National Vaccine Information Center Theresa Wrangham, Executive Director Public Comment 2/7/2012 – National Vaccine Advisory Committee Meeting

Good afternoon, I am Theresa Wrangham, the Executive Director for the National Vaccine Information Center. I thank the committee for the opportunity to provide public comment today. NVIC has long represented the vaccine injured, those who have died as a result of vaccine adverse events and consumers concerned about vaccine safety and the protection of the legal right to informed consent in vaccination.

NVIC does not does not advocate for or against the use of vaccines, and acknowledges the importance of patient safety, the work of the committee and the limitations of their charge regarding Recommendation 4 on health care workers receiving influenza vaccine. The aspirational 2020 Healthy People goal should remain aspirational and not leveraged to punish health care workers for exercising their informed consent rights. NVIC remains opposed to any vaccination requirements for health care workers to receive influenza vaccine that do not include comprehensive and flexible exemption provisions. Specifically, recommendations in this regard must include requirements for policy language to include medical, religious and conscientious/personal belief exemptions in Recommendation 4.

As was demonstrated in the lively public comment this morning, it is no surprise that NVIC continues to hear from many health care professionals that they oppose influenza vaccination mandates for medical, religious and conscientious belief reasons, or that harassment reports we receive from health care professionals for refusing influenza vaccine have risen sharply in the past two years. In reviewing the executive summary of public comments received by the committee, it is clear that the public continues to have concerns regarding mandates with inadequate exemption provisions.

These concerns are legitimate and it is worth noting that the leading claim for the federal Vaccine Injury Compensation Program is for adults injured by influenza vaccine, which are compensated for conditions like GBS, which was discussed earlier in relation to H1N1 vaccine. Additionally, the science on which the draft recommendations have been made is not sufficient to overcome the research deficits that remain in identifying those who are at higher risk for injury and death from vaccines, as acknowledged by the Institute of Medicine's (IOM) report last year, *Adverse Effects of Vaccines: Evidence and Causality*.

As you are aware, the IOM's review of the 27 adverse events reported to be associated with influenza vaccine found that the medical literature was insufficient to make a determination on causality for 23 of the 27 adverse events because there was either an absence of studies or the studies were not methodologically sound. There are also a number of systematic reviews of research for the influenza vaccine which have shown that most studies are poorly designed and have failed to demonstrate that the vaccine is effective or safe, as well as that transmission of influenza by health care workers to patients is inferred rather than established. Our written comments to the committee were well referenced in this regard, so I will not go into any more detail on the science.

In closing, recommendations that do not include flexible exemption provisions and access to accurate information on influenza and influenza vaccine unfairly punish health care workers who may be at greater risk for suffering harm from vaccines with the threat of losing their job for non-compliance. We respectfully request that the draft recommendations on influenza vaccine for health care workers include medical, religious and conscientious belief exemption requirements and recognition of the scientific deficits most recently acknowledged by the IOM and systematic reviews noted in our written comment.

Lastly, the audio of this meeting was very poor and it has been difficult to hear the proceedings. In the interest of transparency, we request the opportunity to purchase the audio of this meeting, and would state that the notice in the Federal Register did specify 5 minutes per person to comment today.

Thank you for the opportunity to comment today.