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## Thimerosal and Autism Spectrum Disorders: Alleged Misconduct by Government Agencies and Private Entities

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United States Senate  
Michael B. Enzi, Ranking Member  
COMMITTEE ON HEALTH, EDUCATION, LABOR AND PENSIONS

*“Thimerosal and Autism Spectrum Disorders:  
Alleged Misconduct by Government Agencies and Private  
Entities”*

**EXECUTIVE SUMMARY OF THE  
REPORT OF THE RANKING MEMBER  
ON  
ALLEGED MISCONDUCT BY GOVERNMENT AGENCIES AND  
PRIVATE ENTITIES RELATED TO THIMEROSAL IN  
CHILDHOOD VACCINES**



September 2007

# Introduction<sup>1</sup>

Beginning in 2005, the U.S. Senate Committee on Health, Education, Labor and Pensions (HELP Committee or Committee) conducted an 18-month investigation into allegations of misconduct on the part of individuals and U.S. government officials related to the use of the preservative thimerosal in childhood vaccines and its possible contribution to an increase in rates of autism. Over the course of the investigation, the Ranking Member's staff interviewed more than 80 individuals and examined tens of thousands of pages of documents, totaling thousands of hours of staff time. The Ranking Member's staff took care to speak with a number of parents of children with autism about their concerns and their experiences, as well as individuals from the scientific community.

In 2006, the HELP Committee passed S. 843, the Combating Autism Act, followed by passage in the full Senate and House of Representatives. The Congress passed S. 843 at the conclusion of the 109<sup>th</sup> Congress. It was signed into law on December 19, 2006 (P.L. 109-416). The bill amends the Public Health Service Act to authorize \$945 million dollars over five years for the Department of Health and Human Services (HHS) to help combat autism through research, screening, intervention and education. This legislation is an important step in isolating the causes of autism and developing new treatments for those with autism.

The Ranking Member recognizes there are active scientific debates regarding a possible causal connection between thimerosal in childhood vaccines and autism. **However, Congress is not in a position to substitute its judgment for that of scientists. Therefore, this report does not render an opinion on the safety of thimerosal in vaccines. Rather, the investigation assessed allegations of misconduct by government officials and private entities in connection with the thimerosal controversy.**

This report serves as a summary of the Ranking Member's staff efforts to address the allegations brought to its attention by family members of children who have autism spectrum disorders, as well as by medical researchers who are active in the autism community. The allegations and the Ranking Member's findings on each are discussed below. The Ranking Member will continue to monitor developments on this issue; however, the Ranking Member is closing this investigation.

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<sup>1</sup> The full report, including names of witnesses interviewed, documents obtained and reviewed, and investigative methodology, is on file with the Committee and will not be released publicly. This summary report is intended to describe the allegations and findings without violating the confidentiality of witnesses or divulging proprietary information. Although all investigative work was conducted while Senator Enzi served as Chairman of the Committee during 2005 and 2006, the report will refer to him as the Ranking Member based on his status on the date of issuance.

## ***Background***

In 1943, Dr. Leo Kanner of Baltimore, Maryland, published his first paper on the disorder described as autism. A year later in Germany, Dr. Hans Asperger published his first papers on a similar disorder. Early records tabbed the children with the disorders as “emotionally disturbed” or “mentally disabled.” The symptoms for their findings were identified as detachment from the world, little or no speech, and an inability to achieve normal relationships with others. Later studies revealed that some diagnosed children showed increased speech over others. Their disease was classified as Asperger’s Syndrome, while the participants in Kanner’s studies results were diagnosed as autistic. Autism is classified under the umbrella category of Pervasive Developmental Disorders (PDD). This class of disorders has in common the following characteristics: impairments in social interaction, imaginative activity, verbal and nonverbal communication skills, and a limited number of interests and activities that tend to be repetitive.<sup>2</sup>

The cause of autism remains a mystery while, reportedly, the number of children diagnosed with autism continues to rise. The cause of the increase in diagnoses may be attributable to changes in classifications of the disorder, according to the Centers for Disease Control (CDC).<sup>3</sup> According to a January 2005 Government Accountability Office report, “...this substantial increase may be due to a number of factors, including better diagnoses and a broader definition of autism.” It further indicated that many of the children now being counted in the category of individuals with autism most likely would have been counted in other categories, such as individuals with learning disabilities, had they been diagnosed ten years ago.

