

CHAMP

CHILDREN HAVING ADVOCATES AGAINST MERCURY POISONING

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Dept. of Health and Human Services
Room 1061, 5630 Fishers Lane
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October 25, 2004

RE: FDA Docket #2004P-0349

To Whom It May Concern:

Part I: Introduction and Charge to FDA

These comments are being submitted in support of the Citizen Petition dated July 30, 2004, filed by Coalition for Mercury-Free Drugs with the FDA Dockets Management Division on August 4, 2004, and subsequently assigned FDA Public Docket number 2004P-0349.

Children Having Advocates Against Mercury Poisoning (CHAMP) admonishes the FDA to immediately suspend authorization for the use of Thimerosal-containing vaccines and to issue the appropriate recalls. CHAMP also urges the withdrawal of any and all FDA-regulated pharmaceutical products containing said mercury-based compound.

According to HHS, the CDC, and the AAP, the number of children with autism is now 1 in 166.

<http://www.medicalhomeinfo.org/screening/Autism%20downloads/AutismAlarm.pdf>

Care for these children is predicted to cost in the trillions of dollars. One family in 68 in our nation is now impacted.

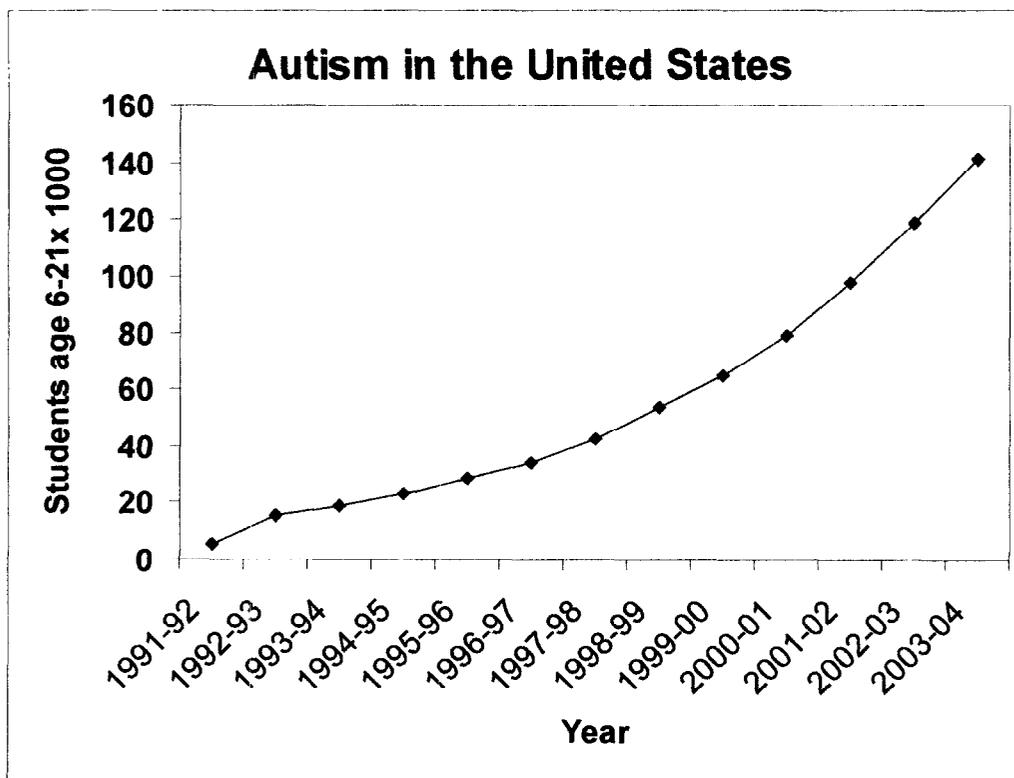
The Individuals with Disabilities Education Act (IDEA) was enacted in 1975. The Department of Education (DOE) reports annually to the United States Congress in compliance with IDEA. Earlier, autism and autistic spectrum disorders were not common and were included with other disabilities. As the prevalence of "autism" increased, a decision was made to list it as a separate entity starting in 1991, and the DOE reported that 5,415 affected students aged 6 to 21 attended US schools during the 1991-1992 school year.

The number of students with autism attending US schools has increased steadily since then and has reached 140,820 students in the 2003-2004 school year. (See Graph 1.)

No other disability listed in the Annual Reports to Congress has increased at that same rate.

