

CoMeD

Coalition for Mercury-free Drugs
Virginia Representative
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March 15, 2005

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Dear Senator Grassley, Congressman Burton, and Congressman Weldon:

The conflicts-of-interest that plague our national health agencies have inflicted an on-going plague of neurological disorders upon our nation's children. We know this is true because our very own children, whose neurological development was compromised by the untested and unsafe mercury-based preservative Thimerosal, are numbered among the stricken and disabled.

By failing to require the drug industry to rigorously prove that drugs, including vaccines, which contain mercury compounds, are no less safe than the same drugs without the mercury, as required by law, the FDA has failed in its mission to protect the public health, and has instead demonstrated gross institutional negligence. Currently, the federal health agencies, culpable for the catastrophic injuries inflicted upon our children, seem to be engaged in criminal conspiracy and collusion with the manufacturers of mercury-containing drugs approved by the FDA.

Incredibly, our federal officials continue to assert that unnecessary and neurotoxic mercury compounds in our medicines present only a "theoretical" risk of harm. Since we have laboratory reports that show our neurologically-damaged children, some only 3 or 4 years old, excrete levels of mercury after chelation that are typically only found in persons poisoned in industrial mercury-exposure accidents, *as the example report on the next page shows*, we know that this risk is NOT "theoretical."

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Patient: [Redacted]
 Doctor: [Redacted]
 c/o: [Redacted]
 Collection Date: 5 Nov 2000
 Date In: 8 Nov 2000

Lab #: 99678-0118
 Age: 4 Sex: Male
 Acct #: 18926
 Collection Type: Random
 Time:
 Date Out: 9 Nov 2000

Elements	Per gram Creatinine		Within Ref. Range	Elevated	Very Elevated
	Result (µg/g creatinine)	Reference Range* (µg/g creatinine)			
Aluminum	26	0 - 35		
Antimony	.4	0 - 5	•		
Arsenic	98	0 - 100		
Beryllium	< dl	0 - .5			
Bismuth	.8	0 - 30	•		
Cadmium	1.4	0 - 2		
Lead	12	0 - 15		
Mercury	15	0 - 3		
Nickel	21	0 - 12		
Platinum	.2	0 - 2	•		
Thallium	.2	0 - 14	•		
Thorium	< dl	0 - 12			
Tin	5.5	0 - 6		
Tungsten	< dl	0 - 23			
Uranium	< dl	0 - 1			

	Result (mg/dl)	Reference Range (mg/dl)	2 SD Low	1 SD Low	MEAN	1 SD High	2 SD High
Creatinine	43.4	21 - 76			***		

Methodology: Analyzed by Induction Coupled Plasma Mass Spectrometry (ICP-MS). Creatinine by Jaffe method.
 "dl"=detection limit.
 *No safe levels established.

Comments:
 (Pos: provocative challenge.)
 cc to pr & file

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Tragically, *as a result of the FDA's ongoing failure to require rigorous proof of safety*, our children, their bodies, their constitutional rights, their bodily integrity, and the Food and Drug Cosmetic Act are being violated on a daily basis. While we have pleaded with the federal agencies to protect American children from this clear and present danger, instead, these agencies act to protect themselves and the pharmaceutical industry, *at the expense of our children who remain in harm's way*. Mandating the injection of poison into the nation's unborn and newborn children is the most insidious corruption of federal policy to have ever marred the history of our great nation, and it must be halted now.

In March of 2004, hundreds of parents, *knowing their children were damaged by the Thimerosal in vaccines administered to their children*, conducted a letter-writing campaign to the Office of Special Counsel, seeking to enlist its help in safeguarding unborn and newborn children from mercury exposure and intoxication. Our letters detailed nine specific charges against Health and Human Services (HHS), the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and the February 9, 2004 Institute of Medicine (IOM) meeting. These allegations prompted official replies from the Office of Special Counsel (OSC—File No. DI-04-1400), the President's Council on Integrity and Efficiency (PCIE—file: IC # 437), and the Government Accountability Office (GAO—case control number 45870), among others, and resulted in calls for the following:

- ❖ A Congressional Investigation, to be directed to Senator Judd Gregg and Congressman Joe Barton, addressing our urgent concerns regarding vaccine safety, and
- ❖ An investigation by the Office of the Inspector General for Health and Human Services to address what Deputy Director for Investigations, Michael E. Little, has deemed a “potential conflict of interest issue which may be criminal in nature(.)”

