

Submissions to IOM via email by Theresa Wrangham and by Sallie Bernard on 4/20/09.

THERESA'S

My name is Theresa Wrangham and I am the President of SafeMinds, one of many organizations with vaccine safety concerns.

Our concern is in part centered on public engagement and how is feedback integrated into this process. The lack of time to review feedback and convening of this meeting only one week after the feedback deadline appears to diminish the integration of main stakeholder concerns. Is this panel now final, or are concerns with regard to possible conflicts of interest and panel expansion under consideration?

Given the existing serious deficit in vaccine safety research there are also grave concerns regarding how recommendations from this committee will be made and interpreted. In the past with regard to plausibility, recommendations have been improperly perceived as reason to not conduct research. This misinterpretation contributes greatly to the ongoing rise of public distrust in vaccines. Appropriate response to inadequate evidence that promotes a safety first agenda would restore that trust and make available to the Vaccine Court appropriate data on which to make vaccine injury compensation decisions. As such, the IOM should refuse to accept HRSA's request to issue findings on questions for which inadequate evidence exists due to the government's failure to conduct the research to produce evidence. Rather, the committee should insist that the government undertake the research.

In terms of transparency, complete transparency, provision for broader public participation in all facets of the process, a balance of scientific views and expertise, and an absence of conflicts of interest on the committee is the expectation of our community, and aligned with the new administration's goal of open government. The deliberations of this panel should be open to the public and incorporate a process by which the public is meaningfully engaged and access given to all transcripts and presentations made to the panel.

SALLIE'S

Several public comments have asked about consumer participation and complete transparency across the entire IOM review process. The IOM staff or committee members have not responded to these points. Can the IOM staff or committee members please state your views on opening this review to full public participation, including:

1. scope and charge
2. final committee composition
3. open deliberation meetings (not just information gathering meetings)
4. comment on the draft final report
5. input on who is presenting to the committee and the type of science considered.

Also, can the HRSA representative please respond to the comment on why the IOM was asked to review AEFIs when the ACCV already has a set of guiding principles and a recommendation for a committee to review this topic?