NVIC Public Comment National Vaccine Advisory Committee Meeting – June 5, 2013 Theresa Wrangham, NVIC Executive Director

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. For over 30 years NVIC has represented the vaccine injured, those who have died from vaccination, the vaccine safety concerned, vaccine hesitant and pro-informed consent in vaccination. We are the largest and oldest consumer led non-profit organization representing these various public interests.

I reiterate today our written comments submitted during February's NVAC meeting regarding IOM recommendations presented to the NVAC yesterday. NVIC supports the IOM committee's first three recommendations as follows.

Specifically, we support the IOM's call for the federal government to assess evidence regarding public confidence in the childhood vaccine schedule and improved communication between doctors and the public. Additionally, we support the IOM's call for federal officials to define potential vaccine adverse health outcomes in special populations at increased risk for suffering vaccine injury and making the evaluation of the childhood schedule for safety a research priority.

These last two recommendations must also be taken in context with previous IOM committee findings from the 2012 report Adverse Effects of Vaccines: Evidence and Causality that investigated 158 of the most commonly reported vaccine adverse events. For 85%, or 135, of these events the IOM was prevented from determining causality due to either an absence of science, or the lack of quality science. These two most recent IOM reports acknowledge significant gaps and lack of quality vaccine safety research. Tellingly the IOM's most recent report addressing the safety of the childhood vaccine schedule identified fewer than 40 studies published in the last 10 years and underscores the urgent research needs.

As many on this committee are aware, NVIC's roots began with parents whose children were injured or died as a result of being vaccinated with the DPT vaccine. From then to now, many routine vaccinations have forever changed the lives of those they have injured, those who have died from them and the families left to care for them or who survived them. These families and individuals deserve answers, but research continues to lag. Independent bench science is urgently needed to define the biologic mechanisms for vaccine injury and death. Vaccine safety research must be an equal priority to the development of new and improved vaccines.

NVIC strongly opposes the IOM's final two recommendations that suggest there is no value in prospective clinical trials in examining the safety of the schedule, and that future vaccine safety research be conducted by DHHS and its corporate partners using existing closed database systems. The gold standard in science is replication because it provides protection against scientific fraud. There are inherent conflicts of interests in the recommendation that federal agencies conduct vaccine safety research when at the same time they are developing and patenting vaccines, regulating their use, and making policy for the promotion and distribution of vaccines. The use of closed patient databases, such as the VSD prevents independent replication of vaccine safety conclusions made by DHHS officials collaborating with HMOs and pharmaceutical corporations in public-private partnerships.

These conflicts of interest and public-private partnerships undermine public trust and confidence in vaccines. Committee discussions about strategies to increase adult vaccine schedule compliance; implementation of maternal vaccine recommendations and resolution of vaccine hesitancy rest on restoring public trust and confidence. The same trust, confidence and hesitancy that the NVAC recognizes as challenges associated with the childhood schedule are likely to exist within the adult population targeted for these new strategies.

Ongoing and well-established stakeholder concerns must be addressed with strategies of transparency, honest communication of risk, independent quality vaccine safety research and respect for the human right to exercise inform consent. Those are the strategies that will foster trust and confidence.

Thank you for the opportunity to comment today.