NVIC Public Comment
National Vaccine Advisory Committee Meeting – February 2, 2016
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 prevent vaccine injury and death through public education and to defend the informed consent ethic in vaccine policies and laws.

Vaccines, like all pharmaceutical products, carry with them the risk for injury and death. We appreciate the NVAC's acknowledgement in their reports of the acknowledged vaccine safety research gaps highlighted by the Institute of Medicine reports spanning twenty years. During today's presentations on vaccine innovations there was no discussion relating to research into vaccine injuries and death resulting from the introduction of new vaccines and the urgent need for an equal commitment in this type of research to assure that vaccine safety research gaps do not continue to grow. This is particularly important to address, as the safety research deficits already highlighted by the IOM continue to be of concern to Americans that NVIC represents, as well as to the Advisory Commission on Childhood Vaccines.

Also absent from these presentations today was information on how informed consent to vaccination is discharged, obtained and assured in poor countries, as well as how vaccine injuries and deaths are tracked and compensated in these countries. Future presentations would benefit from a more balanced approach in providing not only information on vaccine coverage progress, but additional information on what resources are available to care for poor families in these countries for whom vaccination has negative outcomes; what research is being done to prevent those outcomes; and what policies and laws are being put into place to protect human and informed consent rights in vaccination.

NVIC appreciates that some of these efforts are being made with refugee programs and encourages the use of existing vaccine manufacturer product inserts in that process, due to the limited information available in the VIS.

We note that during the Zika presentations that there was no mention of other factors being explored in the occurrence of microcephaly. The NIH notes that babies are born with microcephaly if, during pregnancy, their mother abused drugs or alcohol, were exposed to certain toxic chemicals, or had untreated phenylketonuria (PKU).

Given that vaccine development has been characterized today as risky and expensive, it is worth noting that in an investigative report by Rueters[1] in 2015 Brazil is a leading country in its use of pesticides, and that there is also research suggesting that pesticides may have a role in the development of microcephaly.[2] [3] It is hoped that these and other environmental toxins and their possible role in the development of microcephaly are also under investigation, given that the World Health Organization has noted that a link between Zika and microcephaly has not been scientifically proven.

Relating to vaccine safety needs, the IOM has stated consistently for over twenty years that they have been prevented from making vaccine causality statements due to an absence or lack of quality science. As demonstrated by these IOM reports, vaccine development, licensure and usage outpaces what we know about which vaccines cause what injuries and who is at risk for vaccine injury and death. Yet, the ability of professionals, parents and individuals to exercise their human and informed consent right to voluntarily accept, delay or decline vaccination without sanction is eroding.

As the NVAC undertakes their mid-course review of the National Vaccine Plan, there is an urgent need to address closing the existing vaccine safety research deficits highlighted by the IOM reports, as well as place the same priority for this data on vaccines under development as part of the federal mandate for ongoing vaccine safety research. There is also an equal and urgent need for the NVAC to support the ethical, human, and informed consent rights of the individual in vaccination. The IOM has acknowledged that not all individuals respond the same way to vaccines and that there are individuals who are at increased risk for vaccine injury and death. Because there is risk, there must be choice, and those at risk should not be treated as acceptable collateral damage in the discharge of public health policies and laws.

[1] Reuters Special Report: Fateful Harvest - *Why Brazil has a big appetite for risky pesticides.* Paulo Prada. Reuters. Apr. 2, 2015.

[2] Oral exposure of male and female mice to formulations of organophosphorous pesticides: congenital malformations. *Hum Exp Toxicol March 2008 vol. 27 no. 3 231-240.*

[3] Maternal occupation in agriculture during pregnancy and congenital anomalies: A case-control study. *International Journal of Risk and Safety in Medicine*, vol. 11, no. 4, pp. 217-224, 1998

NVIC Public Comment
National Vaccine Advisory Committee Meeting – February 3, 2016 – Day 2

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. NVIC supports the availability of all preventive health care options, including vaccines, and the right of consumers to make educated, voluntary health care choices, without sanction.

Our comments today focus on the overall lack of discussion of the precautionary and informed consent principles in safeguarding the human right of individuals to make voluntary healthcare decisions. There continues to be a lack of informed consent protections within many aspects of the NVAC's work and more specifically with the ability of consumers to retain privacy with respect to their healthcare decisions, particularly with respect to Immunization Information Systems (IIS) and Electronic Medical Records (EMR).

The use of IIS and EMRs is being leveraged as a way to track consumer health status, target certain individuals for behavior change and "assist" with identifying individuals during an outbreak. This strategy does not acknowledge that people are not all the same, nor do they respond the same way to any medical treatment or pharmaceutical product.

NVIC requests that NVAC uphold the principles of informed consent and precaution in medical risk-taking decisions and pull those invaluable ethics throughout all work undertaken by the NVAC.

In closing, we also ask for the NVAC to state the need for immediate discontinuation of the use of oral polio vaccine (OPV) globally in efforts to eradicate polio, due to the ongoing vaccine injuries occurring, as demonstrated in today's polio update presentation. The risk for OPV vaccine injuries were widely known prior to eradication efforts and OPV should never have been an option. Because OPV use was permitted, people were injured. These people represent cases of preventable vaccine injuries. These lives are forever changed. These lives matter and they are more than numbers in a presentation.