

Facility Automation Management Engineering (FAME) Systems

33 Hoffman Avenue, Lake Hiawatha, NJ 07034

Friday, 30 June 2006

Revised: 3 July 2006

To Whom It May Concern:

The review that follows this introductory letter is a critical assessment of the article, “**Beyond the headlines: Link still claimed between thimerosal and autism,**” written by Kathleen Phalen Tomaselli, a contributing writer, published by the American Medical Association in its American Medical News newspaper published at:

<http://www.ama-assn.org/amednews/site/free/feature.htm>

on 19 June 2006, which I visited as a part of my research in this area on 22 June 2006.

In general, to clearly differentiate between my assessment comments and those of the CDC, the CDC’s printed statements are quoted in a “Times New Roman” font followed by this reviewer’s remarks in indented text written in a “News Gothic MT” font, the font used in this cover letter.

Quotes from general reference articles and documents will be presented in an “Arial” font; and federal laws and statutes will be quoted in a “Lydian” font.

For those who have access to a color printer, this reviewer’s comments are made in a **blue** color with existing text corrections in **red**.

Should anyone find any factual misrepresentations in this reviewer’s remarks, then this reviewer requests that the factual error along with the scientifically sound and appropriate documents that prove your point to this reviewer so that this reviewer can learn from you, incorporate that new knowledge into his understanding, and, where indicated, appropriately correct this document.

Respectfully,

A handwritten signature in black ink that reads "Paul G. King". The signature is written in a cursive style with a large, prominent "K".

Paul G. King, PhD, MS, BA
Founder, **F.A.M.E. Systems**

**“Beyond the headlines: Link still claimed between thimerosal and autism
Activists stand by their argument despite the fact that science has yet to find proof of the
link.”** By [Kathleen Phalen Tomaselli](#), AMNews contributor. June 19, 2006.”

First, the writer, Ms. Tomaselli, begins by misstating what pharmaceutical “science”:

- a. Has been *required by law to have done* with respect to the use of Thimerosal as a preservative in each Thimerosal-preserved vaccine formulation since 1973, and
- b. To date, has *not* done.

As stated in Title 21 of the US Code of Federal Regulations (**21 CFR**) in **Section 610.15(a)**¹, each vaccine maker has been required, *for the vaccine preservative system used*, to establish that “the amount present in the recommended dose of the product will not be toxic to the recipient.”

Moreover, *since 1988*, when the US Supreme Court unanimously ruled² that US Food and Drug Administration (FDA) administrators have no discretion with respect to complying with any applicable clear policy, law, or statute, the FDA administrators in the Center for Biologics Evaluation and Research (CBER), *who have approved the licensing of, or continued to allow the licensing of, any Thimerosal-preserved vaccine formulation without the requisite proof that the “recommended dose of the product will not be toxic to” all recipients after this 1988 ruling, seem to have acted in knowing violation of the law.*

Further, since the manufacturers of Thimerosal-preserved vaccines have knowingly failed to comply with the law (**21 CFR Sec. 610.15(a)**), *by statute*, the lots of any such Thimerosal-preserved vaccines are adulterated (Title 21 of the United States Code [**21 U.S.C.**] **Section 351(a)(2)(B)**) and thus illegal to distribute (**21 U.S.C. Section 331(a)**).

With respect to articles that establish a link between Thimerosal exposure and autism (and other neurodevelopmental and behavioral disorders), this reviewer suggests that the writer of this article simply read two of the most recent peer-reviewed publications, by independent researchers using scientifically sound and appropriate statistical techniques in each case (including, *for the epidemiological*

¹ 21 CFR Sec 610.15(a) with **bolding** added for emphasis:
“TITLE 21--FOOD AND DRUGS - CHAPTER I-FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES--(Continued)

PART 610--GENERAL BIOLOGICAL PRODUCTS STANDARDS - Subpart B--General Provisions

610.15 Constituent materials.

- (a) Ingredients, preservatives, diluents, adjuvants. All ingredients used in a licensed product, and any diluent provided as an aid in the administration of the product, shall meet generally accepted standards of purity and quality. **Any preservative used shall be sufficiently nontoxic so that the amount present in the recommended dose of the product will not be toxic to the recipient. ...”**

² Kevan BERKOVITZ, a Minor by his Parents and Natural Guardians Arthur BERKOVITZ, *et ux., et al.*, Petitioners, v. UNITED STATES. 108 S.Ct. 1954, 100 L.Ed.2d 531, 56 USL W 4549, (Cite as: 486 U.S. 531, 108 S.Ct. 1954)

study, techniques recognized and used by the CDC in similar studies) that clearly establish this link.^{3,4}

“Long before some parents of children with autism backed an April *USA Today* full-page ad criticizing the Centers for Disease Control and Prevention and charging its experts with a cover-up, the thimerosal war was raging.”