Although these urgent requests were made in the first half of 2004, *no* investigations have yet been undertaken and *not one* public warning has been issued to protect citizens, especially children, from “a substantial and specific danger to public health caused by the use of (T)himerosal/mercury in vaccines because of its inherent toxicity” (Special Counsel Scott Bloch's letter to Congress). Joe Barton and Judd Gregg remain unresponsive to inquiries, and HHS-OIG has spent six months conducting “preliminary research” without even opening a formal investigation. Such inaction, resulting in more wasted lives and broken families, is reprehensible. Those forestalling the investigation of these charges would seem to be guilty of obstruction of justice and, possibly, criminal conspiracy.

While, as a nation, we fear terrorist poisoning our water supply, the Food and Drug Administration continues to permit the pharmaceutical industry to poison some of our nation's drug supply with unnecessary poisonous mercury compounds. To no avail, we have repeatedly offered clinical laboratory reports from our children to the government. To no avail, we have submitted (see **FDA Public Docket 2004P-0349**) studies (epidemiological, in vitro and in vivo) that clearly prove that the most commonly used mercury compound, Thimerosal, and its metabolites, are persistent neurotoxins.

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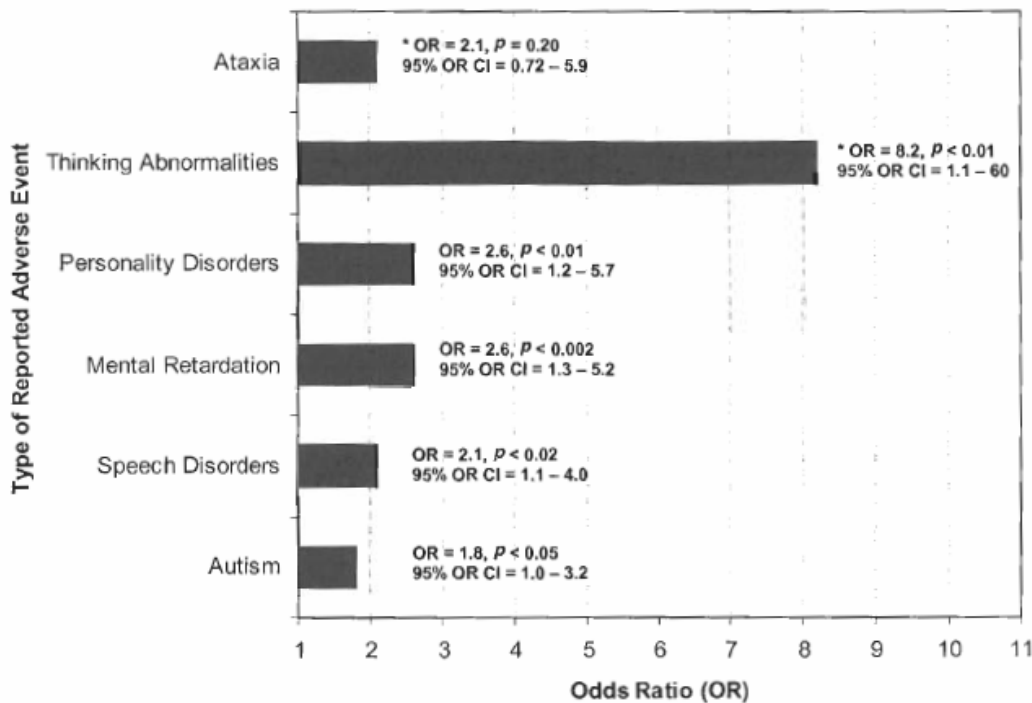
Stalwart in our resolve, we once again offer the following landmark peer-reviewed studies by:

- Dr. Mark R. Geier and Mr. David A. Geier, "Neurodevelopmental Disorders Following Thimerosal-Containing Childhood Immunizations: A Follow-up Analysis," *International Journal of Toxicology (American College of Toxicology)* 2004;23:369-376.

