Editorial

Mercury in vaccines: institutional malfeasance and The Department of Health and Human Services

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Abstract

A historical perspective of the use of Thimerosal, which contains ethylmercury, in vaccines is presented. Despite the availability of evidence that mercurial compounds are toxic, public health institutions have ignored the evidence dating from the 1930s and have instead authorized acceptance of Thimerosal as a so-called "preservative." Removal of Thimerosal from several childhood vaccines in the United States was not accomplished until after the turn of the century. In its report on Thimerosal, the Institute of Medicine in 2001 commented: "The presence of mercury in some vaccines can raise doubts about the entire system of ensuring vaccine safety, and late recognition of the potential risk of Thimerosal in vaccines may contribute to a perception among some that careful attention to vaccine components has been lacking."

The CDC has a responsibility to protect the health of the American public. If there were any doubts about the neurological effects of ethylmercury in vaccines on children – and there were substantial doubts – the prevailing consideration should have been how best to protect children from potential harm. However, it appears that protecting the industry's profits took precedence over protecting children from mercury damage.

Keywords: Thimerosal, ethylmercury

In 1991, Seal et al. [1] published in the Lancet, "Thimerosal is a weak antibacterial agent that is rapidly broken down to products, including ethylmercury residues, which are neurotoxic. Its role as a preservative in vaccines has been questioned, and the pharmaceutical industry considers its use as historical." Despite such strong indictments against Thimerosal, the Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) continue to allow many vaccines that contain Thimerosal to be administered to children and adults, and most recently, Thimerosal-containing influenza vaccine has been added to the required routinely administered childhood immunization schedule [2].

Evidence of ethylmercury's toxicity has been available to Federal regulators and the private sector almost since the product's inception. For far too long, both neglected this evidence. Despite evidence dating to the 1930s that ethylmercury in medicines was potentially hazardous, little was done to remove it from a number of products until the 1980s. Even then, regulatory actions to remove Thimerosal and other mercury compounds from medical products proceeded at a glacial pace. The decision to remove Thimerosal was not finalized until 1998. The removal of Thimerosal from several childhood vaccines in the United States was not accomplished until after the turn of the century [3].

For decades ethylmercury was used as a preservative or antibacterial agent in a range of products, including antiseptic ointment for treating cuts, nasal sprays, eye solutions, diaper rash treatments, and perhaps most importantly, vaccines. Several years after an FDA advisory committee found that Thimerosal was not safe for use in topical ointments, new vaccines containing Thimerosal were still being approved and added to the recommended schedule. It appears that nobody analyzed the potential impact of mercury to which young children were being exposed. In fact, if Congress had not enacted legislation in 1997 requiring the FDA to study the amounts of mercury being used in FDA-approved products, it is questionable that the FDA would have analyzed the mercury in vaccines [3].

It is no wonder that, in its report on Thimerosal, the Institute of Medicine in 2001 commented: "The presence of mercury in some vaccines can raise doubts about the entire system of ensuring vaccine safety, and late recognition of the potential risk of Thimerosal in vaccines may contribute to a perception among some that careful attention to vaccine components has been lacking [4]."

It is clear that the guiding principal for FDA policy makers has been to avoid shaking the public's confidence in the safety of vaccines. For this reason, many FDA officials have stubbornly denied that Thimerosal may cause adverse reactions. Ironically, the FDA's unwillingness to address this more forcefully, and remove Thimerosal from vaccines earlier, may have done more long-term damage to the public's trust in vaccines than confronting the problem head-on. Given the serious concerns about the safety of Thimerosal, the FDA should have acted years earlier to remove this preservative from vaccines and other medicines [5].

Eli Lilly and Company of Indianapolis licensed Thimerosal in 1930. It was marketed under the brand name 'Merthiolate.' It was used extensively both in topical ointments to prevent infections and as a preservative in a variety of medicines. Eli Lilly was not the only manufacturer of Thimerosal or other ethyl-

doi: 10.1588/medver.2004.01.00033

mercury products. In fact, they phased-out their production of Thimerosal in 1974 [5].

In 1974, the FDA undertook a comprehensive review of the safety and effectiveness of over-the-counter (OTC) medicines. As one facet of this review, a panel of experts was assembled to review the safety and efficacy of OTC drugs containing mercury. The Advisory Review Panel on OTC Miscellaneous External Drug Products began its review in 1975. In 1980, the panel delivered its report to the FDA. It reviewed 18 products containing mercury and found them all either unsafe or ineffective for their stated purpose of killing bacteria to prevent infections. In terms of effectiveness, the panel stated, "mercury compounds as a class are of dubious value for anti-microbial use." They also stated, "mercury inhibits the growth of bacteria, but does not act swiftly to kill them." In fact, the panel cited a 1935 study of the effectiveness of Thimerosal in killing staphylococcus bacteria on chick heart tissue. The study determined that Thimerosal was 35-times more toxic to the heart tissue it was meant to protect than the bacteria it was meant to kill. In terms of safety, the panel cited a number of studies demonstrating the highly allergenic nature of Thimerosal and related organic mercury products. For instance, they cited a Swedish study that showed that 10 percent of school children, 16 percent of military recruits, and 18 percent of twins, and 26 percent of medical students had hypersensitivity to Thimerosal. They stated that while organic mercury compounds like Thimerosal were initially developed to decreased the toxicity of the mercury ion, Thimerosal was actually found to be more toxic than bi-chloride of mercury for certain human cells. By way of summary, they stated, "The Panel concludes that Thimerosal is not safe for OTC topical use because of its potential for cell damage if applied to broken skin, and its allergy potential. It is not effective as a topical antimicrobial because its bacteriostatic action can be reversed [5]."

The FDA's action on this matter was already clearly out-of-step with studies that had been conducted dating back to the 1930s showing that Thimerosal preserved vaccines (serums) were extremely toxic.

Pittman-Moore Company had conducted a study in 1935 demonstrating that Merthiolate was not appropriate for use in dogs: "We have obtained marked local reaction in about 50% of the dogs injected with serum containing dilutions of Merthiolate, varying in 1 in 40,000 to 1 in 5,000, and we have demonstrated conclusively that there is no connection between the lot of serum and the reaction. In other words, Merthiolate is unsatisfactory as a preservative for serum intended for use on dogs. Occasionally dogs do not show the local reaction, but in some instances, the reaction is extremely severe. I might say that we have tested Merthiolate on humans and find that it gives a more marked local reaction than does phenol or tricresol [5]."

Warkany and Huber reported in 1953: "In several children of our series and in some recently reported, various immunization procedures preceded the onset of acrodynia in addition to mercurial exposure… It is noteworthy that many vaccines and sera contain small amounts of mercury as preservatives which are injected together with the biologic material. These small amounts of mercurial compounds, which enter the body unnoticed, could act as sensitizing substances. This fact should be kept in mind in the analysis of future cases of acrodynia [6]."