The author begins by:

1. Stating a fact (“some parents of children with autism backed an April *USA Today* full-page ad criticizing the Centers for Disease Control and Prevention and charging its experts with a cover-up”),
2. Ignoring the fact that some of these “parents” are also scientific researchers and healthcare practitioners, and
3. *Without any substantiation*, casting what is a science-based disagreement between:
 - a. An apparently uncaring “healthcare establishment,” *for whom the writer is speaking*, **and**
 - b. Independent scientists and parents, *for whom this reviewer is speaking*, who:
 - i. Ignore such divisive rhetoric **and**
 - ii. Stick to the sound independently verifiable science behind the reality that, *since the 1930s*, there has been an ever-growing body of peer-reviewed published experimental and case evidence that Thimerosal (49.55% mercury by weight):
 - Mercury poisons human tissues at levels below 0.03 parts per million,
 - *In living systems*, at levels of 0.01% and lower, is more bacteriostatic than bactericidal⁵ and,
 - *At a level of 0.1%*, more readily kills human cells (and in some instances babies⁶) than it kills bacterial cells.⁷

In addition,

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- 3 Geier DA, Geier MR. An Evaluation of the Effects of Thimerosal on Neurodevelopmental Disorders Reported Following DTP and Hib Vaccines in Comparison to DTPH Vaccine in the United States. *J Toxicol Environ Health A*. 2006 Aug; **69**(15): 1481-95.
 - 4 Geier DA, Geier MR. An assessment of downward trends in neurodevelopmental disorders in the United States following removal of thimerosal from childhood vaccines. *Med Sci Monit*. 2006 May 29; **12**(6): CR231-239.
 - 5 a. Morton HE, North LL, Engley FD. The bacteriostatic and bactericidal actions of some mercurial compounds on hemolytic Streptococci – In vivo and in vitro studies *JAMA* 1948; **136**(1): 37-41.
b. Engley FB. Evaluation of mercurial compounds as antiseptics. *Annals of the New York Acad Sci* 1950; **53**: 197–206.
 - 6 Fagan DG, Pritchard JS, Clarkson TW, M. R. Greenwood MR, Organ mercury levels in infants with omphaloceles treated with organic mercurial antiseptic. *Archives of Disease in Childhood* 1977; **52**: 962-964.
 - 7 a. Engley FB. Mercurials as disinfectants – Evaluation of antimicrobial action and comparative toxicity for skin tissue cells. *Soap and Chemical Specialties* Dec. 1956:199,201,203,205,223-225.
b. Salle AJ, Lazarus AS. Pacific Coast Section. 7809 C. A comparison of the resistance of bacterial and embryonic tissues to germicidal substances. I. Merthiolate. *Proc Soc Exp Biol and Med*. 1935; **32**(5): 665-667.

- Actual inoculee bacterial contamination by vaccine doses taken from multi-dose Thimerosal-preserved vials, *reported in a 1980s study*,⁸ and
- The recent suspension, *in 2005*, of the license for a Chiron plant in the UK (when viable *Serratia marcescens* bacteria were found by the British Medicines and Healthcare products Regulatory Agency (MHRA) in filled influenza vaccine vials⁹),

have clearly established that Thimerosal at 0.01%, or lower levels, is *not* an effective vaccine preservative.

“And, despite a paucity of scientific evidence linking the mercury-based vaccine preservative to autism, such charges continue to find traction.”

Factually, Thimerosal, ethylmercurithiosalicylate sodium salt, 49.55% mercury by weight, is not, *per se*, a preservative.

Thimerosal (along with its solvolysis products [ethylmercury hydroxide and, in isotonic saline, ethylmercury chloride], impurities [the corresponding methylmercury analogs to the ethylmercury species] and metabolites [“inorganic mercury”]) is a:

- ❖ Severe bioaccumulative poison that is tissue toxic at levels below 0.02 ppm,^{7a}
- ❖ Teratogen¹⁰ and multi-generational mutagen¹¹ at fetal levels below 1 ppm, and
- ❖ Immunogen and autoimmunigen in humans at tissue/fluid levels below 0.03 ppm.¹²

At levels of 0.01% and below in vaccine formulations, Thimerosal is, *based on the studies referenced by this reviewer*, *not* an effective preservative, it is only claimed, *by the healthcare establishment*, to be a “preservative” in vaccines.