Controversy surrounds the past use of thimerosal, a mercury-containing compound<sup>4</sup>, in childhood vaccines and a possible link between thimerosal and autism spectrum disorders. In 1999, thimerosal was voluntarily removed from childhood vaccines distributed in the United States, as a precaution.<sup>5</sup> Presently, according to the Food and Drug Administration (FDA), “all vaccines recommended for children six years of age and younger have contained either no thimerosal or only trace amounts, with the exception of inactivated influenza vaccines, which are marketed in both the preservative-free and

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<sup>2</sup> Pervasive Developmental Disorders, Fact sheet 50, 1998, published by the National Dissemination Center for Children with Disabilities. Available at <http://www.nichcy.org/pubs/factshe/fs20txt.htm>.

<sup>3</sup> Information from the CDC available at [http://www.cdc.gov/ncbddd/autism/asd\\_common.htm](http://www.cdc.gov/ncbddd/autism/asd_common.htm).

<sup>4</sup> Mercury occurs naturally in a variety of forms, but the most common form is methyl mercury. Methyl mercury is well documented as causing significant toxic damage to the body. Thimerosal, however, contains ethyl mercury. The effects of ethyl mercury are less well known, but nonetheless controversial. Some experts and others believe that thimerosal in vaccines given to children, no matter which type of mercury, causes severe neurological damage and possibly autism spectrum disorders. Other experts and individuals see ethyl mercury as less damaging and do not identify it as a possible cause for disorders such as autism. Recent research on isolating genes that may relate to autism was completed at Vanderbilt University and published in the October 2006 issue of *Proceedings of the National Academy of Sciences*.

<sup>5</sup> The removal of thimerosal was prompted by a joint request from the American Academy of Pediatrics (AAP) and HHS, United States Public Health Service (USPHS) to vaccine manufacturers for a clear commitment and a plan to eliminate or reduce as expeditiously as possible the mercury content of their vaccines. *Joint Statement of the American Academy of Pediatrics (AAP) and the United States Public Health Service (USPHS)*, PEDIATRICS Vol. 104 No.3 September 1999.

thimerosal-preservative-containing formulations. In addition, all of the routinely recommended vaccines distributed in the United States that had been previously manufactured with thimerosal as a preservative...had reached the end of their shelf life by January 2003.”<sup>6</sup>

Thimerosal, a preservative, was used in multi-dose vials of vaccines to prevent bacterial and fungal growth in storage. Dating back to the 1930’s, it was the trade name of Merthiolate developed by pharmaceutical company Eli Lilly and used primarily as an over-the-counter skin antiseptic. Once thimerosal was voluntarily removed from most childhood vaccines in the U.S., speculation grew that there should be a corollary drop in autism rates when the vaccines became free of thimerosal. However, autism rates continue to climb, with the CDC estimating that that as many as 3-6 per 1,000 children have autism spectrum disorders.<sup>7</sup>

Autism has been called a national epidemic by the media, medical science and many active in the autism community. Without doubt, autism has an unfathomable impact on the lives it touches. Experts believe that the United States and the entire world community have yet to experience the full effect of autism on our lives and our infrastructures. The societal costs, both emotional and financial, are significant.

### ***Review of Allegations***

The following allegations were derived from various presentations and discussions with parents of children with autism and their representative experts.

**Allegation # 1:** The work of the Institute of Medicine’s (IoM) Safety Review Committee is compromised by Centers for Disease Control (CDC) influence and conflicts of interest.

The HELP Committee received numerous allegations concerning the work of the IoM in evaluating the potential link between vaccines and various neurological disorders, including autism. These allegations include: that the CDC interfered with the work of the IoM’s ISR Committee; that individuals involved with the construction of the ISR Committee’s reports may themselves have had demonstrable conflicts of interest; and that the ISR Committee based its conclusions on studies that had demonstrable conflicts of interest.

