

June 26, 2005

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The New York Times
229 West 43rd Street
New York, NY 10036

**RE: “On Autism’s Cause: It’s Parents vs. Research” by Gardiner Harris and
Anahad O’Connor, June 25, 2005**

Dear Sirs:

Following is a list of corrections for the above mentioned article. Our organization, SafeMinds, was mentioned several times in the report. I would be happy to provide any necessary substantiation for the items listed upon request.

Thank you for your consideration of these changes.

Sincerely,

A handwritten signature in green ink that reads "Sallie Bernard". The signature is written in a cursive style and is centered within a light gray rectangular box.

Sallie Bernard
Executive Director

Corrections to “On Autism’s Cause: It’s Parents vs. Research” by Gardiner Harris and Anahad O’Connor, *New York Times*, June 25, 2005

Submitted to the Editor and to the Public Editor, *New York Times*, by SafeMinds, June 26, 2005

[Note: Statements from the Harris & O’Connor article are provided in bold italics, and the correction is listed beneath.]

Comments at the beginning of the article attributed to Kristen Ehresmann concerning fish, water, and air

Ms. Ehresmann is described in the article as a public health official with the Minnesota Department of Health who has a son with autism, and thus as someone who would invoke authority and empathy. However, the statements attributed to her were in fact made by Patricia Segal-Freeman, an attorney with the Minnesota Department of Health's immunization program. The parent shown in the front page photograph and quoted in the exchange about where mercury comes from, Libby Rupp, has informed us of this error.

“The anti-thimerosal campaign, they say, is causing some parents to stay away from vaccines, placing their children at risk for illnesses like measles and polio.”

The CDC’s National Immunization Program tracks immunization rates through a nationwide study among families with children. Their last annual report on immunization rates among children was published in July 2004 (“Childhood immunization rates at record high levels”, HHS press release of July 29, 2004). According to the latest CDC study, vaccination rates among American children are at their highest level ever. There is no evidence to support declining vaccination rates or higher rates of vaccine-preventable diseases due to awareness among parents of the thimerosal issue.

For clarification, since at least 1970, the polio and measles vaccines have never contained thimerosal.

“...ethylmercury, a form of mercury most scientists consider to be less toxic than methylmercury...”

Toxicologists (the type of scientist that counts on this issue, not immunologists or infectious disease officials) who have followed the ethylmercury literature would say that not enough research has been done on ethylmercury to understand its pharmacokinetics (how it is distributed and metabolized in the body) to make an accurate comparison. The state of the ethylmercury toxicity science is summarized in a recent study by Thomas Burbacher of the University of Washington. His study in primates (*Environmental Health Perspectives*, 2005, <http://ehp.niehs.nih.gov/members/2005/7712/7712.pdf>) funded by

NIH, concluded that the pharmacokinetics of ethylmercury are so different from that of methylmercury, that conclusions about relative adverse effects could not be made.

“The amount of ethylmercury included in each childhood vaccine was once roughly equal to the amount of methylmercury found in the average tuna sandwich.”

The average tuna sandwich is made from chunk light tuna, which has an average mercury concentration of 0.123 ppm (see www.gotmercury.org). The average serving of tuna in a sandwich is 3.5 ounces, or about ½ can. At 0.123 ppm, the mercury content would be about 12 mcg. The typical infant vaccine had 25 mcg of mercury, or twice the amount in the sandwich. Of more critical importance to the layperson’s correct understanding of the tuna sandwich-to-vaccine comparison, are the following necessary components of the complete calculation not mentioned in the article: (a) a sandwich of 12 mcg would be eaten by an adult of average weight of 152 (female) to 180 (male) pounds, versus a vaccine of 25 mcg which would be given to an infant at birth-6 months of only 7-17 pounds average weight, a 9-26 fold difference; and (b) the routine infant vaccine schedule calls for injection of multiple vaccines on one day at 2, 4, and 6 months of age, so a mercury dose on a given day would reach 50-62.5 mcg, which is 4-5 times the amount in the average tuna sandwich.

“By 2001, no vaccine routinely administered to children in the United States had more than half of a microgram of mercury...”

This statement implies that full-dose (12.5-25 micrograms of mercury) thimerosal vaccines were no longer being administered to children in the year 2001, when throughout 2001 both routine and non-routine vaccines with full dose thimerosal were being given.

