

Thimerosal in Childhood Vaccines, Neurodevelopment Disorders, and Heart Disease in the United States

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Abstract

In this study, we evaluated doses of mercury from thimerosal-containing childhood immunizations in comparison to US Federal Safety Guidelines and the effects of increasing doses of mercury on the incidence of neurodevelopment disorders and heart disease. This study showed that children received mercury from this source in excess of the Federal Safety Guidelines for the oral ingestion of methylmercury. Our analyses showed increasing relative risks for neurodevelopment disorders and heart disease with increasing doses of mercury. This study provides strong epidemiological evidence for a link between mercury exposure from thimerosal-containing childhood vaccines and neurodevelopment disorders.

Introduction

Many sources now confirm an autism epidemic in the United States. The prevalence of autism has risen from one in about 2,500 children in the mid-1980s to one in about 300 children in 1996.^{1,2,3} Several studies report that there is an association between mercury exposure and an increased risk of heart disease.^{4,5} Many in the scientific/medical community have, initially, been highly skeptical that thimerosal, an ethylmercury preservative, in childhood vaccines could be associated with neurodevelopment disorders.

Thimerosal is an organic mercury compound. It is metabolized to ethylmercury and thiosalicylate and has been present since the 1930s as a preservative in many vaccines and pharmaceutical products to prevent bacterial and fungal contamination.

In 2001, the Institute of Medicine (IOM) of the US National Academy of Sciences concluded that the hypothesis that exposure to thimerosal-containing vaccines could be associated with

neurodevelopment disorders is not established and rests on indirect and incomplete information, primarily from analogies with methylmercury and levels of maximum mercury exposure from vaccines given in children. They concluded that the hypothesis is biologically possible, but the possible relationship between thimerosal from vaccines and neurodevelopment disorders of autism, attention deficit/hyperactivity disorder (ADHD), and speech or language delay remained seriously suspect.⁷

Since the publication of the IOM report, we published the first epidemiological evidence showing a direct association between thimerosal-containing childhood vaccines and neurodevelopment disorders in children.⁸ We showed that there was from a 2 to 6-fold increased incidence of neurodevelopment disorders following an additional 75-100µg dosage of mercury from thimerosal-containing childhood vaccines in comparison to thimerosal-free childhood vaccines.

As the first part of this study, we evaluated the doses of mercury that children received from thimerosal-containing vaccines, as part of the routine US childhood immunization schedule, in comparison to the US Federal Safety Guidelines for the oral ingestion of methylmercury. In 1999, the US Food and Drug Administration (FDA) determined that under the recommended childhood immunization schedule infants might be exposed to cumulative doses of ethylmercury that exceed some federal safety guidelines established for the oral ingestion of methylmercury.⁹

Secondly, in order to analyze the effects of thimerosal in vaccine recipients, we analyzed the incidence rates of neurodevelopment disorders and heart disease reported following thimerosal-containing vaccines in comparison to thimerosal-free vaccines based upon analysis of the Vaccine Adverse Events Reporting System (VAERS) database. We analyzed thimerosal-containing Diphtheria-Tetanus-whole-cell-Pertussis (DTwcp) and Diphtheria-Tetanus-acellular-Pertussis (DTaP) vaccines in comparison to thimerosal-free DTaP vaccines.

Finally, we analyzed data from the US Department of Education on the number of children of various ages in US schools who were reported with various types of disabilities in comparison to the mercury dose that children received from thimerosal in their childhood vaccines.

