

**F. Edward Yazbak, MD, FAAP
TL Autism Research
70 Viewcrest Drive
Falmouth, Massachusetts 02540
Tel (508) 540 5060 Fax (508) 457 9814**

**Harvey V. Fineberg, MD, PhD
President
Institute of Medicine
500 Fifth Street NW
Washington DC 20001**

May 11, 2005

Dear President Fineberg,

I respectfully request that you

- **Withdraw the report of the Immunization Safety Review Committee Meeting 9 of February 9, 2004**
- **Form a new committee under a new chairman all of whom should be impartial experts independent of influence of Government and pharmaceutical companies.**
- **Reconvene a meeting on vaccines and autism as soon as possible and ensure that all independent research is considered.**

I base my request on the enclosed information.

You and only you, Dr. Fineberg can reverse the damage that has been done to thousands of children and their families by the unfortunate, biased and scientifically flawed report of the committee.

Respectfully,

F. Edward Yazbak, MD

**cc: Julie L. Gerberding, MD, MPH
Congressman Dave Weldon, MD
Congressman Daniel Burton**

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Withdraw the Report

- **The Institute of Medicine should withdraw the report of the February 9, 2004 Immunization Safety Review Committee Meeting 9: Vaccines and Autism**
- **A new Immunization Safety Review Committee should be formed under new chairmanship**
- **A meeting of the committee should be convened as soon as possible**

Background Information

A. IOM Committee conclusions are based on research and information that justify one of the following classifications:

1. No evidence bearing on a causal relation.
2. The evidence is inadequate to accept or reject a causal relation.
3. The evidence favors rejection of a causal relation.
4. The evidence favors acceptance of a causal relation.
5. The evidence establishes a causal relation.

B. Between school years 2002-03 and 2003-04, the number of children with autism and ASD attending school in the United States increased by 18.18% for age 6-21 from 118,603 to 140,922 and by 19.5% for age 3-5 from 19,017 to 22,724. (1-4)

C. HHS, CDC and AAP have conceded in 2004 that 1 in 166 children in the United States are diagnosed with an autism spectrum disorder. (5)

D. On January 15, 2004, Congressman Weldon wrote to CDC Director Dr. Julie L. Gerberding (6): "I am writing to ask that you post-pone the February 9, 2004, Institute of Medicine (IOM) Immunization Safety Review Committee meeting. Pressing forward with this meeting at this time, I believe, will further undermine the credibility of the Centers for Disease Control (CDC) on matters of vaccine safety and do damage to the reputation of the IOM. I believe the proposed date of this meeting, which you have the ability to change, is in the best interests of no one who is seeking the truth about a possible association between vaccines and neurodevelopmental disorders, including autism... Additionally, I am concerned that the agenda set forth in the meeting is inadequate and incomplete. With respect to the MMR/autism concerns, the IOM is dedicating one hour. Two witnesses are woefully inadequate to update the committee on the research to date. The time set aside for a discussion of epidemiology relating to

thimerosal and autism is heavily biased against those who have raised these concerns and will not allow for a fair and balanced discussion of the literature. The time set aside for a discussion of the biological mechanisms of thimerosal and autism is inadequate to allow a full discussion of the issue. To consider two issues of such significance in only seven hours does not serve the public interest. To the outside observer it does not appear to be a serious effort to examine these critical issues. Any conclusions drawn from this meeting, including any report issued, will be viewed as suspect given the very limited time dedicated to examining very incomplete information.”

Dr. Gerberding responded that she had shared Dr. Weldon’s concerns with IOM President, Dr. Harvey V. Fineberg but that the meeting will be held as planned. She wrote: “My own view is that it is extremely important to have the IOM conduct an objective review of emerging data when it has a bearing on vaccine safety as quickly as possible. In addition, the process should be ongoing at regular intervals, to keep up with this science of vaccine safety as new information becomes available. We intend to renew our agreement with the IOM to ensure continuation of the safety review process.” (7)

The Immunization Safety Review Committee meeting of February 9, 2004

At the meeting (8, 9), Dr. Weldon who spoke first remarked: “This atmosphere of intimidation even surrounds today's hearing. I received numerous complaints that this event is not a further attempt to get at the facts but rather a desire to sweep these issues under the rug. I have the utmost respect for the Institute and the Academy nonetheless I shared these concerns with Dr. Gerberding. Last week she called me to assure me that this is not the case. She informed me that she wants to meet with me and some of the parents, clinicians, and researchers to work with them to get the proper answers.”