**Allegation # 1a:** The Centers for Disease Control (CDC) interfered with the 2001 and 2004 Institute of Medicine (IoM) studies on vaccine safety.

**Finding: The allegation is not substantiated.** While it has been alleged that the CDC interfered with the conduct of the ISR Committee there is no evidence that any interference took place.

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<sup>6</sup> Information from the FDA website, available at <http://www.fda.gov/cber/vaccine/thimfaq.htm>.

<sup>7</sup> Information from the CDC website available at <http://www.cdc.gov/programs/bd02.htm>.

An extensive investigation by the HELP Committee, which included a subpoena for thousands of documents from the National Academies of Science and the Institute of Medicine, identified concerns regarding the IoM's process for screening potential committee members for possible conflicts of interest. However the allegation that the work of the ISR is compromised by CDC influence and conflicts of interest proved without merit.

To evaluate this allegation the HELP Committee reviewed hundreds of pages of transcripts and memoranda and interviewed officials at the IoM, CDC and NIH to compile a record of the interaction between the CDC and the ISR Committee. Also, while Chairman, Senator Enzi sent a letter to Dr. Gerberding, Director of the CDC, asking for written clarification of and documentation relating to the relationship between the CDC and the IoM's ISR Committee. The record compiled by the HELP Committee indicates that the CDC did not constrain the discussions of the ISR Committee or limit the ISR Committee's access to studies and/or data. The investigation found that:

- There is no evidence of CDC involvement with the work of the ISR Committee that contravenes any standard operating procedure or standard practice for government-commissioned IoM work.
- The meeting transcript reflects at times there was active debate between the CDC presenters and ISR Committee members.<sup>8</sup>
- While CDC was often a presenter at the ISR Committee meetings, others with an opposing view, such as Dr. Andrew Wakefield on March 8, 2001, were afforded the opportunity to deliver presentations on their findings before the ISR Committee; Dr. Bradstreet gave a presentation to the ISR Committee on July 16, 2001 and February 9, 2004; Dr. Mark Geier gave a presentation to the ISR Committee on February 9, 2004; and on February 9, 2004, the Association of Autistic Spectrum Disorder and MMR presented information to the ISR Committee.

**Allegation # 1b:** There were conflicts of interest among the members of the Immunization Safety Review Committee (ISR Committee) and the studies they relied upon.

**Finding: The allegation is partially substantiated.** While we identified shortcomings in IoM procedures for screening potential committee members for possible conflicts of interest, there is no evidence to support the allegation that the work of the IoM's ISR Committee was compromised by conflicts of interest. To evaluate this allegation the committee reviewed thousands of pages of documents relating to the background of the ISR Committee members and the IoM process for screening potential committee members for possible conflicts of interest.

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<sup>8</sup> For example: January 11, 2001 Transcript, pages 182 and 190.

A number of irregularities in the IoM screening process were identified. The irregularities include:

- Inconsistent exclusionary criteria.
- No verification of self-reported data.
- Inadequate documenting of the screening process.
- Inadequate screening of committee consultants for potential conflicts of interest.

While these shortcomings in the screening process call for corrective measures, there is no evidence to support the allegation that the work of the IoM's ISR Committee was compromised by conflicts of interest.

**Allegation 1c:** The five studies that the Immunization Safety Review Committee (ISR Committee) based its findings upon have conflicts of interest with Centers for Disease Control (CDC) and vaccine manufacturers.

**The allegation is not substantiated:** To evaluate this allegation, the Committee reviewed the sources of funding behind five studies published by Verstraeten et al. 2003; Madsen et al. 2003; Stehr-Green et al. 2003; Hviid et al. 2003; and Miller et al. 2004. Also, the Committee reviewed hundreds of references cited for the three reports issued by the ISR Committee that most closely dealt with the alleged connection between vaccines and autism: Measles-Mumps-Rubella Vaccine and Autism (April 2001); Thimerosal – Containing Vaccines and Neurodevelopmental Disorders (October 2001); and Vaccines and Autism (May 2004).