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Graph 1 Children with a diagnosis of autism ages 6-21 attending US schools
(Source: US DOE Annual Reports to Congress (IDEA))

The Diagnostic and Statistical Manual of Mental Disorders – Fourth Edition (DSM-IV) was published by the American Psychiatric Association in 1994. Since then, uniform criteria have been used for the diagnosis of autism and autistic spectrum disorders. According to the Department of Education (DOE), the average yearly increase among students ages 6-21 in US schools since the introduction of DSM-IV has been 21.92%. (See Table 1.)

School Year	Students	Percent Increase
1994-95	22,780	
1995-96	28,813	26.48
1996-97	34,082	18.28
1997-98	42,487	24.66
1998-99	53,561	26.06
1999-00	65,391	20.86
2000-01	78,717	20.37
2001-02	97,847	20.61
2002-03	118,603	21.21
2003-04	140,922	18.81

Table 1 Number of students with autism ages 6-21
(Source: US DOE Annual Reports to Congress (IDEA))

The longer the FDA waits, the higher the incalculable cost in human suffering, and the higher the cost to overburdened school systems, social service systems, healthcare systems, states, taxpayers, and families. And while these must grapple with the extreme financial burdens in caring for so many autistic/mercury-poisoned citizens, legislators and/or governmental agencies discuss cutting corners, further precluding help to these societal institutions. There are more subtle costs to society, too: Crime and recidivism, for example, arising from the malevolent behavior

of a generation of mercury-impaired youths, the lack of fiscal contribution from the impaired; the inability of these citizens to care for their aged parents; and, the inability of these citizens to care for themselves when their parents are gone.

The only entities not bearing the cost of the autism/mercury-poisoning epidemic – which are also profiting in the meantime - are the entities that poisoned the children. Attempts to protect these entities are made by legislators and/or governmental agencies.

It is time to stop covering up the damage. It is time to prevent further damage.

Part II: Scientific Background

Our nation has seen a huge upsurge in the prevalence of developmental disorders in children since the early 1990's. During this period we have seen a corresponding increase in the use of vaccines that contain thimerosal. Thimerosal is an anti-microbial agent or "preservative" containing 49.6% ethyl mercury by weight. It was first added to vaccines in the 1930's; Leo Kanner "discovered" autism in the 1940's among children born in the 1930's. Mercury and Thimerosal have been shown in thousands of scientific papers to be potent neurotoxins. Thimerosal was placed in many vaccines (e.g. Hepatitis B, DPT, HIB, among others) that are part of the childhood immunization schedule. It is also in the influenza vaccine that is currently being recommended, including for infants, young children, and pregnant women.

In an article in the New York Times of November 10, 2002, entitled *The Not-So-Crackpot Autism Theory*, we read Pediatrician Neal Halsey, MD, who served on the Advisory Committee for Immunization Practices for the CDC and American Academy of Pediatrics committee on infectious diseases, quoted as saying, "My first reaction was simply disbelief, which was the reaction of almost everybody involved in vaccines. In most vaccine containers, thimerosal is listed as a mercury derivative, a hundredth of a percent. And what I believed, and what everybody else believed, was that it was truly a trace, a biologically insignificant amount. My honest belief is that if the labels had had the mercury content in micrograms, this would have been uncovered years ago. **But the fact is, no one did the calculation.**" (Cited: Allen, The New York Times, *The Not-So-Crackpot Autism Theory*, November 10, 2002, emphasis added.)

In view of a recent study published in the November 2003 issue of Pediatrics (Verstraeten et al.), Congressman Dave Weldon, M.D. wrote a letter to Julie Gerberding, M.D., Director of the CDC. In his letter, Congressman Weldon states, "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 found a disturbing pattern which merits a thorough, open, timely, and independent review by researchers outside of the CDC, HHS, the vaccine industry, and others with a conflict of interest in vaccine related issues (including many in University settings who may have conflicts). 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 1990's, there may have been a selective use of the data to make the associations in the earliest study disappear..." Of particular note, is that a CDC official who helped write the report that appeared in the November issue of Pediatrics, scientist Frank DeStefano, admitted that the study contained many children too young to be diagnosed as autistic. (Cited: Munro, National Journal, *Missing the Mercury Menace*, January 3, 2004.)

Toxicological tests show that through chelation, autistic children are excreting large amounts of mercury. Many parents have seen improvement through this treatment. A published study shows that autistic children excrete more mercury through chelation than healthy controls. [Cited: Bradstreet, et al. *A Case-Control Study of Mercury Burden in Children with Autistic Spectrum Disorders*, Journal of American Physicians & Journal of American Physicians & Surgeons (2003).]

