NVIC Public Comment
National Vaccine Advisory Committee Meeting – February 6, 2013
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Note: This comment was submitted in writing after the meeting, due to technical difficulties encountered by NVAC in receiving oral comment during the meeting's allotted public comment time indicated on the agenda.

My name is Theresa Wrangham and I am the Executive Director for the National Vaccine Information Center, the mission of which is to reduce vaccine injury and death through public education and to defend the informed consent ethic in vaccination practices. I appreciate the opportunity to comment today. NVIC is entering its fourth decade of public service and we remain the largest and oldest consumer led non-profit organization representing the vaccine injured, those who have died as a result of vaccine adverse events, those with vaccine safety concerns and those concerned with protecting informed consent in vaccination.

We express the following concerns with regard to vaccine hesitancy and the charge of the NVAC's working group on this topic. NVIC's experience and that of its supporters with regard to hesitancy, as well as surveys and studies on the topic, demonstrate that core concerns center on vaccine safety research deficits and the safety of the ACIP's recommended childhood vaccination schedule.

The two most recent IOM reports acknowledge significant gaps in vaccine safety research, whether the discussion is safety as applied to the schedule, or when considering whether or not the most common adverse events reported for vaccines in use are causally linked to vaccines. The most recent IOM report addressing the safety of the schedule identified fewer than 40 studies and noted the following – and I quote:

- "Few studies have comprehensively assessed the association between the entire immunization schedule or variations in the overall schedule and categories of health outcomes, and no study has directly examined health outcomes and stakeholder concerns in precisely the way that the committee was charged to address its statement of task;" (S-4)

- "No studies have compared the differences in health outcomes that some stakeholders questioned between entirely unimmunized populations and fully immunized children. Experts who addressed the committee pointed not to a body of evidence that had been overlooked but rather to the fact that existing research has not been designed to test the entire immunization schedule;" (S4-5)

- "The committee believes that although the available evidence is reassuring, studies designed to examine the long term effects of the cumulative number of vaccines or other aspects of the immunization schedule have not been conducted; (S-5)

- "Providers are encouraged to explain to parents how each new vaccine is extensively tested when it is approved for inclusion in the recommended immunization schedule. However, when providers are asked if the entire immunization schedule has been tested to determine if it is the best possible schedule, meaning that it offers the most benefits and the fewest risks, they have very few data on which to base their response;" (4-10)

The IOM report previous to this most recent report found that for 85% of the most commonly reported vaccine adverse events they reviewed that research was absent or was lacking in quality and prevented a determination of causality. For the 15% that had adequate research for the IOM's charge, over half of those vaccine adverse events supported, or favored, a causal link to vaccines.

In short, many of the safety concerns held by the public are valid. Today the NVAC discussed the need for better communication on the benefits of vaccination to increase trust, while some committee members acknowledged the need to listen carefully to public concern due to the fact that widespread concern could lead to widespread refusal. Respectfully, parents do not want another communications plan that one-sidedly touts the safety of vaccines, while omitting what is known and unknown in terms of risk. The public deserves honesty in communications and will not be convinced, or coerced, to convey their trust by communications that omit valid concerns and demonize those that raise these concerns and ask for their remedy.

Questions and concerns remain with regard to influenza vaccine mandates for health care workers. Many unions and organizations, NVIC included, opposed healthcare worker influenza mandates due to inadequate exemption provisions within the NVAC's recommendation. Since the NVAC's recommendation, harassment reports from health care workers submitted to NVIC have risen dramatically, with some individuals deciding to quit their jobs and/or considering legal action, as opposed to being coerced to vaccinate. Adult influenza vaccine injury claims are the leading claims submitted to the VICP. Who will pay when a health care worker is injured due to employer mandates, Workman's Compensation? The

VICP? When a health care worker is fired for vaccine refusal, what is the fiscal burden to unemployment funding and taxpayers? Will mandates contribute to heath care worker shortages?

The NVAC also spent a great deal of time during this meeting discussing their disappointment in the uptake of the HPV vaccine. Respectfully, parents have concerns about HPV and other vaccines that are not being addressed by the committee. Efforts that would allow minors to consent to vaccination without parental knowledge and consent should be opposed by the committee, because minors do not have the capacity to understand the nature of the risk-taking involved in vaccination and such action erodes parental rights. Allowing a minor to consent raises many questions, such as who supports/compensates that minor if vaccine injury is sustained; the state, which permitted the minor to consent, or the family? NVIC is opposed to efforts that would allow a minor to consent to vaccination without the knowledge and consent of their parent(s).

Other concerns include the severity of outcomes associated with the disease and its impact in vaccination decision-making as it relates to hesitancy. For example, children who get chicken pox rarely suffer severe complications from the disease. Similarly, a CDC 2004 report to Congress on HPV infections states that the majority of HPV infections resolve within two years without clinical incidence or intervention. Again, parents may be exercising their informed consent rights based on this type of data when deciding whether or not to vaccinate their children and these concerns are not voiced on the committee.

In closing, it may surprise many to learn that NVIC's supporters are comprised of many who vaccinate, as demonstrated in slides presented by Dr. Omer during September's meeting. Because NVIC's platform rests in part on the informed consent ethic, public support of our mission continues to grow. It is from that perspective that I cannot overstate the urgent need for the NVAC to consider meaningful participation of members of the public who are hesitant and who hold valid safety concerns. The path to regaining the public's trust will require more than good communication; it will require meaningful inclusion of the hesitant, clear objectives that respect informed consent, and resolution of vaccine safety research deficits with high-quality, independent research.