Nelson and Gottshall from the Division of Biologic Products, Bureaus of Laboratories, Michigan Department of Public Health published in 1967, "Pertussis vaccines preserved with 0.01% Merthiolate are more toxic for mice than unpreserved vaccines prepared from the same parent concentrate and containing the same number of organisms… An increase in mortality was observed when Merthiolate was injected separately, before or after an unpreserved saline suspension of pertussis vaccine [7]." Heyworth and Truelove stated in 1979, "For many years, Merthiolate was known to have anti-microbial activity. When it was first introduced as an anti-microbial preservative, little information about the fundamental biological effects of organic mercury compounds was available. We should like to suggest that Merthiolate should now be regarded as an inappropriate preservative for anti-lymphocytic globulin preparations and other materials which are intended for administration to human subjects [8]."

In addition to evidence showing that vaccines containing Thimerosal could cause problems, a number of studies were conducted showing that Thimerosal/ethylmercury were toxic in animals and humans. Tryphonas and Nielsen conducted a study supported by the Medical Research Council of Canada to evaluate chronic low-dose exposure to ethylmercury and methylmercury compounds in young swine. The authors determined: "The resulting toxicosis was primarily related to the nervous system, in which neuronal necrosis followed by secondary gliosis, capillary endothelial proliferation, and additional neuronal necrosis due to developing degenerative arteriopathy in the blood vessels supplying injured gray matter were seen. In other systems, degeneration of hepatocytes and renal tubular cells were commonly occurring lesions in pigs given both MMD [methylmercury-containing compound] and EMC [ethylmercury-containing compound]… The results proved that the alkyl mercurial compounds MMD and EMC, if fed at low concentrations for long periods, were highly poisonous to swine [9]."

Fagan et al. in a study funded by the National Institute of Environmental Health Sciences reported that between 1969 and 1975 there were 13 cases of exomphalos treated by Thimerosal. The authors determined that 10 of the patients had died, and their tissues were analyzed for mercury content. The results showed that Thimerosal can induce blood and organ levels of organic mercury which are well in excess of the minimum toxic levels in adults and fetuses. The authors concluded, "Although Thimerosal is an ethyl mercury compound, it has similar toxicological properties to methyl mercury and the long-term neurological sequelae produced by the ingestion of either methyl or ethyl mercury-based fungicides are indistinguishable [10]." The authors also concluded that the fact that mercury readily penetrates intact membranes and is highly toxic seems to have been forgotten, and that equally effective and far less toxic broad-spectrum antifungal and antibacterial antiseptics are currently available [10].

Despite the fact that the FDA expert committee found that Thimerosal and other ethylmercury compounds were unsafe and ineffective for OTC products, the FDA would not formally require the removal of mercury from some of these products for

doi: 10.1588/medver.2004.01.00033

another 18 years. The submission of the committee's report in 1980 set in motion a tortuous bureaucratic process that would not result in the banning of mercury from OTC products until 1998. The agency published Advanced Notice of Proposed Rules or Notice of Proposed Rules regarding these products in 1980, 1982, 1990, 1991, 1994 and 1995. What makes the glacial pace of these proceedings all the more mystifying is that there appears to have been no opposition to this action throughout the process. No individuals sought to appear before the advisory committee in defense of mercury-containing products, and when the FDA sought public comment along the way on proposed rules to ban certain mercury-based products, it received none. At the time of the FDA's final action, there were 20 OTC products containing mercury being marketed by eight different manufacturers. Their silence on this point is telling [5].

It is difficult to understand why it took the FDA 18 years to remove mercury from OTC products. It is equally difficult to understand why the expert panel's 1980 findings on Thimerosal's safety in topical ointments did not prompt the FDA to further and immediately review the use of Thimerosal in vaccines. Surely there must have been concern that if it was not safe to apply ethylmercury to the surface of an individual's skin, it might not be safe to inject ethylmercury deep into an infant's tissue. The Director of the FDA's National Center expressed such a concern at a 1999 meeting for Toxicological Research. Dr. Bernard Schwetz, who went on to serve as the Acting Director of the FDA for nearly a year, stated: "One thing I haven't heard discussed, the fact that we know that ethylmercury is a skin sensitizer when it's put on the skin, and now we're injecting this IM [intramuscularly] at a time when the immune system is just developing, the functionality of the immune system is just being set at this age. So now we're injecting a sensitizer several times. During that period of time, what's the impact of a sensitizer – of something that is known to be a skin sensitizer, what is the effect on the functional development of the immune system when you give a chemical of that kind repeatedly IM [5]?"

Different branches of the FDA regulate OTC products and vaccines. OTCs are regulated by the Center for Drug Evaluation and Research (CDER). Vaccines are regulated by the Center for Biologics Evaluation and Research (CBER). This, however, is little justification for the lack of coordination. The FDA's determination that mercury was unsafe and should be removed from OTC medications was published in the Federal Register no fewer than five times prior to the FDA's belated review of mercury in vaccines [5].

Despite the FDA's outright negligence concerning the dangers posed by Thimerosal as preservative in vaccines, during the 1980s and 1990s many authors published studies demonstrating the toxicity of Thimerosal, calling for vaccines with a safer preservative and also showing that Thimerosal at the concentrations present in vaccines was ineffective as a preservative to prevent bacterial contamination. Forstrom et al. published in 1980, "…reactions can be expected in such a high percentage of merthiolate-sensitive persons that merthiolate in vaccines should be replaced by another antibacterial agent [11]." In 1983, Kravchenko et al. published, "Thus Thimerosal, commonly used as a preservative, has been found not only to render its primary toxic effect, but also is capable of changing the properties of cells. This fact suggests that the use of Thimerosal for the preservation of medical biological preparations, especially those intended for children, is inadmissible [12]." Winship reported, "Multi-dose vaccines and allergy-testing extracts contain a mercurial preservative, usually 0.01% Thimerosal, and may present problems occasionally in practice. It is, therefore, now accepted that multi-dose injection preparations are undesirable and that preservatives should not be present in unit-dose preparations [13]." Cox and Forsyth recommended in 1988, "However, severe reactions to Thimerosal demonstrate a need for vaccines with an alternative preservative [14]." In 1991, Seal et al. recommended the removal of Thimerosal from vaccines [1]. Also, in August of 1998, an FDA internal "Point Paper" was prepared for the Maternal Immunization Working Group. This document recommended, "For investigational vaccines indicated for maternal immunization, the use of single dose vials should be required to avoid the need of preservative in multi-dose vials… Of concern here is the potential neurotoxic effect of mercury especially when considering cumulative doses of this component in early infancy [5]."