Methods

EPA/FDA Exposure Limits

In this study, the amount of mercury children received as part of their routine childhood immunization schedule and the EPA and FDA maximum permissible doses for the oral ingestion of methylmercury were determined from the IOM report.⁷ The maximum permissible doses for the oral ingestion of methylmercury by the EPA and FDA are 0.1 µg/kg body weight/day and 0.4 µg/kg body weight/day, respectively. The average size of infants at various ages was determined from Geigy Scientific Tables.¹⁰

The VAERS Database

The incidence of neurodevelopment disorders and heart disease following thimerosal-containing DTaP and DTwcP vaccines in comparison to thimerosal-free DTaP vaccines was based upon analysis of the VAERS database, using Microsoft Access.[®]

The VAERS database is an epidemiologic database maintained by the Centers for Disease Control and Prevention (CDC) since 1990. All adverse reactions are to be reported to the VAERS database as required by US law. The CDC requires written and telephonic confirmation of serious adverse reactions and follows up these patients one year later. The FDA inquires into deaths reported to the VAERS database by contacting the patient's healthcare provider and physician. The FDA also continually monitors reports to the VAERS database to determine whether any vaccine or vaccine lot has a higher than expected incidence rate of events. The VAERS Working Group of the CDC, the FDA, and we analyze and publish epidemiologic studies based upon analysis of the VAERS database.

The neurodevelopment disorders and heart disease conditions we analyzed were autism, speech disorders, and heart arrest. These categories of adverse events were based upon descriptions of adverse reactions by those reporting them and by defined fields contained in the VAERS database. In addition, as control adverse events we analyzed the number of febrile seizures, fevers, pain, edema, and vomiting following each of the vaccines under study. We determined the number of each type of adverse event reported following doses for two groups of patients, the first receiving an average of 37.5 µg of mercury and the second, an average of 87.5 µg of mercury. This grouping allowed us to be able to ascertain larger numbers for our analyses.

We hypothesize that DTaP or DTwCP vaccines, whether containing thimerosal or not, should have a similar incidence rate of adverse events. The assumption of similar reactogenicity following the vaccines under study forms the basis of our null hypothesis.

We analyzed DTaP and DTwCP vaccines by manufacturer, so that we could compare thimerosal-containing DTaP and DTwCP vaccines administered from 1992 through 2000 against thimerosal-free DTaP vaccines administered from 1997 through 2000. We used denominators obtained from the Biological Surveillance Summaries of the CDC to determine the number of doses of each manufacturer administered. Based upon this information, we were able to calculate incidence rates of adverse events following vaccination.

We are precluded from giving incidence rates, the number of doses administered, or types of DTaP or DTwCP vaccine, because this information could reveal the identities of the manufacturers and the CDC claims that this information is proprietary.¹¹

We compared the incidence rates of adverse events following thimerosal-containing DTaP and DTwCP vaccines against thimerosal-free DTaP vaccines in order to determine relative risk. The relative risk value was obtained by dividing the incidence rate of the adverse event following thimerosal-containing DTaP or DTwCP vaccines by the incidence rate of the adverse event following thimerosal-free DTaP vaccines. The relative risks of the adverse events analyzed were plotted against the amount of mercury that each child had received. By definition, since we assume that the populations under study are similar and we are tracking only the amount of mercury that children received from the thimerosal-containing or thimerosal-free vaccines under study, the initial point

Age (months)	Dose (micrograms)	Permissible EPA Dose (micrograms) P ₀₅ (Ave weight in Kg)	Permissible EPA Dose (micrograms) P ₅₀ (Ave weight in Kg)	Permissible EPA Dose (micrograms) P ₉₅ (Ave weight in Kg)
0	12.5	0.262 (2.62)	0.330 (3.30)	0.404 (4.04)
Instantaneous Relative Excess	-	48	38	31
2	62.5	0.417 (4.17)	0.486 (4.86)	0.558 (5.58)
Instantaneous Relative Excess	-	150	129	112
4	62.5	0.552 (5.52)	0.654 (6.54)	0.760 (7.60)
Instantaneous Relative Excess	-	113	96	82
6	50	0.654 (6.54)	0.780 (7.80)	0.880 (8.80)
Instantaneous Relative Excess	-	76	64	57
15	25	0.918 (9.18)	1.05 (10.5)	1.23 (12.3)
Instantaneous Relative Excess	-	27	24	20
60	25	1.40 (14.0)	1.86 (18.6)	2.32 (23.2)
Instantaneous Relative Excess	-	18	13	11

Table 1. A summary of the instantaneous mercury exposure levels of US infants at various times as part of their childhood immunization schedule in comparison to the maximum daily EPA established limits.

analyzed was zero micrograms of mercury and had a relative risk of one.