These researchers concluded, "Despite, the recent conclusion from the National Academy of Sciences' Institute of Medicine that there is no evidence of relationship between (T)himerosal and autism, and that no further scientific research should be undertaken to evaluate to evaluate the relationship between (T)himerosal and autism, the results of the present study, taken with data recently published by a number of researchers, demonstrate a connection between mercury exposure via infant vaccinations and the dramatic increase in autism and other neurodevelopmental disorders in the United States. It is clear that the results of the present study, mandate that additional research should be undertaken, not only for autism, but other childhood neurodevelopmental disorders, by evaluating childhood mercury-associated exposures, especially from (T)himerosal-containing childhood vaccines."

FIGURE

Neurodevelopmental Disorders Reported to the Vaccine Adverse Events Reporting System (VAERS) Database Following Thimerosal-Containing DTaP Vaccines in Comparison to Thimerosal-free DTaP Vaccines Administered from 1997 through 2000



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- Dr. Richard C. Deth *et al.*, “Activation of Methionine Synthase by Insulin-like Growth Factor-1 and Dopamine: A Target for Neurodevelopmental Toxins and Thimerosal,” *Molecular Psychiatry* 2004;9:358-370.

These researchers from Northeastern University, the University of Nebraska, Tufts University, and the Johns Hopkins University concluded, “The discovery of the PI3-kinase/MAP kinase/MS pathway, and its potent inhibition by developmental neurotoxins, including vaccine components (T)himerosal and aluminum, provides a potential molecular explanation for how increased use of vaccines could promote an increase in the incidence of autism. The increased incidence of ADHD [Attention Deficit/Hyperactivity Disorder], which preceded the more recent rise in autism, could represent an alternative manifestation of vaccine-associated neurodevelopmental toxicity.”

- Dr. Mady Horning *et al.*, “Neurotoxic Effects of Postnatal Thimerosal are Mouse Strain Specific,” *Molecular Psychiatry* 2004;9:833-845.

These researchers from Columbia University reported, “The developing brain is uniquely susceptible to the neurotoxic hazard posed by mercurials. Host differences in maturation, metabolism, nutrition, sex, and autoimmunity influence outcomes. How population-based variability affects the safety of the ethylmercury-containing vaccine preservative, (T)himerosal is unknown. Reported increases in the prevalence of autism, a highly heritable neuropsychiatric condition, are intensifying public focus on environmental exposures such as (T)himerosal.” The researchers administered Thimerosal to mice mimicking the United States’ routine childhood immunization schedule. The authors demonstrated that the genetically susceptible mouse strain developed physical, social, and pathological symptoms similar to autistic spectrum disorders following Thimerosal exposure. Symptoms included growth delay, reduced locomotion, exaggerated response to novelty, increased brain size, decreased numbers of Purkinje cells, significant abnormalities in brain architecture affecting areas sub-serving emotion and cognition, and densely packed hyperchromic hippocampal neurons with altered glutamate receptors and transporters. The authors concluded, “These findings implicate genetic influences and provide a model for investigating (T)himerosal-related neurotoxicity.”

- Dr. Jill James *et al.*, “Thimerosal neurotoxicity is associated with glutathione depletion: protection with glutathione precursors,” *Neurotoxicology* 2005;26:1-8.

These researchers from the University of Arkansas and the United States’ FDA reported, “Thimerosal is an antiseptic containing 49.5% ethyl mercury that has been used for years as a preservative in many infant vaccines and in flu vaccines.