Moreover, any search of the published literature indexed in PubMed using the term “Thimerosal,” finds thousands of references.

The overwhelming majority of those PubMed-indexed articles, which address Thimerosal toxicology and/or actual case studies, clearly show that a 0.01% level

⁸ Stetler HC, Garbe PL, Dwyer DM, Facklam RR, Orenstein WA, West GR, Dudley KJ, Bloch AB. Outbreaks of group A Streptococcal abscesses following Diphtheria-Tetanus toxoid-Pertussis vaccination. *Pediatrics*. February 1985; 75: 299-303.

⁹ <http://www.fda.gov/ola/2005/influenza0210.html>, last visited 25 June 2006. “As you know, on October 5, 2004, the British Medicines and Healthcare products Regulatory Agency (MHRA) suspended Chiron’s license to manufacture influenza vaccine due to sterility failures in filled vials of the vaccine”

¹⁰ Digar A. Sensharma GC, Samal SN. Lethality and teratogenicity of organic mercury (Thimerosal) on the chick embryo. *J Anat Soc India* 1987; 36(3): 153-159.

¹¹ Goncharuk GA. Experimental investigation of the effect of organomercury pesticides on generative functions and on progeny. *Hyg. Sanit – USSR* 1971; 36(1): 40-43 (English translation).

¹² Goth SR, Chu RA, Gregg JP, Cherednichenko G, Pessah IN. Uncoupling of ATP-mediated calcium signaling and dysregulated IL-6 secretion in dendritic cells by nanomolar Thimerosal. *Environ Health Perspect* 114 (48 pages) online 21 March 2006 at <http://www.ehponline.org>

of Thimerosal, *or a lesser level*, in an isotonic-saline-based vaccine formulation either:

- ❖ Is *not* safe to be injected into a pregnant woman, child or adult, or
- ❖ Has *not* been proven to be “safe” for use in vaccines (as required by law [21 CFR Sec 610.15(a)]).

Further, because it is a human teratogen and, *as recent reports have confirmed*, even injecting as little as 50 micrograms of Thimerosal is sufficient to cause some fetal deaths leading to “vaccination-related” fetal abortions¹³, Thimerosal-preserved vaccines are obviously *not* safe to be injected into pregnant women.

Thus, *as this reviewer’s substantiated* (by key references) *comments clearly establish*, Thimerosal at 0.01% in vaccine formulations is *not* an effective preservative and the writer’s “preservative” statement should be rejected because it has been shown to be based on a flawed premise.

Moreover, since:

- ❖ Thimerosal in vaccines at a level of 0.01% has been repeatedly shown *not* to be effective in preserving vaccines from microbiological contamination under real-world usage conditions, and
- ❖ None of the requisite toxicology studies required to prove Thimerosal at a 0.01% is “safe enough” to be allowed to be used as a preservative,

all should be demanding that all Thimerosal be immediately removed from, *not just reduced in*, all vaccines given to pregnant women, children 18 years of age and under, adults, and the elderly.

Hopefully, *after reading this reviewer’s remarks and the referenced article*, the writer will at least understand why independent scientists and concerned parents know that there is an overwhelming body of evidence linking Thimerosal exposure to that form of mercury poisoning whose symptoms are diagnosed as the “causeless” neurodevelopmental disorder having the label “autism.”

“In other words, a growing number of parents doubt the safety and credibility of the very system created to protect the nation's health.”

Given:

- a. the vaccine makers’ ongoing knowing and deliberate failure to comply with the law and prove Thimerosal at 0.01 % in a vaccine formulation is “sufficiently nontoxic” to all given such vaccines,
- b. the healthcare establishment’s continuing knowing mislabeling of Thimerosal-related mercury poisoning cases, as autism and other neurodevelopmental disorders,
- c. the CDC’s knowing addition of a *less-than-effective* Thimerosal-preserved vaccine, the “flu shot,” to the childhood vaccination schedule for children in

¹³ Ayoub DM, F. Yazbak FE. Influenza Vaccination During Pregnancy: A Critical Assessment of the Recommendations of the Advisory Committee on Immunization Practices (ACIP). J Am Phys and Surg. Summer 2006; 11(2): 41-47.