United States Department of Education Report

The 2001 US Department of Education report was analyzed to determine the number of children at various ages who had developed various conditions.¹² The conditions analyzed included: autism, speech disorders, orthopedic impairments, visual impairments, and deaf-blindness. We determined the prevalence of each of these conditions based upon the number of births in each birth cohort as per the CDC's yearly live birth surveillance data.¹³ The birth cohort years analyzed were 1984, 1985, 1990, 1991, 1992, 1993, and 1994.

We then calculated the amount of mercury that had been administered on average to each child in a birth cohort,

based upon the Biologic Surveillance Summaries of the CDC. Then the prevalence of the various conditions analyzed was plotted against the amount of mercury that each child received.

Results

Table 1 presents a summary of the instantaneous mercury exposure of US infants at various times as part of their childhood immunization schedule in comparison to the EPA established limits. This table shows that the instantaneous relative excess mercury that US children received from their childhood immunizations ranged from 11 to 150-fold at a given age in comparison to the US EPA safety guidelines for the daily maximum oral ingestion of methylmercury. In addition, these data show that children received an instantaneous relative excess mercury doses in comparison to the FDA safety

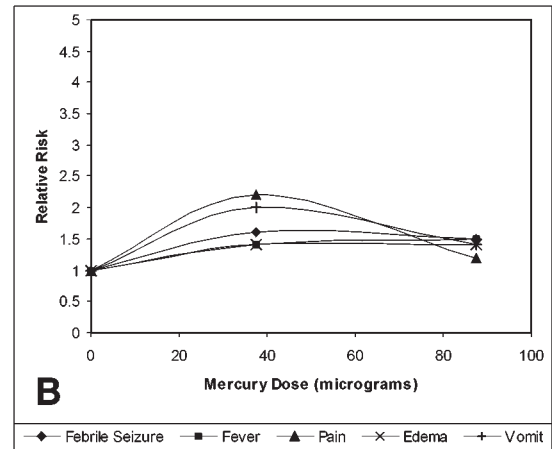
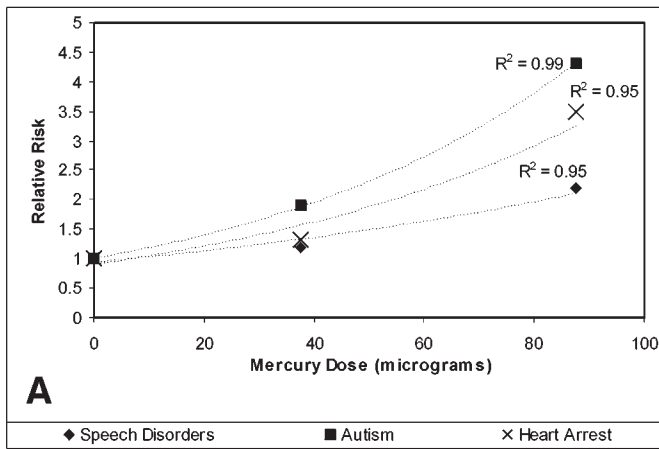


Figure 1. (A) Neurodevelopment disorders and heart disease conditions reported following thimerosal-containing DTaP in comparison to thimerosal-free DTaP vaccines for increasing mercury dosage that children received from thimerosal; **(B)** Control adverse events reported acutely following thimerosal-containing DTaP in comparison to thimerosal-free DTaP vaccines for increasing mercury dosage from thimerosal

