My name is Theresa Wrangham and I am the Executive Director for the National Vaccine Information Center, the mission of which is to reduce vaccine injury and death through public education and to defend the informed consent ethic in vaccination practices. I appreciate the opportunity to comment today.

I would like to thank the Commissioners, DVIC and DOJ for the thoughtful discussion on GBS being added to the Vaccine Injury Table in relation to influenza vaccine. I believe comments made by Mr. Kraus in terms of the limitations of epidemiology and the trend observed in settlements made by the VICP for GBS from the influenza vaccine are key concepts that support this addition to the table. It is reassuring to note that no real objection to this addition should be read into no votes cast by Commissioners and that these no votes were more a commentary on the lack of time given to review addition request. Thank you for keeping generosity and compassion central to these discussions.

My other comments today focus on the need for a higher degree of transparency in reporting the activities of the federal Vaccine Injury Compensation Program.

Recent additions to the Data and Statistics adjudications report of doses of vaccine distributed against the number of petitions for compensation tells an incomplete story. This report does not include the number of vaccine reactions reported to VAERS for the same timeframe, or information regarding the fact that the majority of vaccine reactions go unreported. In addition, there is no mention of the likelihood that the lack of public awareness regarding the VICP impacts the number of claims submitted for compensation, though it was only a few years ago that the ACCV authorized an outreach project to raise public awareness. The absence of this contextual information appears to undercut the seriousness of vaccine injury and death, which is the relevant focus of the VICP and the Commission. This report would benefit from the inclusion of this information, as well as information regarding published and unpublished awards. We would ask that the Commission consider these reporting additions.

Additionally, NVIC again encourages the inclusion and/or combining of existing reports that would meaningfully communicate award amounts made for each vaccine with alleged injuries and outcomes by year. This information is communicated to the ACCV during the regular course of their meetings via various slides presented by the Department of Justice and Division of Vaccine Injury Compensation – all of which is done without violating individual privacy. In short, this information to a very great extent is already public, but requires that one sift through ACCV meeting documents. The public should not have sift through and compile their own report to understand the nature of compensations made by the VICP.

With regard to the revision of Vaccine Information Statements, NVIC notes that the law provides that VIS revisions must be done in collaboration with parent organizations. The March ACCV minutes do not reflect that discussion or the fact that NVIC was specifically mentioned in this context and requested to assist in these revisions. We request the record be corrected in this regard.

As the Commission reviews VIS revisions, we encourage the Commission to recommend the inclusion of information on the statute of limitations in an effort to decrease the number of claims dismissed for exceeding the statute of limitations. For each VIS under review, we would also encourage the inclusion of language regarding deficits in research on the vaccine risks as they apply to many of the most commonly reported reactions as noted by the IOM.

Information on whether or not a vaccine is covered by the VICP should be more explicit in each VIS. Current revisions under consideration appear to contain a blanket statement that “certain” vaccines are eligible for compensation. As many on the phone are aware today, vaccines can cause injuries that can financially ruin families. As consumers consider vaccination they must know in advance when they must bear that financial burden alone.

The inclusion of this information in the VIS revision process is in keeping with the authorizing legislation to provide information on the risks and benefits of vaccines to the consumer prior to vaccination.

In closing, we would like to thank the Commission for providing on the website a historical overview of the ACCV’s previous recommendations to the Secretary since their inception. It is notable that some of the recommendations from past Commissions are the same recommendations under consideration today. The public would benefit from additional information regarding which recommendations to date have been acted upon and which have not, as well as the number of times a recommendation has been requested. The website also contains only one response to date from the Secretary on ACCV recommendations and we would request that all responses be posted to the website.