2003 and 2005 and, thereby, effectively adding back, *for those who get Thimerosal-preserved flu shots*, more than 50% of the mercury removed when, *in 1999*, the healthcare establishment agreed that all of the Thimerosal should be removed from vaccines as soon as possible, and

- d. the knowing addition of the Thimerosal-preserved flu shot to the recommended vaccination schedule for pregnant women in 2003 without any proof of safety for the fetus and with the knowledge that Thimerosal is a proven teratogen at fetal levels below 1 ppm, and
- e. the continuing less-than-accurate rhetoric by vaccine apologists like the writer of this article,

this reviewer finds it hard to believe that any informed parent would think that the “very system created to protect the nation's health”:

- ❖ Has any credibility and
- ❖ Does anything besides try to protect its own interests.

Moreover, if the healthcare establishment does *not* soon repent and confess to the *knowing* harm that it has caused and is causing, then, all those who individuals and companies who are involved should be:

- ❖ Prosecuted under the criminal RICO statutes,
- ❖ Stripped of all of their assets, and, *when convicted*,
- ❖ *In the case of the companies*, operated by the government for the next century, or
- ❖ *In the case of the responsible individuals in every area of the healthcare establishment*, sentenced to help care for the severely disabled, who their knowing actions or inactions have created, at minimum wages, for not less than ten years.

“‘When you can't argue the data, you go after the people. Hardworking, committed public health servants have been maligned, and it is just shocking,’ says Martin Myers, MD, associate director for public health policy and education for the University of Texas Medical Branch at Galveston's Sealy Center for Vaccine Development. ‘This is characterized as a debate. [But] it is not a debate in the scientific realm. This scare has taken on a life of its own, and it's hard to sort out the hysteria.’”

This reviewer finds that Dr. Martin Myers has, *as he has repeatedly done*, again ignored scientifically sound data that has clearly established that Thimerosal is a major factor in the underlying mercury poisoning of developing humans, which has been labeled by the healthcare establishment, and its minions, as the “causeless” psychiatric disorder, autism.

Moreover, this reviewer notes that Myers is a confirmed vaccine apologist, who has long eschewed looking at the data and chosen to use rhetoric and “public policy” to justify the “healthcare establishment's” actions with respect to:

- ❖ Thimerosal-preserved drugs and
- ❖ The mercury poisoning these drugs are known to cause.

“Caught in a flurry similar to public relations campaigns against conventional public health villains such as big tobacco and asbestos manufacturers, the CDC denounced the ad's allegations. Still, many of the activists adamantly believe their children are mercury poisoned.”

First, this reviewer must note that, just as the “conventional public health villains such as big tobacco and asbestos manufacturers” that the writer alludes to earned their position, the healthcare establishment, *including the CDC*, has earned, and is continuing to earn, its reputation.

Moreover, the factual reality is that hundreds of parents have clinical proof that their children have been mercury poisoned by the injected bolus doses of mercury from the Thimerosal-preserved vaccines given to their children even though such dosings exceeded the EPA's putative *low-safety-margin* daily mercury-ingestion limit of “0.1 micrograms of mercury per kilogram of body weight” – a suggested limit based on what-is-now-known-to-be assumptions that are either inaccurate or flawed for developing children (including, **a**) overestimates of daily dietary fish intake, **b**) presumption of a constant excretion rate in all populations, **c**) presuming a “universal” correlation between the level of mercury in hair and the level of mercury exposure, **and d**) the presumption that a 10-fold safety level for data from adults would adequately protect developing humans even though developing humans were known to be more sensitive to mercury than adults [who made up the population from which the dietary-intake estimates were generated]).

“‘We feel like victims of a terrible crime,’ says Bobbie Manning, a Buffalo, N.Y., parent of a son with autism and the founder of A-CHAMP – Advocates for Children's Health Affected by Mercury Poisoning. ‘It is very similar to what we saw with Vioxx or the tobacco industry. The safety information has been suppressed from the public.’”

Here, this reviewer only notes that it is Thimerosal's toxicity and harmful effects that have been “suppressed from the public” and *not* “safety information” *per se* because, *for Thimerosal-preserved vaccines*, the healthcare establishment has knowingly failed to establish (prove) a scientifically sound and appropriate, toxicology-based safe level for Thimerosal in any vaccine given to pregnant women, children or, *for that matter*, adults and the elderly.