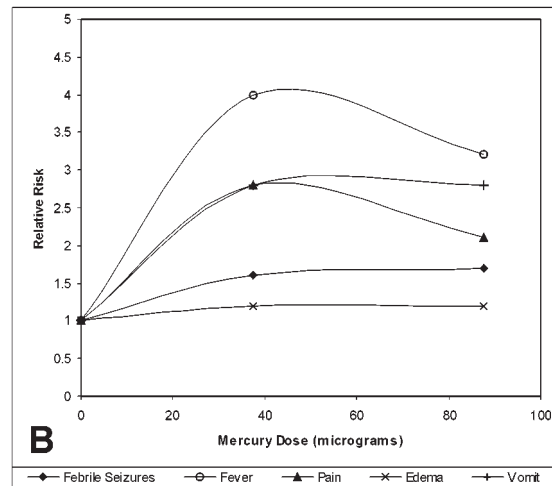
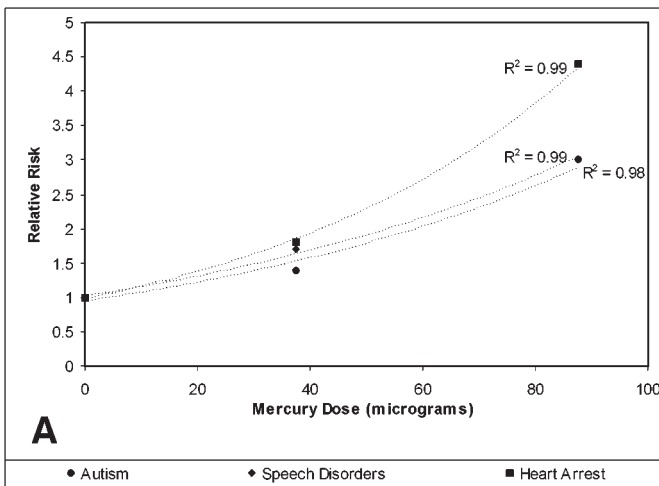


Figure 2. (A) Neurodevelopment disorders and heart disease conditions reported following thimerosal-containing DTwcp in comparison to thimerosal-free DTaP vaccines for increasing mercury dosage that children received from thimerosal; **(B)** Control adverse events reported acutely following thimerosal-containing DTwcp in comparison to thimerosal-free DTaP vaccines for increasing mercury dosage from thimerosal

guidelines for the oral ingestion of methylmercury, ranging from 2.7 to 37-fold at a given age.

Figure 1A plots the relative risk of speech disorders, autism, and heart arrest reported after thimerosal-containing DTaP in comparison to thimerosal-free DTaP vaccines for increasing doses of mercury. We found that the data points for each condition closely followed exponential distributions.

Figure 1B plots the relative risks of febrile seizure, fever, pain, edema, and vomiting reported after thimerosal-containing DTaP in comparison to thimerosal-free DTaP vaccines. We found that administration of thimerosal-

containing DTaP vaccines slightly raised the rate of adverse events compared to thimerosal-free DTaP vaccines, but the increased relative risks did not correlate with the total amount of mercury the children received.

Figure 2A shows the relative risk of speech disorders, autism, and heart arrest reported after thimerosal-containing DTwcp in comparison to thimerosal-free DTaP vaccines for increasing dosage of mercury. We found that the data points closely followed exponential distributions.

Figure 2B shows the relative risk of febrile seizure, fever, pain, edema, and vomiting after thimerosal-containing DTwcp in comparison to thimerosal-free

DTaP vaccines for different mercury doses. We found that administration of thimerosal-containing DTwcp vaccines significantly raised the rate of adverse events compared to thimerosal-free DTaP vaccines, but the increased relative risks did not correlate with the total amount of mercury the children received.

Figures 3A-B show the prevalence of autism and speech disorders as a function of the mercury dose that children received from thimerosal contained in their childhood vaccines. We found that the conditions analyzed closely followed linear distributions with an increase of about one case of autism per 100,000 children for every microgram present in childhood vaccines and about one case of speech