The Congressman was followed by Mady Hornig MD, Mark R. Geier, M.D., Ph.D., H. Vasken Aposhian, Ph.D., David Baskin, M.D., Boyd Haley, Ph.D., Jeff Bradstreet, M.D., FAAFP and Vijendra K. Singh, Ph.D. who presented research supporting a vaccine-autism connection. Dr. Andrew Wakefield was not invited.

The Report

The report of the meeting was released in May 2004.

The following is from the May 18, 2004 press release (10) “MMR Vaccine and Thimerosal-Containing Vaccines Are Not Associated With Autism, IOM Report Says” in the National Academies News: “Based on a thorough review of clinical and epidemiological studies, neither the mercury-based vaccine preservative thimerosal nor the measles-mumps-rubella (MMR) vaccine are associated with autism, says a new report from the Institute of Medicine of the National Academies. Furthermore, the hypotheses regarding how the MMR vaccine and thimerosal could trigger autism lack supporting evidence and are theoretical only. Further research to find the cause of autism should be directed toward other lines of inquiry that are supported by current knowledge and evidence and offer more promise for providing an answer.”

In other words, according to the committee, both MMR-autism and Thimerosal-autism research should be abandoned, because they are based on unsupported hypothetical theories, and any future autism research should be directed elsewhere and never again to the MMR/Thimerosal and autism connection.

In the press release, Marie McCormick MD, Chair of the Committee was quoted as saying: "The overwhelming evidence from several well-designed studies indicates that childhood vaccines are not associated with autism." In an interview, Dr. McCormick also claimed that "The weight of that evidence is pretty substantial"(11)

In a similar situation in 2001, Dr. McCormick stated "It [MMR] is as safe as a vaccine can get" when the Immunization Safety Review Committee "did not exclude the possibility that MMR vaccine could contribute to ASD in a small number of children". Her comments then prompted Walter O. Spitzer, MD, Emeritus Professor of Epidemiology at McGill University to write: "As an epidemiologist who has been a Member of the IOM since 1986 ... I am embarrassed by the process of this latest Report and would urge President Shine of the IOM to retract the Report until the message has been clarified. What was released, the IOM Report or the McCormick Position?" (12)

On May 29, 2004, Dr. Weldon criticized the conclusions of the February 9 meeting and the fact that they were not based on biological evidence but mostly on epidemiological studies by Verstreten, Hviid, Madsen, Stehr-Green and Miller. He then went on to enumerate the multiple limitations and deficiencies of each of the five studies. (13)

A year later, it is evident that Dr. Weldon was correct and that Dr McCormick's "overwhelming evidence" and "well-designed studies" have crumbled. In addition, the findings of the Madsen MMR study were challenged (14-15) and several other epidemiological studies exonerating Thimerosal and the MMR vaccine were effectively neutralized shortly after they were published.

Meanwhile, extensive biological research has taken place. The animal studies by Hornig (16) have been supported by those of Burbacher (17) and other solid and reliable thimerosal studies have been published (18-28).

Wakefield's research has been widely duplicated and many more children with autism have been found to have evidence of measles virus genomic RNA in the blood and cerebrospinal fluid (29, 30) with elevated levels of myelin basic protein autoantibodies.

A significant number of children have exhibited two autistic regressions: one after their initial MMR vaccination and the second after their MMR booster following a period of relative improvement. This Challenge-Dechallenge-Rechallenge was accepted by the IOM as evidence of causation in 1991 in a case of recurrent hemolytic anemia following DPT vaccinations. It was also discussed in detail in a subsequent IOM report in 1994 entitled "Adverse Events Associated with Childhood Vaccines. Evidence Bearing on Causality."

Considering all of the above, the available evidence does not favor rejection of a causal relation between Thimerosal or MMR and autism spectrum disorders.

Official Request

I respectfully request that President Harvey V. Fineberg, MD, PhD:

- Withdraw the report of the Immunization Safety Review Committee Meeting 9 of February 9, 2004
- Form a new committee under a new chairman all of whom should be impartial experts independent of influence of Government and pharmaceutical companies.
- Reconvene a meeting on vaccines and autism as soon as possible and ensure that all independent research is considered.

By supporting this request, Director Gerberding can prove that she really meant to work with parents, clinicians, and researchers to get the proper answers.

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