Special Order by U.S. Rep. Dave Weldon, M.D.
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(Beginning page H4564)

SafeMinds Note – original document is 11 pages and has been condensed verbatim as relevant to the 2004 Institute of Medicine (IOM) Immunization Safety Review: Vaccines and Autism report flaws and conflicts of interest for brevity and reader's ease of use. Blue notations are SafeMinds format changes only with verbatim testimony intact and page number location in original document. The document in its entirety may be found at http://weldon.house.gov/UploadedFiles/RepWeldonMDonIOM.pdf.

AUTISM

At the outset of my remarks, I want to make it extremely clear that I support vaccinations. I have a six-year-old son, and he has received all of his vaccinations. Someone in the media recently tried to portray me as a vaccine skeptic. After reviewing my record on this issue and all of my statements in the past, the newspaper printed a retraction. This, however, seems to be part of the pattern, to vilify those who simply ask if our vaccines could be made safer. (Page 2)

Now, this recent Institute of Medicine report, what exactly is wrong with it? What about it has so many people in the autism community upset? In my 10 years of service in the U.S. Congress, I have never seen a report so badly miss the mark. I have heard some weak arguments here in Washington, D.C., and I can tell my colleagues that the arguments put forward in this IOM report are indeed very weak. (Page 3)

The Institute of Medicine bases their decision almost entirely on five epidemiologic studies. Epidemiology is essentially the statistical analysis of disease in populations. All of the studies had significant shortcomings, all of which the IOM itself declares would miss the association with autism in a genetically acceptable subset of children. (Page 3)

In 2001 the Institute of Medicine concludes: ``Exposure to Thimerosal-containing vaccines could be associated with neurodevelopmental disorders.'' The IOM (2001) also recommended that children not be given mercury-containing vaccines. (Page 4)

By narrowing the scope (in the IOM 2004 report), which largely went unnoticed by the media, the CDC has avoided acknowledging that Thimerosal very well may have caused neurodevelopmental disorders in some children. (Page 4)

FLAWS IN STUDIES USED IN 2004 IOM

COMMON TO ALL STUDIES (Page 4)

- The principal authors of all five of these studies have serious conflicts of interest.
- All were conducted while the CDC and the NIH virtually ignored the Institute of Medicine's 2001 biological and clinical research recommendations.
- It is critical to note the instructions that the IOM was given, primarily by the CDC, which has been funding the IOM… …Unlike 2001, this time the IOM was directed by the CDC to only consider the possible relationship between Thimerosal and autism rather than neurodevelopmental disorders as a whole.

The Verstraeten Study – United States (Page 5 & 6)

- this study did not compare children who got Thimerosal to those who did not.
- The study states ``We found no consistent significant associations between Thimerosal-containing vaccines and neurodevelopmental outcomes.''
- January 2004, the lead coauthor was forced to admit that many children in the study were too young to have received an autism diagnosis. He went on to admit that the study also likely mislabeled young autistic children as having other disabilities, thus masking the number of children with autism.

The Verstraeten Study – United States (Page 5 & 6, cont.)

- Dr. Thomas Verstraeten broke his silence in a letter to Pediatrics (April 2004) stating, ``The bottom line is and has always been the same, an association between Thimerosal and neurological outcomes could neither be confirmed nor refuted and therefore more study is required,''
- The IOM also noted that the study was limited in its ability to answer whether Thimerosal in vaccines causes autism because the study tests a dose response gradient, not exposure versus no exposure.
- Verstraeten study cannot be validated. The earlier data sets have been destroyed, and the only data sets the CDC will make available to outside researchers are the ones they have already manipulated.

2003 Hviid study of the Danish (Page 6)

- conflict of interest of the principal author. Dr. Hviid works for the Danish Epidemiology Science Center, which is housed at the Staten Serum Institute, the government-owned Danish vaccine manufacturer.
- all of his coauthors either work with him (Dr. Hvidd) at the center or are employed by the SSI.
- The SSI, the Staten Serum Institute, makes a considerable profit off the sales of vaccine and vaccine components and the U.S. is a major market for the SSI.
- SSI has $120 million in annual revenue, and vaccines are the fastest-growing business segment, accounting for 80 percent of its profits.
- Both the United States and the United Kingdom are important export markets for SSI's vaccines and vaccine components.
- if Hviid were to find an association between Thimerosal and autism, SSI, with which he and his center are affiliated, would then face significant lawsuits.
- this study looked at autism and not at neurodevelopmental disorders.
- Danish children received 75 micrograms of mercury in their first 9 weeks of life and then another 50 micrograms at 10 months. By comparison, children in the United States received 187.5 micrograms of mercury by the age of 6 months, nearly 2 1/2 times as much mercury as the Danish population.
- Hviid states that the rate of autism went up after they began removing Thimerosal from vaccines in 1992. The numbers in Hviid's study were skewed in that they began to add outpatient autism diagnoses after 1992.

