

**National Vaccine Advisory Committee Meeting – Sept 9-10, 2014**  
**National Vaccine Information Center Public Comment**  
**Theresa Wrangham, NVIC Executive Director**

My name is Theresa Wrangham and I am the Executive Director for the National Vaccine Information Center. We would ask that NVAC set aside appropriate time for oral public comment of at least 3 minutes, as over the past two years there has been no appreciable increase in public comment, which ranges from 0 to 3 comments per meeting. We would also request NVAC be more transparent and provide it's meeting notebook online in addition to presentations and minutes, as does the ACCV, and as provided by the Federal Advisory Committee Act.

The Ebola discussion raises cause for concern with regard to informed consent. While we appreciate that there is an outbreak to contend with, and we would note that mortality for this outbreak was stated as being about 50% vs. the expected 90%. With the use of vaccines that have not been licensed and that have not undergone the expected safety measures are used in this outbreak, it is important that those receiving what is essentially an experimental vaccine for which initial safety data is actively being gathered are aware of these facts prior to vaccination. We would echo the concern expressed by one committee member who stated that it is hoped that the market for this vaccine is not seen as robust.

As for using the Ebola outbreak as an opportunity to communicate safety systems in place domestically to counter hesitancy, we would again note that if this committee truly wants to address vaccine hesitancy, transparency in communication is necessary.

For example, NVIC is participating in VIS revisions. We have advocated in public and written comment to this committee and in the VIS efforts that the use of vaccines in pregnant women is based largely on small observational studies for vaccines that are not licensed for use in pregnant women. Pregnant women should be receiving information about FDA pregnancy categories for these vaccines, which note safety deficits in their use in this population. This information is not being communicated to pregnant women, yet the federal government is obligated to be transparent in risk communications. These actions lead to hesitancy.

Vaccine hesitancy stems safety legitimate concerns highlighted by IOM acknowledged gaps in vaccine safety science – particularly mechanistic evidence that was absent in the RAND review and that are critically important for causality assessments. It also stems from and overall lack of transparency in risk communications, closed governmental databases that prevent duplication of government conducted vaccine safety research, and lack of independent oversight of vaccine safety, all of which undermines public trust and confidence in vaccines.

It is both unreasonable and unethical to expect Americans to vaccinate with confidence in a public health environment that is unwilling to invest in actually addressing the core of hesitancy and that instead invests in new and improved communications packages and policies designed to convince and coerce the public to believe that all is well. All is not well, and many dissatisfied Americans are educating themselves to understand vaccine benefits and risks. The public deserves from you an equal commitment in characterizing vaccine injury risks and preventing vaccine injury and death because the parent who's child is injured or dies as a result a vaccine adverse event is just as aggrieved as the parent who loses their child to a vaccine-targeted disease. They are equal tragedies. The goal of public confidence in vaccines will never reached until legitimate safety concerns and conflicts of interest are resolved and informed consent rights respected.

NVIC supports concerns expressed by NVAC Member Torres regarding the ability of the public to submit reports online. We note today's presentation stated 70% of reports are made via fax and mail and would seem to indicate that manual entry is still very much needed to keep reporting accessible to all Americans. We would add that VAERS continues to remain unknown to the majority of Americans and AEFIs are underreported as a result and thus requires an increase in public awareness efforts and communications by the CDC.

In closing, we would remind the committee that Healthy People 2020 Goals are just that, goals. NVIC opposes leveraging those goals in a manner that fosters mandates and sanctions against individuals and businesses not meeting those goals, as it violates informed consent rights and doesn't acknowledge individual susceptibilities highlighted by the Institute of Medicine reports.