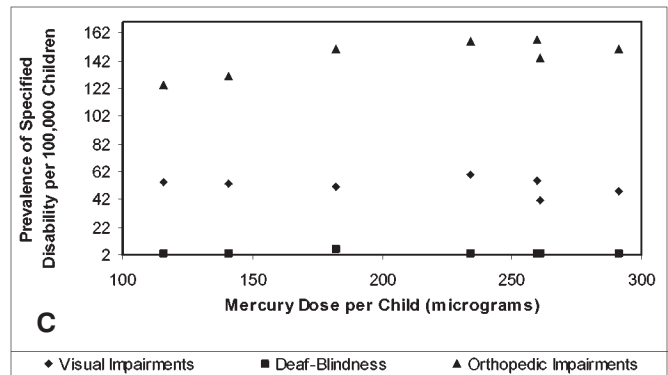
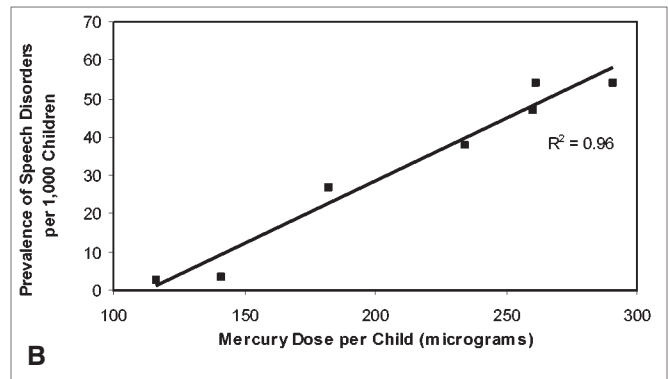
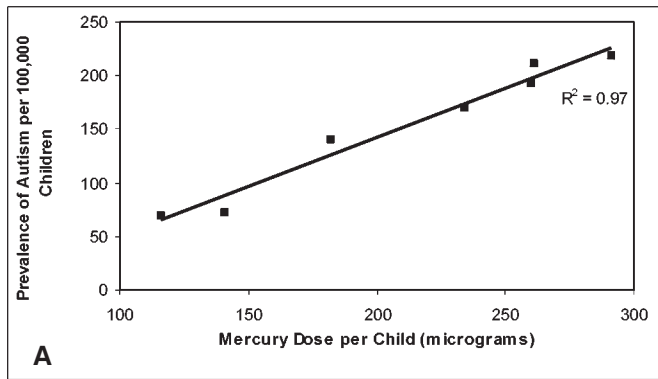


Figure 3. (A) Autism disabilities reported in comparison to the average mercury dosage from thimerosal in childhood vaccines; (B) speech disorders reported in comparison to the average mercury dosage from thimerosal in childhood vaccines; (C) visual impairment, deaf-blindness and orthopedic impairment (control disabilities) in comparison to the average mercury dosage from thimerosal in childhood vaccines

disorders per 1,000 children for every 3 µg of mercury present in childhood vaccines.

Figure 3C shows the prevalence of the control disabilities of visual impairment, deaf-blindness, and orthopedic impairment as a function of the mercury dose that children received from thimerosal contained in their childhood vaccines. We found that the prevalence of these conditions did not correlate with the increasing total amount of mercury the children received.

Discussion

It is clear from our analysis, shown in Table 1, that US infants are exposed to mercury levels from their childhood immunization schedule that far exceed the EPA and FDA-established maximum permissible levels for the daily oral ingestion of methylmercury. The fact that mercury in the vaccines is given by injection rather than by oral ingestion only makes the exposure levels worse because Geier et al. showed that the distribution of foreign particles in mice reached several-logs higher concentration in organs following intravenous or intramuscular injections than via oral ingestion.¹⁴

Our previous studies comparing DTaP with and without thimerosal have shown a statistically and clinically significant increase in neurodevelopment disorders in those vaccinated with thimerosal-containing vaccines.⁸ Our current study not only shows that those vaccinated with

thimerosal-containing DTaP and DTwCP have higher rates of speech disorders, autism, and heart arrest overall, but also that the relative risk of each of these disorders correlated with increasing doses of mercury contained in childhood vaccines, as illustrated in Figures 1A and 2A. Figures 1B and 2B show that exposure to increasing doses of mercury is not correlated to acute vaccine adverse events including febrile seizures, fever, pain, edema, or vomiting.