The IoM did not base its findings on these five studies, but rather on an assessment of hundreds of publications and hours of presentations from stakeholders, government officials and researchers. This included over 200 publications and seven articles by Dr. Mark Geier, two by Dr. Bradstreet, three by Dr. Wakefield, and the Simpsonwood Conference transcript. While the five studies in question may have varying connections to the CDC and/or vaccine manufacturers, their value to consideration of an alleged link between vaccines and autism is a matter for the experts of the ISR Committee, and not for Congress.

**Allegation # 2:** The Centers for Disease Control (CDC) convened the Simpsonwood Conference to cover up the finding that thimerosal causes autism.

**Findings: The allegation is not substantiated.** The CDC organized a discussion regarding Vaccine Safety Datalink (VSD) information on June 7 and 8, 2000 at the Simpsonwood Retreat Center in Norcross, Georgia. Approximately sixty persons, two-thirds of whom were not CDC employees, participated in the discussion. The subject matter of the discussion was whether VSD data showed that thimerosal causes autism.

The CDC's failure to invite to Simpsonwood representatives of advocacy groups, in combination with injudicious remarks by several Simpsonwood participants, did give rise to an appearance of impropriety. Allegations of a cover-up are not substantiated, however. Instead of hiding the data or restricting access to it, CDC distributed it, often to individuals who had never seen it before, and solicited outside opinion regarding how to interpret it. The transcript of these discussions was made available to the public. The data was also discussed at the Advisory Committee on Immunization Practices, a public forum held on June 21 and 22, 2000. Simpsonwood participants generally agreed that the VSD data set was weak, it was difficult to assess causality, and further study and investigation were warranted.

**Allegation # 3:** Dr. Thomas Verstraeten, MD, MSc, was pressured into changing his research position regarding a causal link between thimerosal and autism.

**Finding: The allegation is not substantiated.** Dr. Verstraeten worked on a temporary work visa with the CDC and conducted a study on the safety of thimerosal. The first phase of this study came to the attention of the public and was discussed at the Simpsonwood Conference in June 2000. Dr. Verstraeten publicly stated that he planned the original study on thimerosal and autism and the subsequent follow-up study. Dr. Verstraeten said the push to urgently perform the follow up study came entirely from him because he felt that the first-phase results were too prone to potential biases to be the basis for important health decisions.<sup>9</sup>

HELP Committee staff interviewed Dr. Verstraeten with regard to his findings and his participation in the Simpsonwood Conference. Review of the phases of Dr. Verstraeten's study, "Safety of Thimerosal-Containing Vaccines: A Two-Phased Study of Computerized Health Maintenance Organization Databases," and examination of his voluntary response to Committee questions during his interview reflect that his intention was always to conduct a two-phase study.

Furthermore, there is no evidence that GlaxoSmithKline hired Dr. Verstraeten for the purpose of pressuring him to manipulate his data on a causal link between thimerosal and autism. Both Dr. Verstraeten and his employer, GlaxoSmithKline, explained the circumstances of his employment. Dr. Verstraeten was working in the United States at CDC on a temporary visa. Near the completion of his tenure with CDC, he began searching for employment in his native country and found employment with GlaxoSmithKline where he continues to be employed.

**Allegation # 4:** The Centers for Disease Control (CDC) effectively made the Vaccine Safety Datalink (VSD) non-public contrary to its statement that the link would be accessible to the public.

**Finding: The allegation is not substantiated.** During the course of the investigation, the HELP Committee staff reviewed numerous documents, interviewed employees of the HHS, CDC, National Center for Health Statistics (NCHS) and conducted a site visit of

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<sup>9</sup> Letter to the Editor, Thomas Verstraeten, MD, MSc, available at <http://pediatrics.aappublications.org/cgi/content/full/113/4/932>, and June 13, 2006 interview of Dr. Verstraeten.



the Research Data Center (RDC) lab to meet with agency officials and operators of the lab. Documents provided by the RDC establish that the CDC created a data sharing program in 2002 making the VSD data available to external researchers in an environment that strove to ensure the privacy and confidentiality of the data maintained.