1. A 2003 FDA letter to Rep. Dave Weldon shows that pediatric versions of the Merck hepatitis B vaccine were still being distributed for use in children in 2001.
2. Aventis and the FDA announced the new non-thimerosal version of the Aventis DTaP Tripedia only in March of 2001, which means that the old version with thimerosal was being used up throughout 2001, and certainly it would have been used exclusively in January, February, and March 2001. The FDA letter to Dr. Weldon also references Tripedia.
3. Per a study conducted by CDC in September 2001 and reported at the October 2001 ACIP meeting (SafeMinds report on ACIP meeting of October 2001, available upon request), over 5% of the inventory of DTPs, Hibs, and Hep B vaccines in doctors’ offices participating in the Vaccine For Children’s Program were thimerosal containing. The percentage still at the distributor level was 1% and varied greatly by vaccine type and by state, with up to 12% of some states’ distributor level inventory still containing full dose thimerosal. Since the thimerosal supply was being used up throughout 2001, a study conducted in September means that higher percentages of thimerosal inventory than the

September 5% and 1% would have been found in the months of January-August, 2001.

4. The term “routine” is a technical designation used by the CDC and immunization officials to denote what is recommended for the average child. It is not a term that the average reader understands in that fashion, and it was not explained as a technical term in the article. The average reader would interpret “routine” to mean a vaccine given regularly to children. Using the lay terminology, the influenza and Diphtheria-Tetanus vaccines were given to a substantial percentage of infants in 2001 (as well as each year up to the present). All versions of both of these vaccines contained full dose thimerosal in 2001. Even today, the DT for pediatric use in multi-dose vials still has full dose thimerosal, and last flu season about half of the pediatric flu shots contained thimerosal.
5. The FDA and the CDC have never made a public statement as to when all thimerosal-containing routine infants vaccines were no longer administered. They only state when the new non-thimerosal or trace thimerosal versions were approved for manufacturing and distribution. There was never a recall of thimerosal-containing vaccines, and the shelf-life is many years long (generally 18-30 months but this can be extended depending on a number of factors). Therefore it is not possible to accurately state, as the article did, for the year 2001, that such vaccines were no longer administered.

“And adult flu vaccines still contain the preservative.”

As a point of clarification for readers, infant influenza vaccines still contain the preservative as well as the adult versions. This was true of the flu season just ended and, according to Aventis, will be true for the season starting this fall.

“Dr. Geier and David Geier’s six published studies on the relationship between autism and thimerosal are largely based on complaints sent to the disease control centers by people who suspect that their children were harmed by vaccines.”

The VAERS is a standard post-licensure adverse events reporting system and the reports to the system, as with any AERS, are not called “complaints” but rather reports of adverse events. Per the CDC website containing a paper from MMWR of January 2003 describing the VAERS data 1991-2001 (<http://www.cdc.gov/mmwr/PDF/ss/ss5201.pdf> - page 6), virtually all reports to VAERS were made by health professionals, with less than 5% being made by parents or patients.

VAERS reports were received primarily from vaccine manufacturers (36.2%), state and local health departments (27.6%), and health-care providers (20.0%), with fewer reports filed directly by patients and parents (4.2%), or others (7.3%) (Table 8). Data documented a continuous increase in the proportion of reporting by health-care providers during the 11-year period. The percentage of reports from health-care providers increased from 11.4% in 1991 to 35.3% in 2001.

The improvement in reporting from health-care providers might reflect the efforts of the VAERS working group to enhance communication with physicians through yearly direct mailing, continuing medical education (CME), and other sources. In addition, publications of analyses of VAERS data might have increased health-care providers' recognition of the potential value of reporting.

“In 2003, spurred by parents demands, the C.D.C. asked the Institute of Medicine...to review the evidence on thimerosal and autism”

SafeMinds, as well as other parent groups and Congressman Dave Weldon, MD, asked the IOM not to hold this meeting, saying it was premature to review the evidence when the necessary research had not been completed or published. (The letter from Dr. Weldon is available upon request). A press release by SafeMinds of January 2004 (also available upon request) was finally issued after lengthy but fruitless discussions with the IOM and contains this statement:

The Centers for Disease Control (CDC) has ordered the Institute of Medicine to conduct a February 9th hearing to discuss the relationship between autism and mercury-based vaccines, where reports claiming no link between thimerosal (mercury) in vaccines and autism will be allowed with little response time for opposing scientific views. Safe Minds, an advocacy and research oriented non-profit organization dedicated to eliminating mercury exposure for children, sent the attached letter to the Institute of Medicine (IOM), an arm of the National Academy of Sciences under contract with the CDC, requesting the meeting be postponed and reconfigured to allow the presentation of opposing research. Congressman Dave Weldon (R-FL), a physician, sent a similar letter to the Center for Disease Control's Dr. Julie Gerberding.

“...said Steven Black, director of the Kaiser Permanente Vaccine Study Center. ‘They are doing voodoo science.’ ”

“A study by the World Health Organization...”

“Anders Hviid, et al....”