Madsen et al., (Page 7)

- examined virtually the same population - Danish children.
- two of Madsen's co-authors are employed by the same Staten Serum Institute.
- like Hviid, added outpatient cases into the number of cases of autism after 1995, a methodological flaw. The authors acknowledged that this addition might have exaggerated the incidence of autism after the removal of autism. The IOM acknowledged this but yet used the data anyway.

Stehr-Green (Page 7)

- examined, the Danish population again, along with the Swedish population.
- with regard to Sweden it is important to note that the children there received even less thimerosal than children in Denmark, receiving only 75 micrograms by 2 years of age versus children in the United States receiving 187.5 micrograms by 6 months of age.
- the authors included only inpatient autism diagnoses in the Swedish population.
- The IOM notes that the ecological nature of this data ``limits the study's contribution to causality,'' but they cite it anyway.

Miller – United Kingdom (Page 7)

- …Dr. Miller has actively campaigned against those who have raised questions about vaccine safety. We have a person here who is actively campaigning, testifying in lawsuits, against the theory that thimerosal is linked to neurodevelopmental disorders and autism, doing a study supposedly showing there is no link.

WELDON CONCLUSIONS – PAGES 7 & 8

- IOM is on very shaky ground in drawing the conclusion that it did.
- They based their decision on these five studies, three of them examining genetically homogenous children in Denmark.
- At least one employee of the Staten Serum Institute serves as a co-author on three of the studies.
- Only one study examines the U.S. population, and that study did not compare children who had received mercury with those who had not.
- Four of them are studies of children receiving less than half the amount of mercury that U.S. children received.
- None of them with any ascertainment of prenatal or postnatal background mercury exposures,
- none of them considering prenatal exposure which may have been given to the children,
- none of them have been able to detect a susceptible subgroup in the population,
- three of them failing to address how the addition of outpatient cases of autism in Denmark might have previously skewed their results.
- Four of them examined populations with autism rates considerably less than the United States,

This report (IOM 2004) has dragged the Institute of Medicine under a cloud of controversy that has currently engulfed the CDC. Much like the infamous 1989 study by the National Institute of Child and Human Development which missed the link between folic acid deficiencies and neural tube defects like spina bifida, the epidemiologic studies reviewed by the IOM in drawing these findings could easily have missed an association in susceptible populations. (Page 9)

Other Conflicts of Interest by Weldon in closing remarks (Pages 10 & 11)

- The NIH does not have a concerted effort to fund vaccine safety research. They provide funding for research in a haphazard manner.
- The NIH has funded only a handful of studies over the past 2 years investigating vaccine safety issues.
- The CDC's vaccine safety program amounts to a $30 million,a year program, and half of it goes to pay HMOs for access to the Vaccine Safety Database.
- The biggest conflict within the CDC is that they are also responsible for a $1 billion vaccine promotion program. The CDC largely measures its success by high vaccination rates, and here lies the conflict. Any study raising concerns that there might be adverse reactions to some vaccines in some children has the ability to lower vaccine rates, and lower vaccination rates are in direct conflict with the CDC's top measurement of success.
- Further complicating the CDC's role in undermining the research is the fact that the vaccine safety studies produced by the CDC are impossible to reproduce. External researchers are not granted the same level of access to the raw data sets that the CDC's internal researchers are granted. The bottom line is that the CDC studies related to vaccine safety cannot be validated by external researchers, a critical component in demonstrating the validity of scientific findings.
- The NIH recently recognized the importance of moving patient safety monitoring out of the NIH. I believe the same should be done with vaccine monitoring. It should be completely removed from CDC's jurisdiction. The CDC is too conflicted to oversee this function.
- …the Brighton Collaboration, which began in the year 2000. This is an international group comprised of public health officials from the CDC, Europe, and world health agencies like WHO and vaccine manufacturers. The first task of the Brighton Collaboration, created several years ago, was to define what constitutes an adverse reaction to a vaccine. Particularly troubling to me is the fact that serving on these panels defining what constitutes an adverse reaction to a vaccine are the vaccine manufacturers. What is even worse is the fact that some of these committees are chaired by vaccine manufacturers. It is inappropriate for a manufacturer of vaccines to be put in the position of determining what is and what is not an adverse reaction to its product. This collaboration is fraught with pitfalls, and merges regulators and the regulated into an indistinguishable group.