The NCHS, located in Hyattsville, Maryland, does allow researchers meeting certain qualifications, and under strict supervision, to access confidential statistical micro data files. To qualify, researchers must submit a proposal for review and approval. Researchers can use one of three access methods: (1) Direct on-site access; (2) a remote program submission system through which researchers can submit work to be done in the RDC with the output returned to them by email; or (3) programming services for outside researchers provided by RDC staff.<sup>10</sup> The NCHS endeavors to protect the confidentiality of the data and utilizes necessary steps and measures to ensure that confidentiality.

The IoM did however, review the VSD in 2005 and made the following recommendations: (1) “that a subcommittee of NVAC [National Vaccine Advisory Committee] that includes representatives of a wide variety of stakeholders (such as advocacy groups, vaccine manufactures, FDA, and CDC) review and provide advice to the NIP [National Immunization Program] on the VSD research plan annually. The subcommittee charged with this role could be the existing Subcommittee on Safety and Communications or a subcommittee created specifically for that purpose”; and (2) “that an independent review committee with minimal and balanced biases and conflicts of interest be created to:

- Review independent external researchers’ proposals to use VSD data through the data sharing program.
- Review research proposals from internal researchers and provide oversight of changes in or deviations from research protocols for internal VSD data.
- Provide advice on when and how preliminary findings based on VSD data should be made public.”<sup>11</sup>

The CDC response to the first recommendation was that “there is currently an NVAC Vaccine Subcommittee...[and]...to ensure broad stakeholder participation in a review of the VSD research plan, CDC could be invited to present its proposed immunization safety research for the following year to the NVAC Subcommittee on Safety, supplemented by a group of technical safety experts...and other interested stakeholders. The review would be in the format of a “forum” or “town hall” meeting. The subcommittee would present the outcome of the meeting to NVAC for consideration and deliberation with the potential to offer further additions or modifications for the Department to consider.”

The CDC response to the second recommendation was that the recommendation “cannot be implemented at this time because the authorities and resources are not currently

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<sup>10</sup> CDC, NCHS, Procedure and Costs for Use of the Research Data Center, revised November 7, 2005

<sup>11</sup>IoM Report, Vaccine Safety Research Data Access and Public Trust, 2005.

available.”<sup>12</sup> Citing the recommended approach as labor and resource intensive, the CDC agreed to continue using previously successful *ad hoc* external peer reviews. The CDC also questioned, in its response, why other vaccine safety studies outside the VSD portfolio would not benefit from external peer review.

The allegation that the CDC made the VSD non-public is not substantiated by information gathered by the Committee. The allegation that CDC intentionally made the VSD data inaccessible is also not substantiated, however, the construct of the database for privacy purposes makes access less than open and accessible to all researchers.

**Allegation # 5:** International organizations were established to obscure knowledge about the safety of thimerosal in childhood vaccines.

**Findings: The allegation is not substantiated.** It was alleged that there was an influx of international organizations created in 1999 in response to an MMR vaccine scare to quell fears that additives in the MMR vaccine may lead to behavioral disorders, including autism, in children. HELP Committee staff examined the following international organizations in response to the allegation:

- 1) Global Alliance for Vaccines and Immunizations (**GAVI**)
- 2) Global Advisory Committee on Vaccine Safety (**GACVS**)
- 3) Initiative for Vaccine Research’s (**IVR**) – Global Vaccine Research Forum (**GVRF**)
- 4) Strategic Advisory Group of Experts (**SAGE**)
- 5) Immunization Safety Priority Project (**ISPP**)
- 6) World Health Organization Steering Committee on Immunization Safety
- 7) Sabin Vaccine Institute (**SVI**)
- 8) International Vaccine Institute (**IVI**)
- 9) National Partnership for Immunization (**NPI**)
- 10) NPI National Immunization Council
- 11) Institute for Vaccine Safety at Johns Hopkins Bloomberg School of Public Health (**IVS**)
- 12) Vaccine Education Center
- 13) Aeras Global TB Vaccine Foundation (formerly the Sequella Global Tuberculosis Foundation)
- 14) Bill Gates Foundation
- 15) Brighton Collaboration (**BC**)

In examining the international organizations, the following aspects of the 15 organizations were considered: the mission statement and purpose; the past and present board of directors or governing body; the year of origin; the position on thimerosal; the initial creators or fundraisers; and the reason for establishment.