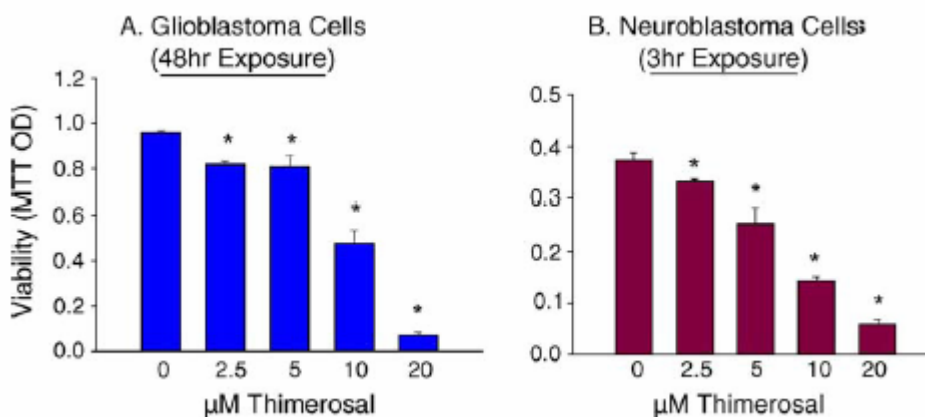
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Environmental methyl mercury has been shown to be highly neurotoxic, especially to the developing brain.” The authors determined that the ethyl mercury in Thimerosal binds to cysteine thiol (-SH) groups on intracellular proteins and inactivates their function, resulting in neurotoxicity. The cysteine-SH group of glutathione binds mercury and protects essential proteins from functional inactivation. Glutathione (GSH) is the major mechanism of mercury excretion, and individuals with genetic deficiencies in glutathione synthesis will be less able to excrete mercury and will be more sensitive to its adverse effects. The authors concluded, “Although (T)himerosal has been recently removed from most children's vaccines, it is still present in flu vaccines given to pregnant women, the elderly, and to children in developing countries. The potential protective effect of GSH or NAC [*N*-acetyl-cysteine] against mercury toxicity warrants further research as possible adjunct therapy to individuals still receiving Thimerosal-containing vaccinations.”

FIGURE

Viability of glioblastoma cells (A) and neuroblastoma cells (B) with increasing concentrations of Thimerosal in the media. Asterisks indicate significant differences from control cells without Thimerosal treatment ($n = 3, p < 0.01$).



- The Environmental Working Group, “Overloaded? New Science, New Insights about Mercury and Autism in Susceptible Children,” Washington, DC: EWG Action Fund; 2004.

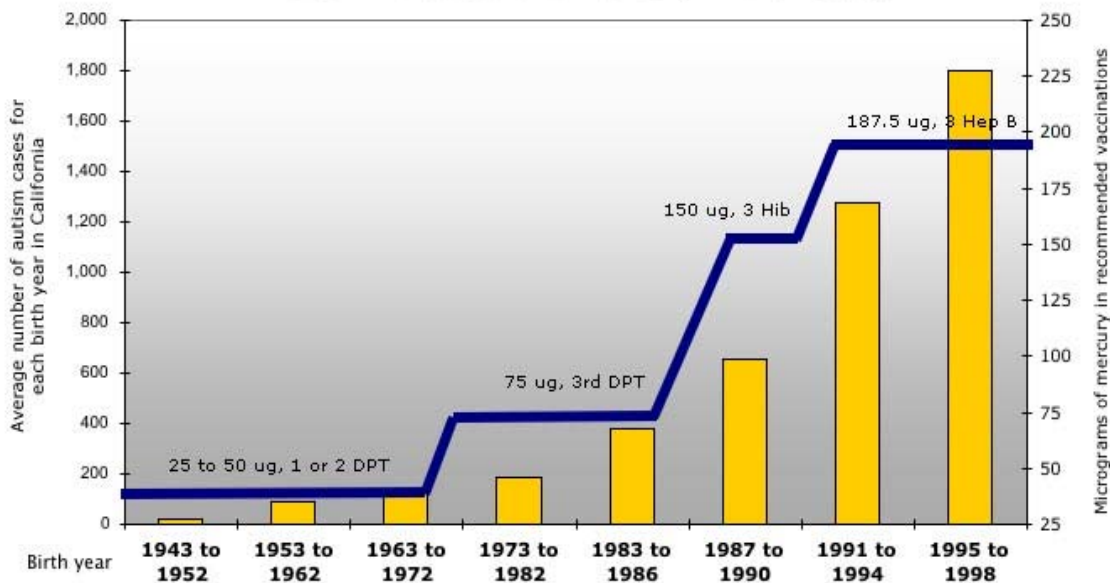
The Environmental Working Group (EWG) has issued a report following an extensive investigation into the relationship between mercury exposure, especially