The striking similarity in symptoms between mercury poisoning and autism is well documented in a seminal article authored by parent/scientist researchers. [Cited: Bernard, et al. *Autism: A Novel Form of Mercury Poisoning, Medical Hypothesis*, 2001.]

The dramatic increase of the prevalence of autism is documented by a study conducted by the MIND Institute of the University of California. This showed that the enormous increase in the 1990's in the incidence of autism was real and "cannot be explained by a loosening in the criteria used to make the diagnosis," "misclassification" of other disorders, greater awareness of the disorder, or migration by parents to California seeking services. [Cited: The

Epidemiology of Autism in California, MIND Institute, 2002.] “Coincidentally” once the Thimerosal that children received in California recently decreased, *so did the rate of autism*.

The evidence that Thimerosal has been a major cause of the increased prevalence of autism is based on laboratory and epidemiological studies. The affidavit of Boyd Haley, Ph.D., Chair, Chemistry Dept., University of Kentucky, presents evidence showing that thimerosal is a cause of developmental disorders in children. [Cited: *Affidavit of Boyd E. Haley*, Professor and Chair, Department of Chemistry, University of Kentucky, 2002.] Dr. Haley concludes that biochemical toxicity studies and other evidence show that the only explanation for the increased incidence of autism and related disorders is the release of ethyl mercury from Thimerosal injected into children. Recent discoveries made by researchers investigating biochemical processes demonstrate that Thimerosal has a powerful inhibitory effect on essential metabolic processes that are required for our children to develop properly. [Cited: Deth, Molecular Origins of Human Attention-The Dopamine-Folate Connection, Ch. 13 "Autism", Kluwer press, 2003.] “The ethylmercury-containing preservative thimerosal inhibited both IGF-1- and dopamine-stimulated methylation with an IC(50) of 1 nM and eliminated MS activity. Our findings outline a novel growth factor signaling pathway that regulates MS activity and thereby modulates methylation reactions, including DNA methylation. The potent inhibition of this pathway by ethanol, lead, mercury, aluminum and thimerosal suggests that it may be an important target of neurodevelopmental toxins.” [Cited: Waly, M, Deth, R, et al., *Activation of methionine synthase by insulin-like growth factor-1 and dopamine: a target for neurodevelopmental toxins and thimerosal*, Mol Psychiatry, 2004 Apr;9(4):358-70.] Additional research by Dr. Haley and others has shown that infants with autism are excreting less mercury from their bodies than normal children even though their exposure to mercury is greater. [Cited: Holmes, Blaxill, Haley, *Reduced Levels of Mercury in First Baby Haircuts of Autistic Children*, International Journal of Toxicology, August 2003]

The neurotoxicity of methyl mercury in fish has been well documented. Some have argued against the neurotoxicity of thimerosal in vaccines by pointing out that it contains ethyl mercury, which purportedly acts on the body differently from methyl mercury. Dr. Haley explains, however, that thimerosal has a delayed breakdown rate in the human body, the “partitioning” factor, that enables the ethyl mercury component to be more toxic than it would be if not contained in the thimerosal compound. (Haley Affidavit) Recent research shows that thimerosal is highly toxic to human cells in very minute (“micromolar”) concentrations and kills human cells at a rapid rate. [Cited: Baskin, et al., *Thimerosal Induces DNA Breaks, caspase-3 activation, membrane damage, and cell death in cultured human neurons and fibroblasts*, ToxSci Advance Access, published May 28, 2003.] These findings are consistent with the findings of Doctors Haley and Deth. The findings show that Thimerosal, like lead, is toxic to humans in concentrations much lower than originally thought. The FDA itself, moreover, has discovered that “[t]himerosal ... crosses the blood-brain and placental barriers and results in appreciable mercury content in tissues including brain.” [Cited: Slikker, Division of Neurotoxicology, National Center for Toxicological Research/FDA Jefferson, AR., quoted from Neurotoxicology, 2000 Feb-Apr;21(1-2):250.] Thus, the scientific literature shows that this highly toxic substance can easily poison a child’s brain. More than twenty years ago researchers examining Thimerosal concluded as follows,

“Thus thimerosal, commonly used as a preservative, has been found not only to render its primary toxic effect, but also 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.” [Cited: English abstract (emphasis added) of Kravchenko, AT, Dzagurov, SG, Chervonskaia GP. *Evaluation of the toxic action of prophylactic and therapeutic preparations on cells cultures. Communication III. Revealing cells cultures. Revealing the toxic properties of medical biological preparations from the degree of cell damage in continuous cell line L132.* Zh Mikrobiol Epidemiol Immunobiol 1983; 3:87-92.]