The WHO study was identified in the sidebar at the bottom of the page as authored by Elizabeth Miller, but failed to identify her as a senior official in Britain's Immunization Department who was responsible for decisions on whether to purchase thimerosal or thimerosal-free diphtheria-tetanus-pertussis vaccine for use in the U.K. during the 1990s to the present. She has a potential conflict of interest about which the reader should be informed.

Anders Hviid, an investigator for one of the Denmark studies shown in the sidebar, is an employee of Statens Serum Insitut, a for-profit government owned vaccine manufacturer which produced thimerosal vaccines for Denmark and for the U.S. market in the 1990s.

He likewise has a potential conflict of interest which should have been noted in the article.

Similarly, Stephen Black of the Kaiser Permanente Vaccine Study Center was quoted as criticizing the Geiers' research. Kaiser Permanente is a partner HMO in the CDC's Vaccine Safety Datalink (VSD) project and the Center receives substantial dollars from the CDC National Immunization Program to conduct vaccine safety and effectiveness work. The VSD process has been a target of criticism by the Geiers. Dr. Black therefore has a potential conflict of interest in his statements, and his ties to the CDC NIP should have been disclosed.

Graphic at bottom sidebar of E Miller study

The graphic is from a study on the safety of the MMR vaccine, also authored by Elizabeth Miller, which had nothing to do with thimerosal.

“But CDC researchers said it was not unusual for studies to evolve as more data and controls are added.”

“The Institute of Medicine said that it saw “nothing inherently troubling” with the C.D.C.’s adjustments...”

Actually, it is unusual for studies to evolve as more data and controls are added, and it is not considered good science to do so. Such practices are regularly criticized by health advocates when occurring during pharmaceutical clinical trials as a technique to obscure unwelcome results. Research protocols are supposed to be designed before study implementation and should not change without valid reasons. When possible beneficial changes are identified after the study is started, these changes must be presented to external independent reviewers for approval. A recent (2005) IOM panel report recognized these deficiencies in the thimerosal VSD study process when it concluded in its executive summary (*Vaccine Safety Research, Data Access, and Public Trust*, IOM, page 6):

The [IOM] committee recommends that an independent review committee with minimal and balanced biases and conflicts of interest be created to...review research proposals from internal researchers and provide oversight of changes in or deviations from research protocols for internal VSD studies...

Mr. Harris and Mr. O'Connor are aware of this IOM panel finding since they wrote an article about it in the *Times* on February 25, 2005. Thus, the IOM vaccine safety panel may not have found fault with the VSD thimerosal analysis adjustments, but a subsequent IOM panel convened specifically to review VSD study protocol practices did. The CDC itself recognized the problems in its practices by removing the CDC's vaccine safety oversight responsibilities from the NIP and placing them in a separate division, as reported by Harris and O'Connor in February.

“The early versions of the study, they said, failed to control for factors like low birth weight...”

The earlier versions of the VSD did in fact control for factors such as low birth weight, as the letter from Lyn Redwood of SafeMinds to the IOM back in 2001 shows (available upon request). An excerpt from the letter is provided below.

When you compare the eligible children in the initial *Risk* presentation (p.15) enrolled from 1992-1996, you will see the population started at 172,280 and decreased to 108,009 with addition of exclusion criteria. The population further decreased from 108,009 to 73,017 with the exclusion of congenital or perinatal disorders. This represents exclusion of an additional 35,082 children, or approximately 1/3rd of the population with congenital or perinatal disorders. If this is true, then these findings are a concern within itself and should be addressed! In the *Assessment* presentation (p.11) the 1997 data was added to the previous population studied. Eligible children at this time were 213,185 and decreased to 132,114 with exclusion criteria. This number further decreased to 109,993 with exclusion again of congenital and perinatal disorders by 22,121, approximately 1/6th of the population. Did changes occur in the exclusion criteria that resulted in 1/6th of the population being excluded verses 1/3rd from the previous investigation? When CDC was queried as to why these children were removed for analysis, their response was that they wanted the “cleanest” possible data. I must question if removing this large percent of the population represents a real life scenario, whereas these congenital and perinatal abnormalities, especially those as mild as 7793: Feeding problems newborn, 7671: scalp injury, and 7706: transient tachypnea of the newborn, would not necessarily result in medical exemptions from vaccination. I think it is also very difficult to exclude some perinatal abnormalities, when many of these infants received their first dose of vaccine at birth and the “perinatal” abnormality may have arisen from the thimerosal exposure itself.

“No such decline followed thimerosal’s removal from vaccines during the 1990s in Denmark, Sweden, or Canada, researchers say.”

There have been no published epidemiology studies of autism prevalence among Canadian children born after thimerosal was removed from infant Canadian vaccines.