Additionally, Stetler et al. [one of the co-authors is Dr. Walter Orenstein who was later to become Director of the National Immunization Program (NIP), CDC] from the CDC evaluated the use of Thimerosal as a preservative in vaccines in 1985. The authors determined, "Laboratory experiments in this investigation have shown up to 2 weeks' survival of at least one strain of group A Streptococcus in multidose DTP [Diphtheria-Tetanus-Pertussis] vials. The manufacturer's preservative effectiveness tests showed that at 4ºC, 4.5% of the challenge Streptococcus survived 14 days after inoculation into a multi-dose DTP vaccine vial. At currently used concentrations, Thimerosal is not an ideal preservative." The authors also warn that, "However, because Thimerosal is an organic mercurial compound, higher concentrations might reduce vaccine potency or pose a health hazard to recipients." The authors also make the following calculations and recommendations regarding the use of multi-dose vials with Thimerosal preservatives: "Single-unit packaging would approximately double the cost of DTP per dose. For example, one manufacturer charges $5.12 for a 15-dose vial of DTP vaccine or $0.34, per dose. If the $0.20 cost of a disposable syringe is added, the total cost per dose to the physician would be about $0.54. The same manufacturer charges $10.40 for a package of ten single DTP doses (needle and syringe pre-packed) or $1.04 per dose… Given the prices mentioned above and the fact that approximately 18 million doses of DTP are administered each year, the cost of switching to single-dose packing might be approximately $9 million. Neither research to develop a better preservative nor recommendations to consider single-dose packaging appear to be warranted… The Thimerosal preservative present in DTP vaccine requires substantial time to kill organisms and cannot be relied upon to prevent transmission of bacteria under conditions of practice when a vial is used over a short period. Instead, the most important means of preventing abscesses secondary to DTP vaccination is to prevent contamination by careful attention to sterile technique [15]."

What finally prompted the FDA to review mercury in vaccines was not its own regulatory process, but rather an act of

doi: 10.1588/medver.2004.01.00033

Congress. In 1997, Congress passed and the President signed into law, the Food and Drug Administration Modernization Act (FDAMA). Among other things, this law required the FDA to compile a list of foods and drugs that contained intentionally-introduced mercury, study its effects on the human body, and restrict its use if found to be harmful.

Once the FDA did initiate its review of mercury in vaccines, it kicked off a vigorous debate among Federal regulators over the dangers of using Thimerosal in childhood vaccines. This debate, which at times pitted one health-care bureaucracy against another, has spanned more than four years. Given the fact that almost twenty years had passed since an expert panel had determined that Thimerosal was unsafe in topical ointments, it is surprising that there was any further debate at all.

There was tremendous reluctance on the part of some officials to admit that a mistake had been made in allowing ethylmercury to be used in vaccines. However, the institutional resistance to change was counter-balanced by the growing realization that there was more ethylmercury in childhood vaccines than previously thought, and that nobody had thought to calculate the cumulative amounts. The essence of the debate was captured in a 1999 e-mail from a former FDA official weighing the pros and cons of taking action. He opined that hastening the removal of Thimerosal from vaccines would "…raise questions about FDA being 'asleep at the switch' for decades by allowing a potentially hazardous compound to remain in many childhood vaccines, and not forcing manufacturers to exclude it from new products. It will also raise questions about various advisory bodies regarding aggressive recommendations for use. (We must keep in mind that the dose of ethylmercury was not generated by 'rocket science'. Conversion of the percentage Thimerosal to actual micrograms involves ninth grade algebra. What took the FDA so long to do the calculations? Why didn't CDC and the advisory bodies do these calculations when they rapidly expanded the childhood immunization schedule?) [5]"

It is clear that each time an important decision had to be made, the factions that were skeptical of Thimerosal's dangers and favored a "go-slow" approach, were able to water down the actions. In 1999, when the Federal government could have ordered Thimerosal removed from vaccines by a specific date, or stated a preference for Thimerosal-free vaccines, a statement was instead issued asking for a commitment from vaccine manufacturers to eliminate or reduce mercury in vaccines as expeditiously as possible. As a result, almost two years passed before the three major Thimerosal-containing vaccines–DTaP, Haemphilous influenza Type b (Hib), and hepatitis B–were being manufactured in Thimerosal-free formulations. In 2001, when the CDC and its influential advisory committee could have stated a preference for Thimerosal-free vaccines, they chose not to do so. As a result, Thimerosal-containing vaccines that remained in stock in doctors' offices continued to be used. In point of fact we have no proof that in 2003, some children in the United States were still not receiving Thimerosal-preserved vaccines that have lingered in medical offices or clinics. The CDC's decision not to endorse Thimerosal-free vaccines in 2001 is particularly troubling. With the exception of the influenza vaccine, all major childhood vaccines were being manufactured without Thimerosal at that time, so there was little threat of shortages. Their failure to state a preference was an additional abdication of their responsibility [5].

The task of analyzing the amount of mercury in vaccines and its ramifications was assigned to Dr. Leslie Ball, and pediatrician employed at the FDA, and her husband and colleague Dr. Robert Ball, a medical office at FDA's CBER. The pair developed two working conclusions following their review: (1) The recommended guidelines for exposure to methylmercury were a good starting point for reviewing exposure to ethylmercury; and (2) the amount of ethylmercury in children's vaccines exceeded the EPA's guidelines for exposure to methylmercury. An exchange of e-mails in October of 1998 makes clear that Dr. Leslie Ball was already leaning toward the removal of Thimerosal from vaccines. It also makes clear that there was internal resistance to such an action. Dr. Marion Gruber of the Office of Vaccine Research and Review forwarded an internal memo to Dr. Ball, which concluded, "…no scientific data to take regulatory actions and to recommend to take Thimerosal either out of vaccines or to leave it in." Dr. Ball's response on October 15, 1998 was sharp, "I disagree about the conclusion regarding no basis for removal of Thimerosal… However, there are factors/data that would argue for the removal of Thimerosal, including data on methylmercury exposure in infants and the knowledge that Thimerosal is not an essential component to vaccines. In addition, the European community is moving to ban Thimerosal [5]."

An important part of the FDA's review was a comparison of the amount of ethylmercury in vaccines to the recommended safe levels for exposure to methylmercury established by the EPA and the FDA. In 1999 (June 28, 1999), a consultant to the FDA, Dr. Barry Rumack, developed a pharmacokinetic model to analyze the amount of mercury to which infants were being exposed. The charts developed by Dr. Barry Rumack demonstrated that most children in the 1990s received doses of ethylmercury in their vaccines that exceeded the EPA's limits for exposure to methylmercury (0.1 micrograms per kilogram per day) for at least the first six months of their lives. Even more significantly, the charts also indicated that most children received doses of ethylmercury that exceeded the FDA's less-restrictive limits (0.4 micrograms per kilogram per day) for at least the first two months of their lives. It is noteworthy that the charts produced by Dr. Rumack, and the FDA's analysis in general, failed to take into consideration background levels of mercury to which children were exposed from other sources. Dr. Ball pointed out this weakness in her June 1999 e-mail, "These calculations do not account for other sources of Hg [mercury] in the environment. Even infants can have additional exposures, e.g., breast milk." One document written by Dr. Ball estimated that exposure to mercury from other sources than vaccines could total roughly 80 to 100 micrograms per year. Background levels were included in all calculations prepared by the European Medical Evaluation Agency (EMEA), which was at the time reviewing Thimerosal in vaccines in Europe [5].