A recent study showed that inoculation of susceptible mice with Thimerosal in amounts mimicking the childhood vaccine schedule causes neurological and immune disorders similar to disorders found in our children. [Cited: Hornig et. al, *Neurotoxic effects of postnatal thimerosal are mouse strain*, Molecular Psychiatry, 2004.]

An epidemiological study by Dr. Mark Geier and David Geier published in 2003, based on data collected in the Centers for Disease Control’s VAERS (Vaccine Adverse Event Reporting System) database concluded that a causal link does exist between thimerosal and neurodevelopmental problems. [Cited: Geier, *Thimerosal in Childhood Vaccines, Neurodevelopmental Disorders, and Heart Disease in the United States*, Journal of American Physicians and Surgeons, Vol. 8, No. 1, Spring 2003.] These and other peer-reviewed articles by Dr. Geier strongly support the Thimerosal link to neurodevelopmental disorders.

As far as epidemiology goes, we have learned that the Centers for Disease Control knew in 2000, through an unreleased confidential study, that Thimerosal was a problem. At a CDC conference of leading vaccine experts held in Norcross, Georgia on June 7-8, 2000 the author of a CDC epidemiological study, Thomas Verstraeten reported: **"...we have found statistically significant relationships between the exposure and outcomes for these different exposures and outcomes. First, for two months of age, an unspecified developmental delay, which has its own specific ICD9 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 ICD9 codes. Exposures 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."** [Cited: Minutes of Scientific Review of Vaccine Safety Datalink Information (Simpsonwood minutes), June 7-8, 2000, Simpsonwood Retreat Center, Norcross, Georgia, page 40.]

Later, Dr. Verstraeten states, **"Now for speech delays, which is the largest single disorder in this category of neurologic delays. The results are a suggestion of a trend with a small dip. The overall test for trend is highly statistically significant above one."** [Cited: Simpsonwood minutes, page 44.]

Another participant at the conference stated, **"One, up until this last discussion we have been talking about chronic exposure. I think it's clear to me anyway that we are talking about a problem that is probably more related to bolus acute exposures, and we also need to know that the migration problems and some of the other developmental problems in the central nervous system go on for quite a period after birth. But from all of the other studies of toxic substances, the earlier you work with the central nervous system, the more likely you are to run into a sensitive period for one of these effects, so that moving from one month or one day of birth to six months of birth changes enormously the potential for toxicity. There are just a host of neurodevelopmental data that would suggest that we've got a serious problem. The earlier we go, the more serious the problem. The second point I could make is that in relationship to aluminum, being a nephrologist for a long time, the potential for aluminum and central nervous system toxicity was established by dialysis data. To think there isn't some possible problem here is unreal."** [Cited: Simpsonwood transcript, page 24.]

One wonders why neither the Simpsonwood transcript nor the Verstraeten report that was discussed at the Simpsonwood conference were made public. Both documents were finally obtained through Freedom of Information Act requests. These documents raise a host of questions about vaccine safety and government accountability. [Cited: Verstraeten et al, Thimerosal VSD Study, Phase One, Update, 2/29/00.]

Insufficient safety testing was done before using Thimerosal in vaccines. Numerous articles are in the National Library of Medicine contraindicating the use of mercury-containing substances. The company that held the patent on Thimerosal was advised of contraindications for use, but the government attempted to protect that corporation from liability.

The FDA can view the destructiveness of mercury upon neurons, as researchers at the University of Calgary have visually demonstrated that mercury kills brain neurons:
http://www.fp.ucalgary.ca/unicomm/news/March_01/mercury.htm

Dr. Boyd Haley explains that Thimerosal has a delayed breakdown rate in the human body, the "partitioning" factor, which enables the ethylmercury component to be more toxic than it would be if not contained in the Thimerosal compound. [Cited: *Affidavit of Boyd E. Haley*, Professor and Chair, Department of Chemistry, University of Kentucky, 2002] Also according to Dr. Haley, "If the protein component of a vaccine contains any cysteine amino acid residues in its basic structure then this cysteine would most likely have an ethyl-mercury moiety [group] bound to it if the vaccine protein were exposed to thimerosal during any time in its manufacture." This is due to the high affinity of the sulfhydryl group (-SH group) for ethylmercury." This indicates that even if thimerosal is simply used in the manufacturing process, that it is likely that ethylmercury will remain in the finished product.