Our demonstration of a significant overall increase in the relative risks of acute adverse events following DTwCP vaccine when compared to thimerosal-free DTaP vaccine is not surprising since our previous studies have shown that DTwCP vaccines are far more reactogenic than DTaP vaccines.^{15,16} However, we observed that only those events for which causation by thimerosal is biologically plausible were found to be correlated with the mercury levels children received in their vaccines.

Our analyses of a completely independent source, the US Department of Education's report on the prevalence of various childhood disease among school children of various ages, showed autism and speech disorders were correlated with increasing mercury from childhood vaccines, as shown in Figures 3A-B. No correlation was seen between increasing mercury exposure from childhood vaccines and the prevalence of visual impairments, deafness-blindness, or orthopedic impair-

ments, as shown in Figure 3C.

The lack of correlation between acute events and increasing mercury exposure levels in the VAERS data argues against reporting bias or differences in the vaccines themselves and argues for the specific effects of thimerosal on neurodevelopment disorders and heart disease. Likewise, the lack of correlation between visual impairments, deaf-blindness, or orthopedic impairments and the increasing mercury exposure levels in the US Department of Education data also argues for the specific effects of thimerosal in childhood vaccines on the prevalence of autism and speech disorders.

As an additional epidemiological confirmation of our findings, we analyzed the CDC's Phase I Thimerosal Vaccine Safety Datalink (VSD) data.¹⁷ We found this data showed that the increasing relative risk of developmental neurologic disorder, autism, speech disorder, and attention deficit disorder all closely followed exponential distributions with increasing mercury levels from the thimerosal that children received as part of their childhood immunizations.

We conducted a MEDLINE (1966-2003) search for the terms merthiolate and thimerosal and found almost 1,500 references, primarily about various adverse outcomes following exposure. Of particular interest, Bernard et al. have compared the similar biological abnormalities commonly found in autism and the

corresponding pathologies arising from mercury exposure.^{1,8} Distinct similarities were found between autism and mercury exposure in their effects upon biochemistry, the immune system, the central nervous system structure, neurochemistry, and neurophysiology.

A study performed by Magos et al. in rats compared the effects of the administration of similar doses of ethylmercury and methylmercury.^{1,9} They found that higher concentrations of inorganic mercury in the kidneys and brain were present in ethylmercury-treated rats compared to methylmercury-treated rats. They determined that there was little difference in the neurotoxicity found in ethylmercury and methylmercury-treated rats when effects on the dorsal root ganglia or coordination disorders were compared. The authors also determined that microgram quantities of organic mercury alone in the rat brain were in some cases associated with neurotoxicity, indicating that the presence of inorganic mercury was not necessary for neurotoxicity.

It has been reported that administration of thimerosal results in the immediate release of ethylmercury to the surrounding tissues.^{2,9} The reason for this stems from the fact that thimerosal contains the ethylmercury radical attached to the sulfur atom of the thiol group of salicylic acid. Generally, mercuric ions bind tightly but reversibly to thiol ligands.^{2,1} It is likely, therefore, that the ethylmercury cation will dissociate from the thiosalicylic acid moiety immediately after injection to bind to the surrounding thiol ligands present in great excess in tissue proteins.^{2,9}

Rapid deposition of ethylmercury in tissues following administration of thimerosal from vaccines is suggested by a recent publication by Pichichero et al.^{2,2} The authors examined the concentrations of mercury in the blood, urine, and stool from 3 to 28 days following thimerosal-containing vaccines in 40 full-term infants aged 6 months and younger in comparison to 21 control infants receiving thimerosal-free vaccines. The mean mercury doses of the infants exposed to thimerosal were 45.6 µg (range 37.5-62.5) for 2-month-olds and 111.3 µg (range 87.5-175.0) for 6 month-olds. Blood mercury in thimerosal-exposed 2-month-old infants ranged from less than 3.75 to 20.55 nmol/L; in 6 month-old infants all values were lower than 7.50 nmol/L. Only 15 blood samples from controls contained quantifiable mercury. Concentrations of mercury were low in the urine after vaccination but were high in the stools of thimerosal-exposed 2-month-old infants (mean 82 ng/g dry weight) and in 6-month-old infants (mean 58 ng/g dry weight).