In mid-June of 1999, CBER's findings came to the attention of Dr. Neal Halsey, Director of the Johns Hopkins Institute for Vaccine Safety. Halsey is a pediatrician and highly respected vaccine expert. When he learned of the CBER findings, he was finishing up a four-year term as chairperson of the AAP Com-

doi: 10.1588/medver.2004.01.00033

mittee on Infectious Diseases, the committee that determines AAP vaccination policy and edits the Red Book. Long before he heard about the Thimerosal findings, Halsey had become worried about the progress of vaccination protest groups in the United States. In May, Congress had held a contentious hearing on the dangers of vaccination. Halsey feared that the tide was turning against childhood vaccination, with potentially dangerous consequences. Halsey confirmed CBER's calculations and did his own research on mercury, consulting with experts around the country. He became convinced that the findings were worthy of alarm, and he worried if they became public prematurely, vaccination protesters would use them to stage yet another attack on the nation's immunization programs. Halsey met with officials as CBER on June 22nd and then called Dr. Walter Orenstein, director of the CDC's NIP [16].

The next day, on June 23, 1999, Dr. Halsey wrote a letter to the members of the AAP's Committee on Infectious Diseases that stated, "In the past few days, I have become aware that the amount of Thimerosal in most hepatitis B, DTaP and Hib vaccines that we administer to infants results in a total dose of mercury that exceeds the maximum exposure recommended by the EPA, the FDA, CDC, and WHO… [5]"

The EMEA, which is responsible for establishing guidelines for the use of drugs and biologics in the European Union, issued a report on June 29, 1999, following an initial meeting in London on April 19, 1999 (Dr. Norman Baylor of the FDA attended this meeting), encouraging the removal of Thimerosal from childhood vaccines: "Vaccines: The fact that the target population for vaccines in primary immunization schedules is a health one, and in view of the demonstrated risks of Thimerosal and other mercurial-containing preservatives, precautionary measures (as outlined below) could be considered…For vaccination in infants and toddlers, the use of vaccines without Thimerosal and other mercurial preservatives should be encouraged [5]."

On June 30th, NIP staff flew to Washington to meet with FDA, AAP, and vaccine manufacturers. From the start Halsey and his colleagues at AAP, including the new chairperson of the Infectious Disease Committee, Dr. Jon Abramson, took a strong proactive stance. They argued that physicians should be told – soon – about the amount of mercury in vaccines and the conflict with a federal guideline. CDC was surprised by the urgent and undoubting position taken by Halsey and his colleagues at AAP. CDC officials argued that there was no need for precipitous actions. They were loath to undermine confidence in existing vaccines by labeling some vaccines "bad" (Thimerosal-containing) and "good" (Thimerosal-free). But, in further discussions through the first few days of July, it became clear that Halsey and AAP would not retreat - they believed that immediate action was needed [17].

In a July 2, 1999 e-mail, Dr. Ruth Etzel of the Department of Agriculture also noted the Public Health Service's resistance: "We must follow three basic rules: (1) act quickly to inform pediatricians that the products have more mercury than we realized; (2) be open with consumers about why we didn't catch this earlier; (3) show contrition. As you know, the Public Health Service informed us yesterday that they were planning to conduct business as usual, and would probably indicate no preference for either product. While the Public Health Service may think that their 'product' is immunizations, I think their 'product' is their recommendations. If the public loses faith in the Public Health Services recommendations, then the immunization battle will falter. To keep faith, we must be open and honest and move forward quickly to replace these products [5]."

Within AAP the issue ascended quickly from Halsey's committee to the executive board. AAP executives felt that their members needed more than just information about Thimerosal – they also needed a way to reduce mercury exposure in their tiny patients. They feared that pediatricians who continued to administer Thimerosal-containing vaccines could face a flurry of lawsuits, perhaps claiming that children had acquired learning disabilities from mercury exposure [17].

The discussion quickly veered toward pushing vaccine doses back from the first six months of life to a later time, when infants' bodies were larger and better able to tolerate mercury. Delaying vaccinations against DTP or Hib was not practical or could expose children to serious infections. It soon became evident that the delayed vaccine would have to be hepatitis B. Only two single-antigen pediatric hepatitis B vaccines exist on the United States' market. Energix-B (SmithKline Beecham) and Recombivax HB (Merck). Both contained Thimerosal and 12.5 micrograms of mercury per 0.5 ml dose. AAP pressed CDC to agree to a delay of the hepatitis B vaccination series, usually started at birth for children born to hepatitis surface antigen (HBsAg)-seronegative mothers. The Academy argued that the delay would only be temporary because both Merck and SmithKline Beecham had promised that they could quickly shift manufacturing to Thimerosal-free vaccine perhaps in just a few months. FDA had already promised to review applications for Thimerosal-free hepatitis B vaccine rapidly – within 30 days. At the CDC Hepatitis Branch in Atlanta, Dr. Harold Margolis, Chief of the Branch, and staff epidemiologist Eric Mast saw trouble. Margolis and Mast began working furiously to build a case against delaying hepatitis B vaccination [17].

Negotiations continued with AAP nearly around the clock. Everyone was becoming exhausted. AAP insisted on a six-month delay of hepatitis B vaccination of HBsAg-negative moms. CDC resisted. As the groups continued negotiations over days, worries increased that the story would leak to the press in an uncontrolled way, triggering a general vaccination scare. "Everyone worried that with the vaccination protest groups looking over our shoulders, if they got the sense that some [toxicological] standard was broken, all hell would break loose," said a senior official who worked on the issue. Finally, after a week of late night meetings involving the AAP executive board, Surgeon General Dr. David Satcher, CDC Director Dr. Jeffrey Koplan and other CDC officials, FDA, the manufacturers, and others, the exhausted group, struck a compromise. An AAP-USPHS joint statement was issued on July 7 at 4:15 PM [17].

Dr. Johns Clements, a physician from the World Health Organization (WHO) said at the NIH workshop regarding the United States' policy of removing Thimerosal from vaccines, "the U.S. has gone on its due process to identify a problem and correct it. But there is a knock-on effect which the world must bear as a consequence." Clements pointed out that only multi-dose, multi-puncture vials can be used in developing countries

doi: 10.1588/medver.2004.01.00033

because of cost and cold-chain considerations. Removing Thimerosal from these vials is not an option for WHO, at least for the next several years, he said. In an August interview, Dr. Halsey defended the Thimerosal decision-making process used by AAP and CDC. It would not have been possible to deal with Thimerosal in the usual public forums like Advisory Committee on Immunization Practices (ACIP), Halsey said, because the presence of vaccination protestors would have made rational discussion hopeless. Deliberations were handled in the only way possible he said. But Halsey acknowledged that many of his immunization colleagues are angry with him and miffed about the way the issue was handled [17].