In the abstract for **"Inhibitory action of thimerosal, a sulfhydryl oxidant, on sodium channels in rat sensory neurons"** we read, "The effects of thimerosal, a sulfhydryl oxidizing agent, on tetrodotoxin-sensitive (TTX-S) and tetrodotoxin-resistant (TTX-R) sodium channels in rat dorsal root ganglion neurons were studied using the whole-cell patch clamp technique. Thimerosal blocked the two types of sodium channels in a dose-dependent manner. The inhibitory effect of thimerosal was much more pronounced in TTX-R sodium channels than TTX-S sodium channels. The effect of thimerosal was irreversible upon wash-out with thimerosal-free external solution. However, dithiothreitol,

a reducing agent, partially reversed it. Thimerosal shifted the steady-state inactivation curves for both types of sodium channels in the hyperpolarizing direction. The voltage dependence of activation of both types of sodium channels was shifted in the depolarizing direction by thimerosal. The inactivation rate in both types of sodium channels increased after thimerosal treatment. All these effects of thimerosal would add up to cause a depression of sodium channel function leading to a diminished neuronal excitability." [Cited: Song J, et. al, *Inhibitory action of thimerosal, a sulfhydryl oxidant, on sodium channels in rat sensory neurons*, Brain Res, 2000 May 2;864(1): 105-13.]

Up until 1999, children were receiving, via vaccinations, more than 100 times the amount of mercury than EPA would consider "a level not likely to cause harm". (Note that it does not say "safe".) However, the EPA's guidelines pertain to methylmercury that, again, is less toxic than the ethylmercury in vaccines. *Ethylmercury is preferentially taken up by the brain.* Though the levels of mercury have been reduced, mercury still remains in many vaccines and no agency has established that the current levels are safe. Children often receive more than one vaccine at a time, increasing the cumulative amount of mercury in their bodies and brains. This is *mercury*, a known neurotoxin and the second most toxic substance on earth after plutonium. The material safety data sheet (MSDS) for Thimerosal says: "DANGER! POISON! MAY BE FATAL IF INHALED ABSORBED THROUGH SKIN OR SWALLOWED...MAY CAUSE DAMAGE TO CENTRAL NERVOUS SYSTEM."

(<http://www.setonresourcecenter.com/MSDS/EMD/Docs/wcd00026/wcd026b4.pdf#xml=http://www.setonresourcecenter.com/dtSearch/dtisapi6.dll?cmd=getpdfhits&DocId=107871&Index=D%3a%5cINDEX%5cMSDS&HitCount=9&hits=d+10d+258+3b3+479+57c+6a0+738+74e+&.pdf>)

Incredibly, children in the U.S. now receive 45 injected vaccines by the age of 6 months, 64 by 18 months and 74 by 4-6 years. (See: <http://www.cdc.gov/nip/default.htm>.) The general public is unaware of these numbers because some of these injections combine up to eight vaccines in one "shot", obscuring the fact that there are such a large number of actual vaccines. These multiple doses are some of the most dangerous.

Pharmaceutical companies have more than 200 vaccines in the pipeline, and government agencies, such as CDC, are only too eager to assist in recommending them since these agencies are little more than mouthpieces and revolving doors for industry, promoting pharmaceutical-sponsored studies as "science". Independent researcher Dr. Sherri Tenpenny has studied CDC's own data, exposing insufficient vaccine testing and unsupported safety claims. (See, for example: http://www.mercola.com/forms/vaccine_video.htm http://www.worldnetdaily.com/news/article.asp?ARTICLE_ID=36023 <http://www.mercola.com/2002/jun/5/thimerosal.htm>.)

The Committee on Government Reform's 80-page Mercury in Medicine report concludes as follows. "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." [Cited: Subcommittee on Human Rights and Wellness, Committee on Government Reform, United States House of Representatives, Mercury in Medicine: Taking Unnecessary Risks, May 2003].

