regardless of its impact to vaccine uptake.

In closing, we would note that incentivizing providers, practices and healthcare facilities to meet Healthy People 2020 vaccination goals undermines the informed consent ethic by pressuring compliance at the price of delivering care according to individual needs and treatment decisions. Healthy People 2020 goals are just that – goals. They are not mandates and should not be leveraged in a manner that leads to mandates that unduly pressure consumers to accept medical procedures and/or result in sanctions and threats to employment.