HELP Committee staff found that only 5% of the individuals listed as members or former members on the governing bodies of the international organizations were listed on one or

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<sup>12</sup> CDC Responses to recommendations made in the Institute of Medicine report, *Vaccine Safety Research, Data Access, and Public Trust* (February 2005).

more boards. Specifically, there were only 17 of 313 board or governing body members who served on more than one governing body during the past seven years.

In response to the allegation that an influx of international organizations were formed in 1999, HELP Committee staff found that only six of the 15 organizations were formed in 1999; one was formed in 1969; one in 1993; one in 1996; two in 1997; and four in 2000. Additionally, it was found that the reason the majority of the organizations were established was to advocate for access to safe and effective vaccination as a method of disease prevention, especially in impoverished countries. The mission of most did not address the use of thimerosal.

In light of these factual findings, there is insubstantial evidence to conclude that these organizations reflect a coordinated effort to obscure knowledge about the safety of thimerosal in vaccines. Further, the organizations provide scientifically-based information on the safety of vaccines to the public as well as help improve public access to vaccines.

**Allegation # 6:** Thimerosal remains in childhood vaccines being supplied to third-world and developing countries.

**Findings: The allegation is substantiated.** The contention that thimerosal is used in vaccines provided to third-world and developing countries is accurate. According to the CDC, NIP, the vaccination of children in much of the world will continue to require the use of multiple-dose vials for reason of cost, production, and storage capacity.<sup>13</sup> The less expensive multiple-dose vials require the presence of a preservative. If developing countries were unable to buy the less expensive multiple-dose vials containing thimerosal, diseases would spread more rapidly. The position of the IoM is that: “given the lack of direct evidence for a biological mechanism and the fact that all well designed epidemiological studies provide no evidence of association between thimerosal and autism, it recommends that cost benefit assessments regarding the use of thimerosal-containing versus thimerosal-free vaccines, whether in the U.S. or other countries, should not include autism as a potential risk.”<sup>14</sup>

**Allegation #7:** FDA inappropriately utilized Environmental Protection Agency (EPA) guidelines regarding the dangers of mercury in vaccines containing thimerosal.

**Findings: The allegation is substantiated.** In the spring of 1998, staff within the FDA’s Center for Biologics Evaluation and Research (CBER) began to informally consider the increased number of recommended vaccines and the amount of substances, such as mercury, contained in them to which vaccine recipients were exposed. Section 413(a) of the Food and Drug Administration Modernization Act required the FDA to

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<sup>13</sup> CDC, NIP, Joint Statement Concerning Removal of Thimerosal from Vaccines available at [http://www.cdc.gov/nip/vacsafe/concerns/thimerosal/joint\\_statement\\_00.htm](http://www.cdc.gov/nip/vacsafe/concerns/thimerosal/joint_statement_00.htm)

<sup>14</sup> IoM Report, Immunization Safety Review: Vaccines and Autism, 2004.

compile a list of drugs and food that contain “intentionally introduced” mercury compounds within two years of enactment.<sup>15</sup>

Available literature to help quantify the FDA’s concern was limited.<sup>16</sup> The risk assessment that followed evaluated the potential for exposure to thimerosal and the amount of mercury by weight present in the vaccines. Because no guidelines existed for ethyl mercury exposures, the FDA used the guidelines for safe exposure to methyl mercury, formulated by EPA, as a guide for determining whether the dose from thimerosal in vaccines approached levels of concern.<sup>17</sup> In July 1999, HHS agencies, the American Academy of Pediatrics (AAP), and vaccine manufacturers agreed that thimerosal should be reduced or eliminated in infant and childhood vaccines as a precautionary measure and to reduce human exposure to mercury from all sources.