Part III: Current Situation

According to an October 4, 2004 news report of KLKN-TV (Lincoln, Nebraska), "**Aventis Ships 30 Million Doses of Influenza Vaccine to Health-care Providers.**" (See: <http://www.klkntv.com/Global/story.asp?S=2385064>). According to an article, "**Flu Shots Will Be Earmarked for Neediest,**" (found on the worldwide web [www] at <http://www.medicinenet.com/script/main/art.asp?articlekey=39803>), "Aventis is producing 55 million doses of shots." So, if, according to Julie Gerberding, director of the CDC, in the same article, "Gerberding estimated that 42 million to 50 million people will meet the CDC's high-risk criteria and will request a vaccination," then how many of the "neediest," including infants, will be receiving 25 mcg. of mercury? Unfortunately, according to Dr. William Egan, Acting Director, Office of Vaccines Research and Review, CBER, FDA on October 5, 2004, before the Subcommittee on Labor, Health and Human Services, Education and Related Agencies, Committee on Appropriations, House of Representatives, "For the current flu season, AP is producing about 4.6 million doses of the preservative-free pediatric presentation" (See: <http://www.fda.gov/ola/2004/vaccines1005.html>). That's a difference of about 50 million doses. How many infants, young children, and pregnant women will not have a "Thimerosal free" (factually, Thimerosal reduced, but not Thimerosal free) version available to them? Also, at this same meeting, an eyewitness reports that Egan said that he "was not aware" of any safety studies on Thimerosal, except the 1930's meningitis one. He was trying to say that somewhere maybe someone had done a study, but "he

was not aware" of it. Aventis makes Fluzone. The Fluzone vaccine package insert states: "Fluzone vaccine is supplied in a 0.5 mL prefilled syringe and 5 mL vial of vaccine, both of which contain the preservative thimerosal [(mercury derivative), (25 mcg mercury per dose)]. Why does the prefilled syringe need 25 mcg of thimerosal? What is the rationale for needing this amount in a single-dose delivery system? This is not what remains from the manufacturing process

Does Thimerosal even function reliably effectively as a preservative as publicly proclaimed? In "**Outbreaks of Group A Streptococcal Abscesses Following Diphtheria-Tetanus Toxoid-Pertussis Vaccination**," (Stetler, et. al, Pediatrics, Vol. 75 No. 2, February 1985) we read. "At currently used concentrations, Thimerosal is not an ideal preservative. However, because Thimerosal is an organic mercurial compound, higher concentrations might reduce vaccine potency or pose a health hazard to recipients". This article was co-authored by Dr. Walter Orenstein, then of the CDC. And, if it is not reliably effective as a so-called "preservative," then 1) it should not be advertised or on labels as such, and 2) if it is really used as a sterilizing agent / bactericide so that vaccines can be produced in sub-optimal conditions, then, why did the Chiron influenza vaccines of 2004 get discarded due to bacterial contamination, being contaminated with *Serratia marcescens* despite the use of Thimerosal? (Note: Dr. Orenstein was the head of the National Immunization Program (NIP) of the CDC until March 2004.)

How can Americans be expected to trust vaccines? In part, because the preceding health and safety issues and others have been concealed from them, they cannot. Furthermore, in a World Health Organization (WHO) memo, *WHO Informal Meeting on Removal of Thimerosal From Vaccines And Its Implications For Global Vaccine Supply*, May 21, 2002 at the WHO Headquarters in Geneva, we read: "The participants recognized that risk of contamination in the field is a real and serious safety risk, whereas safety problems associated with uptake of ethyl mercury following vaccination with thimerosal-containing vaccines is as yet unproven." And, "Develop a strong advocacy campaign to support ongoing use of thimerosal." This doesn't make sense because:

- 1) We have seen that Thimerosal does not reliably prevent bacterial contamination;
- 2) We have seen that Thimerosal-containing vaccines with bacterial contamination have posed a risk;
- 3) We have seen the risk of ethylmercury; and
- 4) We have seen that there is a real epidemic and a real risk of autism spectrum and neurodevelopmental and behavioral disorders.