The joint statement that was released on July 7, 1999 by the AAP and the USPHS included the following points: (1) acknowledged that some children may have been exposed to levels of mercury that exceed one Federal guideline on methylmercury during the first six months of life; (2) asserted there is no evidence of any harm caused by Thimerosal in vaccines; (3) called on vaccine manufacturers to make a clear commitment to reduce as expeditiously as possible the mercury content of their vaccines; (4) urged doctors and parents to immunize all children, even if Thimerosal-free vaccines were not available; and (5) encouraged doctors and parents to postpone the hepatitis B vaccine (which contained Thimerosal at the time, and was generally given immediately after birth) until the child was two to six months old, unless the mother tested positive for hepatitis B [5].

Given the information that the Federal agencies had at the time, the plan of action laid out in the joint statement was inadequate. They could have, but did not, acknowledge that the amount of Thimerosal vaccines exceeded every Federal Guideline for exposure to methylmercury for the majority of infants. They could have, but did not, require vaccine manufacturers to remove Thimerosal from vaccines by a specific date. They could have, but did not urge pediatricians to choose Thimerosal-free vaccines when both Thimerosal-containing and Thimerosal-free vaccines were available. As a result of the limited steps taken in 1999, vaccines containing Thimerosal remained on the market for nearly two years. GlaxoSmithKline's hepatitis B vaccine did not become Thimerosal-free until March of 2000, and Aventis Pasteur's DTaP vaccine did not become Thimerosal-free until March 2001. In addition, Thimerosal-containing vaccines on the shelves in doctors' offices around the country continued to be used in spite of the fact that Thimerosal-free versions were available [5].

The fact that more forceful action to remove Thimerosal from the vaccine marketplace was not taken in 1999 is disappointing. Just as disappointing, and even more difficult to understand, is the fact that the CDC on two separate occasions refused to publicly state a preference for Thimerosal-free vaccines.

In June of 2000, the CDC's Advisory Committee on Immunization Practice met in Atlanta. Among other things, the Advisory Committee was called upon to recommend whether the CDC should issue a public statement of preference for Thimerosal-free vaccines. At the time, the industry was in the midst of transition to Thimerosal-free childhood vaccines, and several vaccines containing Thimerosal were still on the market. Of particular concern was the DTaP vaccine. In June of 2000, three of the four DTaP manufacturers (Aventis Pasteur, North American, and Wyeth) were still producing DTaP with Thimerosal. Only SmithKline Beecham produced a Thimerosal- free DTaP. In addition, because manufacturers of the Hib and hepatitis B vaccines had just recently converted to formulas that were Thimerosal-free or contained trace amounts of Thimerosal, older versions of these vaccines containing Thimerosal were still in inventories and being used around the country. A statement of preference by the CDC would have been a clear signal to pediatricians not to use vaccines containing Thimerosal, when Thimerosal-free versions were available. This action would have substantially reduced the exposure to ethylmercury for many infants. Despite this knowledge the advisory committee voted unanimously not to state a preference [5].

CDC officials guided the Advisory Committee toward this conclusion. For example, while three different options were presented to the Advisory Committee members, a detailed policy statement to be issued to the public had been prepared for only one of these options - as statement of no preference. In describing the three options, Dr. Roger Bernier of the CDC clearly indicated the CDC's desire not to state a preference for Thimerosal-free vaccines. He said, "We believe that such a policy would be consistent with the evidence that we have at this time. This policy seems to be working… As I said the policy seems to be working. So this indicates that on this particular factor, this policy is moving us in an upward direction towards- it's a positive thing [5]."

In rejecting a statement for preference of Thimerosal-free vaccines, the Advisory Committee considered a number of factors. These included a desire to avoid confusion, and a concern that immunization rates might fall, allowing for an outbreak of diseases such as pertussis or hepatitis B. However, one of the factors that was also considered was the financial health of the vaccine industry. In describing the pros and cons of each option, Dr. Bernier returned several times to financial issues: "We think that having this type of a more staged transition reduces the potential for financial losses of existing inventories, and is somewhat akin to what was done in the transition form oral polio to inactivated polio. It could entail financial losses of inventory if current vaccine inventory is wasted. It could harm one or more manufacturers and may then decrease the number of suppliers. The evidence justifying this kind of abrupt policy change does not appear to exist, and it could entail financial losses for all existing stocks of vaccines that contain Thimerosal [5]."

The financial health of industry should never have been a factor in this decision. The financial health of vaccine manufacturers certainly should never have been more important to the Federal health officials than the health and well being of the nation's children. The CDC has a responsibility to protect the health of the American public. If there were any doubts about the neurological effects of ethylmercury in vaccines on children - and there were substantial doubts – the prevailing consideration should have been how best to protect children from potential harm. However, it appears that protecting the industry's profits took precedence over protecting children from mercury damage [5].

doi: 10.1588/medver.2004.01.00033

In opting not to state a preference for Thimerosal-free vaccines, the Advisory Committee shrugged off two sensible proposals that were presented during the meeting. A representative of SmithKline Beecham stated that her company could supply sufficient amounts of Thimerosal-free DTaP vaccine to ensure that the youngest infants receive Thimerosal-free doses, "I think it's important that you know that, although we cannot supply the entire U.S. market right now for all five doses immediately, we would be able to supply the vast majority of the U.S. market for the primary series, that is with targeting of the first three doses." Given the repeated concerns expressed about the effects of mercury on the developing central nervous system in very young babies, ensuring Thimerosal-free doses for the first three doses of DTaP would seem to merit serious consideration. However, this suggestion was passed over without any comment. Later in the discussion, Dr. Neal Halsey made another suggestion that would limit the exposure of infants to ethylmercury. He suggested that the Advisory Committee adopt a policy that no children should receive more than one Thimerosal-containing vaccine per day, "Roger you said that after July, the maximum exposure will be 75 micrograms. My understanding from the manufacturers is that there really is some Hib out there in the market that is being used that does contain Thimerosal as a preservative. There also is hepatitis B out there that does contain it. So there's no guarantee the maximum exposure would be 75 micrograms. What I proposed last October was that they put a limit of one Thimerosal-containing vaccine as a preservative per visit which would then guarantee what you're looking for. And I think that's the right policy because that allows for the continued use, though very limited. It eliminates the maximum exposure, but you do have the problems of what's in the pipeline." Again, it appears that this seemingly sensible proposal received no serious consideration [5].