The use of inappropriate guidelines from EPA was a source of confusion and contention in determining the appropriate response to concern regarding thimerosal in vaccines. Nevertheless, the existing methyl mercury guidelines were the best information available at the time for assessing risk from ethyl mercury exposure.<sup>18</sup> This error has caused countless individuals to conclude that ethyl mercury can be linked causally to autism.

## ***CONCLUSION***

In summary, the Ranking Member investigated allegations of misconduct in connection with the finding by public health authorities that thimerosal does not cause autism. Two allegations were substantiated, one allegation was partially substantiated, and four allegations were not substantiated.

The Ranking Member substantiated two allegations:

- Thimerosal does remain in childhood vaccines shipped to developing countries.
- The EPA mercury guidelines were an inappropriate basis for evaluating mercury in vaccines.

The Ranking Member partially substantiated shortcomings in the IoM’s conflict screening procedures, but did not find evidence that any conflicts improperly influenced the IoM’s findings. Further with regard to the IoM findings, the Ranking Member did find the following:

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<sup>15</sup> *Pediatrics*, The Process of Public Policy Formulation: The Case of Thimerosal in Vaccines, Freed, et.al. Vol. 109 No. 6 June 2002, pp. 1153-1159

<sup>16</sup> *Pediatrics*, The Process of Public Policy Formulation: The Case of Thimerosal in Vaccines, Freed, et.al. Vol. 109 No. 6 June 2002, pp. 1153-1159

<sup>17</sup> *Pediatrics*, The Process of Public Policy Formulation: The Case of Thimerosal in Vaccines, Freed, et.al. Vol. 109 No. 6 June 2002, pp. 1153-1159

<sup>18</sup> From the October 5, 2004 testimony of Anthony S. Fauci, M.D., Director, National Institute of Allergy and Infectious Diseases, NIH available at [http://www3.niaid.nih.gov/about/directors/congress/2004/10052004\\_testimony.htm](http://www3.niaid.nih.gov/about/directors/congress/2004/10052004_testimony.htm)

- CDC did not interfere with the 2001 and 2004 IoM vaccine safety studies.
- The ISR Committee did not rely on five studies that were manipulated by CDC and vaccine manufacturers.

Following an exhaustive investigation, four other allegations of misconduct proved unsubstantiated:

- The CDC did not convene the Simpsonwood Conference to cover up findings of causality.
- Dr. Thomas Verstraeten was not pressured into changing his findings.
- The CDC did not hide the Vaccine Safety Datalink from the public.
- There was no organized plan to establish numerous international public health organizations in order to cover up the truth about a causal link between childhood vaccines and autism.

The Ranking Member did not attempt independently to answer the scientific question of whether thimerosal, in fact, causes autism. The answer to this question continues to be controversial, and is the subject of continuing litigation. Because this question has not been answered to the satisfaction of the American people, Congress passed the Combating Autism Act (P.L. 109-416), which funds nearly a billion dollars in further research, screening, intervention and education.

Great strides are being made in understanding the etiology of autism and other childhood neurological disorders. The National Institute of Neurological Disorders and Stroke, the National Institute of Mental Health (NIMH), and the National Institute of Child Health and Human Development are leading an ambitious research effort to better understand the causes of autism and options for treatment. A recent report to Congress from the NIMH<sup>19</sup> outlined that across HHS, significant resources have been devoted to the cause of better understanding autism. These efforts include a network of 129 researchers at 23 universities, working with more than 2,200 families to conduct research on the possible genetic, immunological, neurobiological, and environmental causes of autism in addition to a National Institute of Environmental Health Sciences and EPA collaboration to research the possible environmental aspects of autism. The Ranking Member of the HELP Committee will continue to support these efforts and will continue to monitor the progress that is being made in addressing this important public health concern.

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<sup>19</sup> Pages 1 – 5 of the report, available at <http://www.nimh.nih.gov/autismiacc/autismreport2005.pdf>.