Public Comment by Theresa Wrangham Executive Director, National Vaccine Information Center National Vaccine Advisory Committee June 3, 2010

My name is Theresa Wrangham and I am the Executive Director representing the National Vaccine Information Center (NVIC), a consumer advocacy organization founded in 1982 to prevent vaccine injuries and deaths through public education and protect the informed consent ethic. We thank the committee for the opportunity to comment again today.

NVIC was gratified to participate in the NVAC's landmark review and drafting of recommendations for the CDC ISO's draft research agenda known as Task 1, which identified many deficits in the ISO's draft vaccine safety research agenda. To date, the CDC's response to the NVAC addresses only a portion of the NVAC's vaccine safety research recommendations. NVIC supports and encourages the pending written response from the CDC address all NVAC recommendations to more fully meet the public's expectation of a robust vaccine safety research agenda.

We also take this opportunity to express our concern regarding H1N1 pandemic vaccine and seasonal flu vaccine. We applaud the recommendation made earlier this year the NVAC's H1N1safety working group's to evaluate potential vaccine injury signals from the H1N1pandemic vaccine. We note that during December's ACCV meeting, the DOJ stated that flu vaccine claims are the leading claim submitted to the VICP.

Our concern today is the fact that the H1N1 pandemic vaccine will be a component in this year's seasonal flu vaccine and the aggressive flu vaccination campaign underway. CSL, a manufacturer of the new seasonal flu vaccine, has recently removed their vaccine from the Australian market due to the many reports adverse vaccine reactions reported and that have caused many children to be hospitalized and triggered an investigation. Our own flu season fast approaches and these reactions are not limited to CSL vaccine. There is a need for preparedness to accurately evaluate data on the new seasonal flu vaccine that now includes the H1N1 pandemic component. NVIC would encourage the NVAC to consider the continuation of this group's work in an effort to monitor potential adverse events that may result in America in light of what we are now seeing in Australia and current uncertainty.

We hope that this Committee will take seriously the legitimate vaccine safety concerns of the public, many of which were also contained in Task 1 recommendations. Thank you again for the opportunity to comment today and the continued and varied opportunities NVIC has had recently and in the past to improve vaccine safety and informed consent.