



Statement by Dr. Harvey Fineberg, President of the Institute of Medicine of the National Academies, on the Immunization Safety Review Committee

Questions have been raised about the work and integrity of one of the committees of the Institute of Medicine (IOM) and its staff. The Immunization Safety Review Committee, which was convened in January 2001 and completed its work in 2004, continued a long history of work related to vaccine safety at the IOM. This document offers information about the established processes and policies of the National Academies that ensure the impartiality and integrity of all IOM studies.

The Immunization Safety Review Committee produced eight reports over the course of 3.5 years on vaccine safety-related topics. A list of the topics is available online at: <http://www.iom.edu/imsafety>. The IOM conducted this work at the request of the Centers for Disease Control and Prevention and the National Institutes of Health. The scope and sponsorship of the committee is, and has always been, a matter of public record. Other than publicly posing the scope of study to the committee and delineating the specific hypotheses to be explored, the sponsoring agencies had no relationship with the committee other than when invited to present scientific information to the committee, either in public sessions or in written submissions that were placed in a publicly available file.

The public sessions of this committee were attended by many scientists and the public. **Audiofiles and transcripts of the public sessions are posted on the IOM Web site.** Print material provided by the federal agencies or any other party are available through the National Academies' Public Access Records Office. Allegations that the Centers for Disease Control and Prevention had any control over the committee's findings are false.

The Immunization Safety Review Committee operated at all times in adherence with National Academies' policies to assure openness and scientific integrity, which are outlined in a brochure available online at: <http://www.nationalacademies.org/studyprocess>. **The members of the committee underwent a stringent review process that ensured all were free of financial conflicts of interest and were not biased for or against any vaccine safety hypothesis.** The general criteria by which this impartiality was assured has been a matter of public record and is discussed by the president of the IOM in the foreword of each of the eight reports issued by this committee.

Specifically, members of Immunization Safety Review Committee had no ties to vaccine manufacturers, had not made policy statements regarding vaccines; had not served as expert witnesses--paid or unpaid--in any vaccine-related litigation; and had not worked for nor received recent funding for research on vaccine safety from the agencies that sponsored the study. As is the case with all IOM projects, their service was entirely voluntary; they received no compensation.

As with all IOM projects, the Immunization Safety Review Committee operated under a scope of work that was requested by the sponsoring organization. The committee was asked to provide an assessment of the scientific and societal significance of specific vaccine safety hypotheses and make recommendations for appropriate public health responses. The scientific assessment included conclusions about whether there exists a cause-and-effect relationship between particular vaccines and certain serious health problems and about the plausibility of any biological means by which a vaccine might adversely affect health. The recommendations address the need for policy review, research and surveillance, and communication.

The charge to the committee was discussed at length in a **public session in January 2001** prior to the start of its review of the extensive body of research related to its first report on vaccine safety. The committee continued its discussions of its charge and its work plans in a closed session. The discussions during this closed session focused on the committee members' efforts to make sure that they fully understood their charge and reached agreement on the best way to conduct their study. Part of the discussions focused on the concerns, interests, and stakes held by various parties, including both CDC and parents. Some individuals have taken words and phrases from a transcript of this closed session out of context, combined these fragments, and misrepresented them as direct quotes designed to suggest that committee members had biases.

It has also been suggested that the committee reached its conclusions about thimerosal's possible associations with autism based on just a few scientific papers. On the contrary, IOM committees review all relevant literature, data, and other information when conducting their studies. The Immunization Safety Review Committee reviewed vast amounts of information for each of its eight reports and deliberated thoroughly and independently before issuing each report. More than 215 references are cited in the **2004 report on vaccines and autism**. The committee members' detailed analysis of the

strengths and weaknesses of the scientific papers they reviewed is included in their report, which is a public document available to anyone who wishes to read it.

The value of IOM studies is that they provide evidence-based guidance. IOM committee members can state only conclusions and recommendations that are supported by evidence. This is illustrated by the conclusions of the Immunization Safety Review Committee's **2001 report on thimerosal and neurodevelopmental disorders** and its **2004 report on vaccines and autism**.

In 2001, the little evidence that was available provided only weak and inconclusive information about an association between thimerosal and neurodevelopmental disorders, including autism. Because the committee could say only what the evidence enabled them to deduce--not what any individual or organization wished that they could conjecture from it--the committee concluded that the evidence was insufficient to either accept or reject an association between thimerosal and neurological disorders.

When the committee looked at the topic of thimerosal and autism in 2004, data from a number of studies was then available. The committee members had much more evidence to consider. Their finding that the evidence favored rejection of an association between thimerosal and autism was based on the totality of the available evidence.

Every report written by IOM committees must go through an extensive peer-review process and committees must respond to any questions and comments raised about their work before any report is approved for publication. Since the Immunization Safety Review Committee's reports have been published, their findings and conclusions have not been challenged or questioned by any major medical or public health association.

The Institute of Medicine and the National Academies have full confidence that the Immunization Safety Review Committee operated independently, impartially, and in accordance with the highest scientific standards.