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mercury exposure from Thimerosal-containing childhood vaccines, and autistic disorders. They reported that a signature metabolic impairment or biomarker in autistic children strongly suggests that these children would be susceptible to the harmful effects of mercury and other toxic chemical exposures. This impairment manifests as a severe imbalance in the ratio of active to inactive glutathione, the body's most important tool for detoxifying and excreting metals. It was determined that autistic children showed a significant impairment in every one of five measurements of the body's ability to maintain a healthy glutathione defense. The EWG concluded that these new findings significantly strengthen the possibility that mercury could cause or contribute to autism and other neurodevelopmental disorders, by identifying a metabolic imbalance common to nearly all autistic children that would make these children poorly equipped to mount a defense against a number of neurotoxic compounds, including mercury. In addition, they concluded that their findings raise serious concerns about the studies that have allegedly proven the safety of mercury in vaccines.

Autism cases and infant exposure to mercury in vaccinations both increased dramatically in the 1990s



Mercury was gradually removed from infant and maternal vaccinations between August 1999 and Nov 2002 (infant) or 2003 (maternal).
Autism data from California Department of Developmental Services 2004. Reliable data on autism rates in children born after 1998 are not available.

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and the following legislation:

- The California Environmental Protection Agency, Office of Environmental Health Hazard Assessment, “Response to the Petition of Bayer Corporation for Clarification of the Proposition 65 Listing of ‘Mercury and Mercury Compounds’ as Chemicals Known to Cause Reproductive Toxicity,” February 2004.

The California EPA has declared that Thimerosal is a developmental toxin, meaning that it can cause birth defects, low birth weight, biological dysfunctions, or psychological or behavior deficits that become manifest as the child grows, and that maternal exposure during pregnancy can disrupt the development or even cause the death of the fetus.

- California Assembly Bill No. 2943.

The state of California has passed a bill to prohibit, on and after July 1, 2006, a person who is knowingly pregnant or who is under 3 years of age from being vaccinated with a mercury-containing vaccine or injected with a mercury containing product that contains more than a trace of mercury (< 1 microgram of mercury per milliliter).

- Iowa Senate Bill No. 2209

The state of Iowa has passed a bill to prohibit, on and after January 1, 2006, a person who is under 8 years of age from being vaccinated with a mercury-containing vaccine that contains more than a trace amount of mercury (where the Iowa law states, “‘Trace amounts’ means trace amounts as defined by the United States food and drug administration” and the US FDA currently treats 1 microgram or less of mercury per milliliter as a “trace amount”).

as proof of the gravity of this issue. It is a stinging indictment and a national embarrassment that individual states must ban the administration of a dangerous neurotoxin, at levels in excess of EPA safety guidelines, while federal health agencies blindly contend there is no evidence of harm. In pursuing their chosen objectives, the FDA (in its quest to approve new drugs) and the CDC (in its promotion of the administration of certain drugs) have “overlooked” their primary objective – ensuring the safety of all drugs. Such conflicting and out-of-order priorities are a recipe for disaster – one such disaster we now see everyday in the vacant eyes of our children. No federal health official with scruples can, *in good conscience*, characterize the injection of mercury, *at levels ten times the EPA’s safety guidelines for an adult* into an infant, or *at any level*, into a pregnant woman, as “safe” nor should they protect those who do so.

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Based on an ever-increasing body of research that offers proof of harm caused by mercury, we seek an end to the maiming of our children's minds and a crippling of their lives by demanding that the urgent federal investigations, called for by those at the highest levels of our government, be initiated immediately and pursued avidly. The Office of the Inspector General, the Senate Committee on Health, Education, Labor and Pensions, and the House Committee on Energy and Commerce must immediately investigate this catastrophe, which can only be described as domestic terrorism successfully waged upon American children, or be considered complicit in it.

Any official, *who does not come immediately to the rescue of our nation's ailing mercury-toxic children, and who does not demand an immediate recall and ban of Thimerosal-containing products*, is not worthy of their office or the trust we have placed in them.

Respectfully,



Rev. Lisa Karen Sykes,
CoMeD, Representative from Virginia

Other organizations/individuals supporting this letter:

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