In July 2000 the Government Reform Committee of the United States Congress held hearings on mercury. Congresswoman Helen Chenoweth-Hage (R-ID) eloquently expressed the view of many: "...I have a staffer who is in the Navy Reserve right now, but he used to be active with the airborne divisions, and he was in for a test in one of the medical military hospitals, and upon taking his temperature, they broke a thermometer, and mercury splattered across his glasses and some got in his eye. Well, the first thing they did was cutoff his clothes. The second thing was call in OSHA to clean up the mercury. And then they worked on him to make sure his eyes were irrigated, and you guys, you witnesses, absolutely amaze me. I wonder where the disconnect is, for Pete's sake. You listened to the testimony just as I did, and you are willing to, with a straight face, tell us that you are eventually going to phase this out after we know that a small baby's body is slammed with 62 times the amount of mercury that it is supposed to have, and OSHA reacts like they did in the case of this accident of this naval man. It doesn't make sense. No wonder people are losing faith in their government. And to have one of the witnesses tell us it is because mothers eat too much fish? Come on. We expect you to get real. We heard devastating testimony in this hearing today, and we heard it last April. And this is the kind of response we get from our government agencies? I am sorry. When I was a little girl, my daddy talked to me about something about a duck test. I would ask each one of you to read this very excellent work by Sallie Bernard and Albert Enayati, who testified here today. My daddy used to say if it walks like a duck and talks like a duck and sounds like a duck, for Pete's sake it is a duck. I recommend that you read this, side-by-side, page after page of analysis of the symptoms of people who are affected with mercury poisoning compared to autism, this is the duck test, and you folks are trying to tell us that you can't take this off the market when 8,000 children are going to be injected tomorrow; 80 children may be coming down, beginning tomorrow with autism? What if there was an E. coli scare? What if there was a problem with an automobile? Their recall would be like that. We are asking you to do more than analyze it. We are asking you to tell this body and the American people that it is more than inconclusive. It passes the duck test, and we need you to respond. We need that to come off the market now because you think that we are elevating the case today? Just wait until it gets in the courts. This case could dwarf the tobacco case. And we would expect you to do something now before that circus starts taking place. Denial is not proper right now. You know, I still go back to the fact–I still want to talk about the duck test, Mr. Egan [FDA], I will address this to you. You know, it was shown in the last panel that autistic symptoms emerge after vaccination. It was shown that vaccines contain toxic doses of mercury. It was shown that autism and mercury poisoning, the physiological comparison is striking. There is altered neurotransmitter activity, abnormal brain neuronal organization, immune system disturbance, EEG abnormalities. It goes on and on and on, the comparisons. That is why I say, I back up what the Chairman and the ranking members are all asking you, that we cannot wait until 2001 to have this pulled off. You know, if a jury were to look at this, the circumstantial evidence would be overwhelming. Let's do something before we see it in the courts [5]."

One year later, in June of 2001, the Advisory Committee again rejected the idea of expressing a preference for Thimerosal-free vaccines, despite the fact that all manufacturers of Hib, hepatitis B and DTaP had shifted to Thimerosal-free products at that point. The CDC's decision not to express a preference for Thimerosal-free vaccines, and the Advisory Committee's concurrence in this policy, was an abdication of their responsibility. As a result of their inaction, children continued to receive vaccinations containing ethylmercury at a time when there were serious doubts about its safety [46].

What makes the CDC's decision even more vexing is that just prior to the Advisory Committee meeting in 2000, a study conducted by the CDC suggested that there was at least a weak correlation between exposure to Thimerosal and several types of neurological disorders. The study initiated in 1999 reviewed the medical records of 110,000 children in the CDC's Vaccine Safety Datalink (VSD). The VSD is a massive database that tracks the medical records of hundreds of thousands of patients belonging to seven major health maintenance organizations. Phase I of the study was designed to screen data for potential associations between Thimerosal-containing vaccines and selected neurological disorders. Phase II was designed to test the hypotheses generated in the first phase. Phase I produced a statistically-significant association between exposure to Thimerosal during the first three months of life and tics, atten-

doi: 10.1588/medver.2004.01.00033

tion deficit disorder, language and speech delays, and general neurodevelopmental delays. The study did not find a correlation between Thimerosal and autism because the sample size of children diagnosed with autism was in all probability not large enough [5].

The findings of Dr. Verstraeten, the primary author of the study, set off a fierce debate within the Federal health agencies when they were internally released in June 2000. Enough concern was generated that a closed-private conference of medical experts was assembled at the Simpsonwood Retreat Center near Atlanta. Among those in attendance included representatives from CDC, FDA, Aventis Pasteur, Wyeth, Merck, SmithKline Beecham, and North American Vaccine. The following are some statements that were recorded as part of the official transcript, and illustrate the conspiratorial acts committed:

Dr. Bernier: Page 113: "We have asked you to keep this information confidential… So we are asking people who have done a great job protecting this information up until now, to continue to do that until the time of the ACIP meeting…That would help all of us to use the machinery that we have in place for considering these data and for arriving at policy recommendations."

Dr. Verstraeten: Page 31: "It is sort of interesting that when I first came to the CDC as a NIS officer a year ago only, I didn't really know what I wanted to do, but one of the things I knew I didn't want to do was studies that had to do with toxicology or environmental health. Because I thought it was too much confounding and it's very hard to prove anything in those studies. Now it turns out that other people also thought that this study was not the right thing to do, so what I will present to you is the study that nobody thought we should do."

Dr. Verstraeten: Page 40: "...we have found statistically significant relationships between the exposures and outcomes for these different exposures and outcomes. First, for two months of age, an unspecified developmental delay which has its own specific ICD-9 code. Exposure at three months of age–Tics. Exposure at six months of age–an attention deficit disorder. Exposure at one, three and six months of age–language and speech delays which are two separate ICD-9 codes. Exposure at one, three and six months of age–the entire category of neurodevelopmental delays, which includes all of these plus a number of other disorders."

Dr. Weil: Page 75: "I think that what you are saying is in term of chronic exposure. I think that the alternative scenario is that this is repeated acute exposures, and like many repeated acute exposures, if you consider a dose of 25 micrograms on one day, then you are above threshold. At least we think you are, and then you do that over and over to a series of neurons where the toxic effect may be the same set of neurons or the same set of neurologic processes; it is conceivable that the more mercury you get, the more effect you are going to get."

Dr. Chen: Page 151: "One of the reasons that led me personally to not be so quick to dismiss the findings was that on his own Tom independently picked three different outcomes that he did not think could be associated with mercury (conjunctivitis, diarrhea and injury) and three out of three had a different pattern across different exposure levels as compared to the ones that again on a priority basis we picked as biologically plausible to be due to mercury exposure."

Dr. Johnston: Page 198: "This association leads me to favor a recommendation that infants up to two years old not be immunized with Thimerosal containing vaccines if suitable alternative preparations are available… My gut feeling? It worries me enough. Forgive this personal comment, but I got called out a eight o'clock for an emergency call and my daughter-in-law delivered a son by C-Section. Our first male in the line of the next generation, and I do not want that grandson to get a Thimerosal containing vaccine until we know better what is going on. It will probably take a long time. In the meantime, and I know there are probably implications for this internationally, but in the meantime I think I want that grandson to only be given Thimerosal-free vaccines."

