

Public Comment by Theresa Wrangham
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National Vaccine Advisory Committee
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I am Theresa Wrangham, the Executive Director of the National Vaccine Information Center (NVIC), a consumer advocacy organization founded in 1982 to prevent vaccine injuries and deaths through public education and to protect the informed consent ethic in medicine. We thank the committee for the opportunity to comment.

We have three concerns that we would encourage the NVAC to address:

- First, to date CDC's Charge 1 response to the NVAC's many recommendations have been only partially addressed. We sincerely hope recommendation three on public engagement will be pursued by the CDC. Recent national polls reveal growing concern about vaccine safety and a desire for more informed vaccine decision making by Americans, as reflected by the many questions raised by the public during the 2009 H1N1 pandemic public health emergency declaration. Additionally, we encourage NVAC to request that CDC's upcoming written response be a reasoned address of all recommendations from Charge 1, including whether it is their intent to pursue or not pursue a recommendation.
- Second, the H1N1 pandemic vaccine has been incorporated into the 2010/2011 trivalent influenza vaccine, even though adverse effects, including convulsions in young children, have been reported during use of the trivalent formulation in Australia earlier this year. There are also outstanding potential safety signals for GBS and thrombocytopenia for pandemic H1N1 vaccine reported by the VSRAWG that are not completely understood at this time. Also, during last December's ACCV meeting, the Department of Justice presentation stated that influenza vaccine claims now lead in claims submitted to the VICP.

Due to the presence of the 2009/2010 H1N1 component in this season's trivalent formulation, NVIC maintains that there is a need to thoroughly and accurately evaluate data pertaining on the 2010/2011 influenza vaccine similar to the increased safety monitoring and evaluation of the 2009/2010 H1N1 pandemic vaccine with the formation by NVAC of the VSRAWG.

- Lastly, NVAC's efforts during Charge 1 on public engagement were notable, as were the efforts put forth by the CDC during the pandemic influenza preparedness exercise in 2009. Given the scope of Charge 2 in reviewing the entire federal vaccine safety system, and in the interest of government transparency and public participation in government, NVIC encourages broader public engagement in this very important process and the announcement of the public engagement schedule as soon as possible to ensure adequate public notice and participation.

Again, we thank the committee for the opportunity to offer public comment.