Back on July 16, 2001, at the Institute of Medicine Immunization Safety Review Committee meeting, Thimerosal-Containing Vaccines and Neurodevelopmental Outcomes, Dr Neal Halsey stated, "I was also asked to answer the question, why are additional studies needed now when Thimerosal has been removed. Again, at least three other people have answered, and I'll give the same answer. I wrote a letter a long time ago to CDC about this. The public does deserve an answer. If there really is an effect that is there, then this should be brought in front of the Vaccine Injury Compensation Program, and that process will take years to sort out. The exposures are going on in other countries. There are at least 70 different manufacturers of whole-cell DTP around the world. Those developing country manufacturers are never going to remove Thimerosal as a preservative on their own. They are going to need international help. We aren't going to be able to mobilize international bodies to help them, unless there is more evidence of an effect, because they don't believe it right now. So we do have an obligation in my opinion to generate the data, since we have the potential for looking at that. ... I was reassured in January of 2000 when there was a publication in *Weekly Epidemiological Record* indicating that the WHO expanded immunization program was making a commitment to do what they could to make the changes, after input from some representatives from our FDA, who reviewed all of this data with them in depth. **I think unfortunately, I don't see that action as happening.** The answer is, based on what I have learned from January of 2000 until now, and especially at this meeting from many of the others who have presented, I believe the evidence is more than sufficient that they should be moving as fast as possible. We need to do what we can to assist other countries in removing Thimerosal as a preservative ..." (Emphasis added.) [Cited: National Academy of Sciences, Institute of Medicine, Immunization Safety Review Committee; *Thimerosal-Containing Vaccines And Neurodevelopmental Outcomes Public Meeting minutes*; July 16, 2001.]

So, did the WHO influence the CDC, and did the CDC influence the IOM, and did the IOM issue a deceptive determination on February 9, 2004 saying that there was no causal association between Thimerosal and autism, and was any of this intended to influence the Special Master towards not ruling in favor of vaccine-injured/mercury-poisoned/autistic children with regard to vaccine court, and influence the Special Master towards ruling in favor of pharmaceutical company protection from liability? And how much do pharmaceutical companies influence the FDA?

Part IV: Additional Background and Query as to FDA Inaction

“Fagan et al. reported, in a study funded by the National Institute of Environmental Health Sciences, 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 (emphasis added).”** The authors also concluded 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.” (Cited: *Mercury in Vaccines: “Institutional Malfeasance” & the Department of Health and Human Services*, 2004, referencing [Fagan DG, et. al; *Organ Mercury Levels in Infants with Omphaloceles Treated with Organic Mercurial Antiseptic*; Arch Dis Child 1977;52:962-964]).

“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.... 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.... **They stated that while organic mercury compounds like thimerosal were initially developed to decrease 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.” (Cited: *Mercury in Vaccines: “Institutional Malfeasance” & the Department of Health and Human Services*, 2004, referencing [Subcommittee on Human Rights and Wellness, Government Reform Committee; *Mercury in Medicine Report*; Washington, DC: Congressional Record, May 21, 2003]).

“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 another 18 years.... It is difficult to understand why it took the FDA 18 years to do this with regard to 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: “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?” (Cited: *Mercury in Vaccines: “Institutional Malfeasance” & the Department of Health and Human Services*, 2004, referencing [Subcommittee on Human Rights and Wellness, Government Reform Committee; *Mercury in Medicine Report*; Washington, DC: Congressional Record, May 21, 2003]).

In the FDA Consumer magazine article entitled “*OTC Options: Help for Cuts, Scrapes and Burns*” of May 1996 we read, “The proposal would ban numerous antiseptics, including mercurials, as ineffective and some, including thimerosal, as also unsafe,” and, “The proposal would ban numerous mercury ingredients and cloflucarban, fluorosalan and tribromsalan antiseptics as not generally recognized as safe and effective for OTC use.” (See: http://www.fda.gov/fdac/features/496_cuts.html). So, why is it safe to inject it?

In the abstract for “*Evidence for delayed neurotoxicity produced by methylmercury*,” we read: “Delayed toxicity as a result of developmental methylmercury exposure was identified in mice two decades ago by Spyker, who observed kyphosis, neuromuscular deficits, and other severe abnormalities as the mice aged. Delayed neurotoxicity was also

