

**NVIC Public Comment**  
**National Vaccine Advisory Committee Meeting – June 7, 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.

I would like to express concern on behalf of our donor supports relating to privacy and IRB interaction discussed during the vaccine innovation. Its important that as testing vaccines on pregnancy women that prior samples and the conditions under which the samples were given meet the privacy expectations of participating individuals. Where there is no permission to use this repository of samples outside the original intent, privacy must be respected as the condition under which informed consent for the original procedure was given and nothing more. Relating to redefining pregnant women as a “scientifically complex” population we also have concerns. Currently pregnant women are considered to be a vulnerable population and it is difficult to imagine that there is anything more vulnerable than an unborn child or the mother of the child who is pregnant.

We ask that the NVAC exercise extreme caution on any recommendations that would lower the bar to allow pregnant women to undergo clinical trials within the context of the benefits of the greater good, when there is admittedly little data to support that context where pregnant women are concerned. Mother’s to be are primarily concerned with the health of their unborn child and to put benefit into a context that is not supported by data is misleading. Additionally, it is important that if pregnant women do agree to participate in vaccine clinical trials that the risks, both known and unknown, and any use of their information and/or samples being used as some sort of repository for future use be clearly spelled out as part of the informed consent process.

We echo the concerns of an earlier NVAC member today in suggesting that pregnant women, the group most impacted by the maternal vaccine plans, be the primary stakeholders in any process by which they will be asked to vaccinate. Their input, concerns and wishes must be primary to any process put into place, as well as their ability to opt out of any maternal vaccination plan.

Relating to the panel discussion on the immunization conference, while there are challenges with coding and reimbursement that are deserving resolution, the incentivization of health care providers to administer vaccines is a conflict of interest where patient care is concerned. The provider must at all times be discharging informed consent, which means no coercion or harassment for decisions made by a patient who delays or declines one or more vaccines, regardless of their reason for doing so. NVIC receives reports daily from consumers of patients being kicked out of practices and denied medical care for exercising their informed consent rights to delay or decline a vaccine, which is a pharmaceutical product acknowledged as carrying the risk for injury and death. The health care provider’s primary duty is to their patient and incentivizing them to deliver healthy people 2020 goals undermines patient autonomy.

Lastly, we continue to express concern relating to the security of immunization information systems and the ability of individuals to exercise control over their private health information. Many people do not even know that they are participating in efforts to create federal databases for tracking vaccine status. Participation in such systems should be voluntary and there needs to be more transparency with the public on the use and security of these databases so that consumer can decide what health information they wish to share with the government.

Thank you for the opportunity to provide public comment today.