Dr. Weil: Page 207: "The number of dose related relationships are linear and statistically significant. You can play with this all you want. They are linear. They are statistically significant. The positive relationships are those that one might expect from the Faeroe Islands studies. They are also related to those data we do have on experimental animal data and similar to the neurodevelopmental tox data on other substances, so that I think you can't accept that this is out of the ordinary. It isn't out of the ordinary."

Dr. Brent: Page 229: "The medical legal findings in this study, causal or not, are horrendous and therefore, it is important that the suggested epidemiological, pharmacokinetic, and animal studies be performed. If an allegation was made that a child's neurobehavioral findings were caused by Thimerosal-containing vaccines, you could readily find a junk scientist who would support the claim with 'a reasonable degree of certainty.' But you will not find a scientist with any integrity who would say the reverse with the data that is available. And that is true. So we are in a bad position from the standpoint of defending any lawsuits if they were initiated and I am concerned."

Dr. Clements: Page 247: "I am really concerned that we have taken off like a boat going down one arm of the mangrove swamp at high speed, when in fact there was not enough discussion really early on about which way the boat should go at all. And I really want to risk offending everyone in the room by saying that perhaps this study should not have been done at all, because the outcome of it could have, to some extent, been predicted, and we have all reached this point now where we are left hanging, even though I hear the majority of consultants say to the Board that they are not convinced there is a causality direct link between Thimerosal and various neurological outcomes. I know how we handle it from here is extremely problematic. The ACIP is going to depend on comments from this group in order to move forward into policy, and I have been advised that whatever I say should not move into the policy area because that is not the point of this meeting. But nonetheless, we know from many experiences in history that the pure scientist has done research because of pure science. But that

doi: 10.1588/medver.2004.01.00033

pure science has resulted in splitting the atom or some other process which is completely beyond the power of the scientists who did the research to control it. And what we have here is people who have, for every best reason in the world, pursued a direction of research. But there is now the point at which the research results have to be handled, and even if this committee decides that there is no association and that information gets out, the work that has been done and through the freedom of information that will be taken by others, will be used in ways beyond the control of this group. And I am very concerned about that as I suspect it is already too late to do anything regardless of any professional body and what they say … [18]"

It was clear in subsequent documents that Dr. Verstraeten was not pleased with the response to his study. During the Simpsonwood conference he stated, "When I saw this, and I went back through the literature, I was actually stunned by what I saw – because I thought it was plausible." A month later he sent an e-mail to Dr. Phillippe Grandjean, the author of several groundbreaking studies on the toxicity of mercury. Dr Verstraeten wrote, "I know that much of this is very hypothetical and, personally, I would rather not drag the Faeroe and Seychelles studies into this entire Thimerosal debate, as I think they are as comparable as apples and pears at the best. Unfortunately, I have witnessed how many experts, looking at this Thimerosal issue, do not seem bothered to compare apples to pears and insist as if nothing is happening in these studies, then nothing should be feared of Thimerosal. I do not wish to be the advocate of the anti-vaccine lobby and sound as if I am convinced that Thimerosal is or was harmful; but at least I feel we should use sound scientific argumentation, and not let our standards be dictated by our desire to disprove an unpleasant theory [5]."

It appears that many who participated in the Thimerosal debates allowed their standards to be dictated by their desire to disprove an unpleasant theory [5].

Phase II of the VSD study, which provided enough data to analyze only speech delay and attention deficit disorder, did not detect an association between those disorders and Thimerosal, as had Phase I. In part, Phase II of the VSD study failed to confirm the findings of Phase I because of the small sample size employed (16,000 as opposed to 110,000 children in Phase I) [5]. Additionally, at the time that the Phase II data was brought in from a Massachusetts HMO (Harvard Pilgrim, HP): HP was in receivership by the state of Massachusetts; its computer records had been in shambles for years; it had multiple computer systems that could not communicate with one another; it used a health care coding system totally different from the one used across the VSD; and there are significant questions relating to a significant underreporting of autism in the state of Massachusetts [19].

In November 2003, an article was published by Verstraeten et al. in *Pediatrics* reporting on the CDC results of their VSD analysis of Thimerosal and neurodevelopmental disorders [53]. On October 31, 2003, Congressman Dr. Weldon wrote a letter to Julie Gerberding, Director of the CDC, stating, "I have reviewed the article and have serious reservations about the four-year evolution and conclusions of this study." The Congressman continued: "I am a strong supporter of childhood vaccinations and know that they have saved us from considerable death and suffering. A key part of our vaccination program is to ensure that we do everything possible to ensure that these vaccines, which are mandatory, are as safe as possible. We must fully disclose adverse events. Anything less than this undermines public confidence. I have read the upcoming *Pediatrics* study and several earlier versions of this study dating back to February 2000. I have read various e-mails from Dr. Verstraeten and coauthors. I have reviewed the transcripts of a discussion at Simpsonwood, GA between the author, various CDC employees and vaccine industry representatives. I have found a disturbing pattern… A review of these documents leaves me very concerned that rather than seeking to understand whether or not some children were exposed to harmful levels of mercury in childhood vaccines in the 1990s, there may have been a selective use of the data to make the associations in the earliest study disappear… Furthermore, the lead author of the article, Dr. Thomas Verstraeten, worked for the CDC until he left over two years ago to work for GlaxoSmithKline (GSK), a vaccine manufacturer facing liability over TCVs [Thimerosal-containing vaccines]. In violation of their own standards of conduct, *Pediatrics* failed to disclose that Dr. Verstraeten is employed by GSK and incorrectly identifies him as an employee of the CDC. This revelation undermines this study further. The first version of the study, produced in February 2000, found a significant association between exposure to TCVs and autism and neurological developmental delays (NDDs). When comparing children exposed to 62.5 μg [micrograms] of mercury by 3 months of age to those exposed to less than 37.5 μg, the study found a relative risk for autism of 2.48 for those with the higher exposure levels… For NDDs the study found a relative risk of 1.59 and a definite upward trend as exposure levels increased. A June 2000 version of the study applied various data manipulations to reduce the autism association to 1.69 and the authors went outside of the VSD database to secure data from a Massachusetts HMO (Harvard Pilgrim, HP) in order to counter the association found between TCVs and speech delay. At the time that HP's data was brought in, HP was in receivership by the state of Massachusetts, its computer records had been in shambles for years, it had multiple computer systems that could not communicate with one another, and it used a health care coding system totally different from the one used across the VSD. There are questions relating to a significant underreporting of autism in Massachusetts. The HP dataset is only about 15% of the HMO dataset used in the February 2000 study. There may also be significant problems with the statistical power of the dataset. In June 2000 a meeting was held in Simpsonwood, GA, involving the authors of the study, representatives of the CDC, and the vaccine industry. I have reviewed a transcript of this meeting that was obtained through the Freedom of Information Act (FOIA). Comments from Simpsonwood, meeting include: (summary form, not direct quotes): We found a statistically significant relationship between exposures and outcomes. There is certainly an under ascertainment of adverse outcomes because some children are just simply not old enough to be diagnosed, the current incidence rates are much lower than we would expect to see (Verstraeten); we could exclude the lower exposure children from our database. Also suggested was removing the children that got the highest exposure levels since they represented an un-