observed in monkeys treated with methylmercury from birth to seven years of age. When these monkeys reached 13 years of age, individuals began exhibiting clumsiness not present previously. Further exploration revealed that treated monkeys required more time to retrieve treats than did nonexposed monkeys and displayed abnormalities on a clinical assessment of sense of touch in hands and feet, despite the fact that clinical examinations performed routinely during the period of dosing had not yielded abnormal results. Another group of monkeys, dosed from in utero to four years of age, also took longer to retrieve treats when assessed years after cessation of exposure. These observations were pursued in both groups of monkeys by objective assessment of somatosensory function in the hands: both groups of monkeys exhibited impaired vibration sensitivity. These results are strongly suggestive of a delayed neurotoxicity manifested when these monkeys reached middle age. **Data from persons with Minamata disease also provide evidence for delayed neurotoxicity. Perhaps the strongest pieces of evidence comes from a study of over 1100 Minamata patients over 40 years old, in which difficulty in performing daily activities increased as a function of ages compared to matched controls.** Methylmercury may represent the only environmental toxicant for which there is good evidence for delayed neurotoxicity that may be manifested many years after cessation of exposure ” (Emphasis added.) [Cited: Rice DC, *Evidence for delayed neurotoxicity produced by methylmercury*, Neurotoxicology, 1996 Fall-Winter; 17(3-4): 583-96.]

In a recent article entitled *Japanese Government Found Partly to Blame for Minamata Disease*, (see <http://quote.bloomberg.com/apps/news?pid=10000101&sid=a8SulqiNMJE4&refer=japan>), we read, “Japan’s Supreme Court said the government shares responsibility for the spread of Minamata mercury-poisoning disease in the 1950s and 1960s, closing years of litigation in the environmental contamination case. It was the first Supreme Court judgment on the government’s responsibility in the 48-year history of the disease. Judge Hiroharu Kitagawa upheld a 2001 high court ruling that the central government and a local government must compensate victims, along with chemical maker Chisso Corp... The disease killed hundreds of people, disabled thousands and produced birth defects in the city of Minamata, Kumamoto prefecture, on Kyushu Island. The poisoning was caused by seafood contaminated with organic mercury that Chisso dumped into the local bay. Chisso, founded in Minamata in 1908, was using methyl mercury to make acetaldehyde, a material for polyvinyl chloride. Minamata disease was detected in 1953. The company discharged untreated factory waste into Minamata Bay until 1968, when the government recognized the emissions as the cause of the disease.” I have a brief video of clips showing children who were mercury poisoned by the Minamata Bay debacle interspersed with children with autism – that is, children who have been poisoned by the Thimerosal debacle. Please examine and post this very brief video to the FDA website. The comparison is chilling and saddening. In fact, though not one of those filmed, my son could have been one of the children filmed in this video, as could so many other vaccine-injured / mercury-poisoned / “autistic” children in this country. I have included with this letter one of my son’s Urine Toxic Metals tests; this lab report shows a very elevated level of mercury. My son was injected with mercury via many of his routine, recommended childhood vaccines. You can find lab tests such as this one from a multitude of children across the United States.

Mercury is genotoxic. One study that substantiates this is, “*Inhibition of the human erythrocytic glutathione-S-transferase T1 (GST T1) by thimerosal.*” In the abstract for this we read, “We have investigated the interaction of thimerosal, a widely used antiseptic and preservative, with the human erythrocytic GST T1 (glutathione-S-transferase T1). This detoxifying enzyme is expressed in the erythrocytes of solely the human species and it displays a genetic polymorphism. Due to this polymorphism about 25% of the individuals of the Caucasian population lack this activity (“non-conjugators”), while 75% show it (“conjugators”) (Hallier, E., et al., 1993). Using our newly developed HPLC-fluorescence detection assay (Muller, M., et al. 2001) we have profiled the kinetics of enzyme inhibition in erythrocyte lysates of two individuals previously identified as “normal conjugator” (medium enzyme activity) and “super-conjugator” (very high activity). For the normal conjugator we have determined a 2.77 mM thimerosal concentration to inhibit 50% of the GST T1 activity. In the case of the super-conjugator a 2.3 mM thimerosal concentration causes a 50% inhibition of the enzyme activity. For both phenotypes a 14.8 mM thimerosal concentration results in residual enzyme activities equal to those typically detected in non-conjugator lysates. Thus, sufficiently high doses of thimerosal may be able to change the phenotypic status of an individual – **at least in vitro** – by inhibition of the GST T1 enzyme. (Emphasis added.) [Cited: Muller et al, *Inhibition of the human erythrocytic glutathione-S-transferase T1 (GST T1) by thimerosal*, Int J Hyg Environ Health, 2001 Jul; 203(5-6):479-81].

The FDA began to recommend over two decades ago for caution and/or removal of mercurial ingredients from pharmaceutical products; so, **WHY IS IT STILL IN – AND NEWLY BEING PROMOTED – IN INJECTABLE VACCINES FOR FETUSES, INFANTS, AND CHILDREN?**

Thank you,

Mrs Teri Small
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