The authors estimated that the blood half-life of ethylmercury was 7 days (95% confidence interval of 4 to 10 days). The study was unable to determine the ultimate disposition of most of the mercury with which infants were injected. However, it has been determined that uptake of mercury in the brain is 5 to 7 times greater than in the blood.^{2,9,2} Therefore, because of the similar theoretical and experimental toxicities of ethylmercury and methylmercury, and the immediate buildup of ethylmercury from thimerosal in the tissues of the body, especially the preferential buildup in the brain, there appears to be good biologic plausibility for the neurodevelopment disorders and heart conditions observed in this study.

On July 7, 1999, the American Academy of Pediatrics and the US Public Health Service issued a joint statement calling for the removal of thimerosal from vaccines, prompted by a risk assessment from the FDA.⁹ The 2001 IOM report stated that technology is available to manufacturers in the US to allow for the removal of thimerosal from childhood vaccines in a timely manner and that only a small number of thimerosal-containing vials remain on the shelf.⁷

We have recently reviewed the 2003 US Physician's Desk Reference (PDR) and found that some childhood vaccines still contain thimerosal. DTaP manufactured by Aventis Pasteur contains 25 µg of mercury, *Hemophilus influenzae* b (Hib) vaccine manufactured by Wyeth contains 25 µg of mercury, and pediatric hepatitis B vaccine manufactured by Merck contains 12.5 µg of mercury.^{2,4} In addition, influenza vaccine that is recommended for an increasing segment of the pediatric population in the US also contains 25 µg of mercury. Therefore, it is indeed possible that children in the US in 2003 may be exposed to levels of mercury from thimerosal contained in their childhood vaccinations that are at a higher level than at any time in the past. Possible total childhood mercury in 2003 is more than 300 µg.

Because of the data implicating thimerosal levels with increasing rates of autism, speech disorders, and heart disease, it would seem prudent to completely remove thimerosal from all childhood vaccines immediately. The use of single-dose vials would alleviate the need for any preservative in the vaccines.

Parents should be encouraged to avoid exposing their children to additional mercury from sources other than vaccines. Until recently, Rh-negative women were routinely given Rhogam injections, which contained significant amounts of thimerosal, several times during their pregnancies. Fortunately, thimerosal has

been removed from Rhogam. Pregnant women and children should avoid eating seafood that may contain significant quantities of mercury. The mean mercury levels in various seafood species have been determined by the Center for Food Safety and Applied Nature Section of the FDA.^{2,5} The FDA currently recommends that pregnant women and those women who may become pregnant avoid species with the highest average amounts of methylmercury and that a "balanced" diet of seafood consumption should be followed so as to keep methylmercury levels low.^{2,6} Additionally, fetuses may be exposed to mercury from the amalgam used in their mother's fillings. Also, patients should be made aware that there are other prescription drugs and over-the-counter medications that contain significant amounts of thimerosal.^{2,4}

These other sources of mercury, while potentially significant, probably had a limited effect on the results of this study because the populations analyzed were large and there should have been equal exposure to other sources of mercury among the populations examined.

Conclusion

This study provides strong epidemiological evidence for a link between increasing mercury from thimerosal-containing childhood vaccines and neurodevelopment disorders and heart disease. In light of voluminous literature supporting the biologic mechanisms for mercury-induced adverse reactions, the presence of amounts of mercury in thimerosal-containing childhood vaccines exceeding Federal Safety Guidelines for the oral ingestion of mercury, and previous epidemiological studies showing adverse reactions from such vaccines, a causal relationship between thimerosal-containing childhood vaccines and neurodevelopment disorders and heart disease appears to be confirmed. It is to be hoped that complete removal of thimerosal from all childhood vaccines will help to stem the tragic, apparently iatrogenic epidemic of autism and speech disorders that the United States is now facing.

Dr. Mark Geier has done consulting work and appeared as an expert witness, and David Geier has done consulting work in cases before the National Vaccine Injury Compensation Program (NVICIP) and in civil suits involving vaccine adverse reactions. To date, none of these cases have involved thimerosal.

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