doi: 10.1588/medver.2004.01.00033

usually high percentage of outcomes (Rhodes); the significant association with language delay is quite large (Verstraeten); this information should be kept confidential and considered embargoed; we can push and pull this data anyway we want to get the results we want; we can alter the exclusion criteria any way we want, give reasonable justifications for doing so, and get any result we want; There was really no need to do this study. We could have predicted the outcomes; I will not give TCVs to my grandson until I find out what is going on here. Another version of the study – after further manipulation – finds no association between TCVs and autism, and no consistency across HMOs between TCVs and NDDs and speech delay. The final version of the study concludes that "No consistent significant associations were found between TCVs and neurodevelopmental outcomes," and that the lack of consistency argues against an association. In reviewing the study there are data points where children with higher exposures to the neurotoxin mercury had fewer developmental disorders. This demonstrates to me how excessive manipulation of data can lead to absurd results. Such a conclusion is not unexpected from an author with a serious, though undisclosed, conflict of interest. This study increases speculation of an association between TCVs and neurodevelopmental outcomes. I cannot say it was the author's intent to eliminate the earlier findings of an association. Nonetheless, the elimination of this association is exactly what happened and the manner in which this was achieved raises speculation. The dialogue at the Simpsonwood meeting clearly indicates how easily the authors could manipulate the data and have reasonable sounding justifications for many of their decisions. The only way these issues are going to be resolved – and I have only mentioned a few of them – is by making this particular dataset and the entire VSD dataset open for independent analysis. One such independent researcher, Dr. Mark Geier, has already been approved by the CDC and the various IRBs to access this dataset. They have requested the CDC allow them to access this dataset and your staff indicated to my office that they would make this particular dataset available after the *Pediatrics* study is published. Earlier this month the CDC had prepared three similar datasets for this researcher to review to allow him to reanalyze CDC study datasets. However when they accessed the datasets – which the researchers paid the CDC to assemble – the datasets were found to have no usable data in them. I request that you personally intervene with those in the CDC who are assembling this dataset to ensure that they provide the complete dataset, in a usable format, to these researchers within two weeks. The treatment these well-published researchers have received from the CDC thus far has been abysmal and embarrassing. I would be curious to know whether Dr. Verstraeten, an outside researcher for more than two years now, was required to go through the same process as Dr. Geier in order to continue accessing the VSD [19]."

The lead author, Dr. Verstraeten has subsequently published a letter to the editor in which he concluded that his study was neutral (i.e., could neither accept nor reject a causal relationship) regarding the relationship between Thimerosal and NDDs [21].

A report prepared by the staff of the Subcommittee on Human Rights and Wellness, Committee on Government Reform of the United States' House of Representatives, concluded following a three-year investigation: The Food and Drug Administration's (FDA) mission is to "promote and protect the public health by helping safe and effective products reach the market in a timely way, and monitoring products for continued safety after they are in use." However, the FDA uses a subjective barometer in determining when a product that has known risks can remain on the market. According to the agency, "at the heart of all FDA's product evaluation decisions is a judgment about whether a new product's benefits to users will outweigh its risks. No regulated product is totally risk-free, so these judgments are important. FDA will allow a product to present more of risk when its potential benefit is great – especially for products used to treat serious, life-threatening conditions." This argument – that known risks of infectious diseases outweigh a potential risk of neurological damage from exposure to Thimerosal in vaccines – is one that has continuously been presented to the Committee by government officials. FDA officials have stressed that any possible risk from Thimerosal was theoretical, that no proof of harm existed. However, the Committee, upon a through review of the scientific literature and internal documents from government and industry, did find evidence that Thimerosal did pose a risk. Thimerosal used as a preservative in vaccines is likely related to the autism epidemic. This epidemic in all probability may have been prevented or curtailed had the FDA not been asleep at the switch regarding the lack of safety data regarding injected Thimerosal and the sharp rise of infant exposure to this known neurotoxin. Our public health agencies' failure to act is indicative of institutional malfeasance for self-protection and misplaced protectionism of the pharmaceutical industry [5].

Additionally, the U.S. Office of Special Counsel (OSC), an independent federal agency, has issued a letter to Congress stating: "I have recently received hundreds of disclosures from private citizens alleging a widespread danger to the public health, specifically to infants and toddlers, caused by childhood vaccines which include Thimerosal, a mercury-containing preservative... The disclosures allege that Thimerosal/mercury is still present in childhood vaccines, contrary to statements made by HHS agencies, HHS Office of Investigations and the American Academy of Pediatrics. According to the information provided, vaccines containing 25 micrograms of mercury and carrying expiration dates of 2005 continue to be produced and administered. In addition, the disclosures allege, among other things, that some datasets showing a relationship between Thimerosal/mercury and neurological disorders no longer exist, that independent researchers have been arbitrarily denied access to the Centers for Disease Control and Prevention (CDC) databases, and that government-sponsored studies have not assessed the genetic vulnerabilities of subpopulations. Due to their heightened concern that additional datasets may be destroyed, these citizens urge the immediate safeguarding of the Vaccine Safety Datalink database and other relevant CDC information so that critical data are not lost. The disclosures also allege that the CDC and the Food and Drug Administration colluded with pharmaceutical companies at a conference in Norcross, Georgia, in June 2000 to prevent the release of a study which showed a statistical correlation between Thimerosal/mercury exposure through pediatric vaccines and neurological disorders including autism, Attention-Deficit/Hyperactivity Disorder,

doi: 10.1588/medver.2004.01.00033

stuttering, tics, and speech and language delays. Instead of releasing the data presented at the conference, the author of the study, Dr. Thomas Verstraeten, later published a different version of the study in the November 2003 issue of *Pediatrics*, which did not show a statistical correlation. No explanation has been provided for this discrepancy. Finally, the disclosures allege that there is an increasing body of clinical evidence on the connection of Thimerosal/mercury exposure to neurological disorders which is being ignored by government public health agencies... I believe that these allegations raise serious continuing concerns about the administration of the nation's vaccine program and the government's possibly inadequate response to the growing body of scientific research on the public health danger of mercury in vaccines. The allegations also present troubling information regarding children's cumulative exposure to mercury and the connection of that exposure to the increase in neurological disorders such as autism and autism-related conditions among children in the US [22].”

Acknowledgement

The Editorial Staff of *MedicalVeritas* wishes to thank David Geier for his contribution of sources and information that proved invaluable to this article.

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