Moreover, based on:

- ❖ The appropriately correction of the EPA basis assumptions for safe daily intake for dietary mercury and
- ❖ The fact that injection of the Thimerosal bypasses the absorption slowing and metallothionein heavy-metal detoxification systems in the human gastrointestinal system,

this reviewer is forced to conclude the safe level for the amount of Thimerosal injected as a bolus dose is certainly less than 0.01 microgram per kg of body mass, and probably less than 0.001 microgram per kilogram of body mass, for those whose circulating mercury sequestering and detoxification systems, *for whatever reason (genetic, dietary, medicinal, or some combination thereof)*, retain

mercury for extended periods. [Note: Those at risk of mercury poisoning from Thimerosal-preserved vaccine doses are estimated to be more than 15% of the US population (and, based on peak asthma rates in children and annual Thimerosal-preserved influenza vaccinations, could be 25%, or more, of the public).]

“But, except for the flu vaccine, childhood immunizations are now thimerosal-free, so this heightened unrest leaves some wondering about the continued focus.”

First, the writer is mistaken because some early childhood vaccines still contain reduced levels of Thimerosal and, thus, all of them are not “thimerosal-free”¹⁴ as the writer claims.

Second:

- a. Published studies have shown that the “flu vaccine” is:
 1. Not effective in children 2 years of age and under,
 2. Is, at best, minimally effective in children over 2, and
 3. Children are not the significant spreaders of influenza (unless inoculated with the three [3] live-virus influenza strains in MedImmune’s FluMist),
- b. In spite of **Point a**, the CDC recommended:
 1. Adding the Thimerosal-preserved flu vaccine to the general vaccination schedule for pregnant women (without any proof of fetal safety to justify recommending its use in pregnant women) in December 2003. [Note: VAERS has subsequently received reports of fetal death and abortion linked to pregnant women getting the flu shot.⁶]
 2. Adding the Thimerosal-preserved flu shot to the general vaccination schedule for children from 6 months of age to 23 months of age in December of 2003 – immediately adding back more than 25% of the Thimerosal removed by removing/reducing it in the other previously Thimerosal-preserved vaccines. [Note: This decision only benefited what is now sanofi aventis because all other US-licensed influenza vaccines are not licensed for use in children under 5 years of age.]
 3. In 2005, extending their childhood flu-shot recommendation to children up to 5 years of age – effectively adding back, for those receiving Thimerosal-preserved vaccines, more than 50% of the maximum Thimerosal level in 1998, before Thimerosal reductions were started and slightly more than 100% of the maximum Thimerosal level in the mid-1980s.

Based on the preceding facts, this reviewer finds it *unbelievable* that the writer does not understand the reasons for “this heightened unrest” on the part of those who

¹⁴ <http://www.fda.gov/cber/vaccine/thimerosal.htm>, as visited on 25 June 2006. [Based on the tables on this page, allowing for maximum levels of “120%” of nominal of label, omitting all other Thimerosal-containing vaccines that a young child might receive, and presuming that a child got “10” micrograms of mercury from his mother’s “25”-microgram flu-shot dose and then received all Thimerosal-containing vaccines that had a nominal Thimerosal level claimed, the nominal dose of mercury a child could be given by the time they are 5 years old would be about 135 micrograms of mercury. By comparison, a child born in 1998 with no Rho(D) incompatibility issues and receiving all Thimerosal-preserved vaccines would, nominally receive, if given all Thimerosal-preserved vaccines as soon as possible (Hep B [(3 x 25) micrograms], DTaP [(5 x 25) micrograms], Hib [3 x 25 micrograms]), by age 5, up to 250 micrograms of mercury. Thus, through age 5, a fully vaccinated child receiving all Thimerosal-containing vaccines will now maximally receive about 54% of the maximum dose in 1998.

oppose putting any amount of any *unnecessary* bioaccumulative poison in any drug, much less in vaccines that the “healthcare establishment,” *without any scientifically sound toxicological proof of long-term safety*, represents to be the “safest” of drugs.

How can the writer of this article *not* understand that people, *who are being lied to by the misrepresentation of the removal of Thimerosal from the US-licensed vaccines allowed to be given to any US child*, would be justifiable upset by this duplicity by the “healthcare establishment,” in general, and vaccine apologists, like the writer of this article, in specific?

Moreover, *since developing countries are still using the Thimerosal-preserved vaccines (which have been converted to reduced-Thimerosal or Thimerosal-free vaccines in the US)*, those concerned about the harm being done are also concerned because of the failure of the US “healthcare establishment” to be truthful about the lack of proof of safety of Thimerosal in vaccines at any level!

Hopefully, after reading this reviewer’s remarks and checking the references cited, the writer will understand reality and publish an article admitting her lack of candor here.

“‘I have been working with autistic kids for 35 years, and there have been concerns about different vaccines since I was 22,’ says Catherine Lord, PhD, director of the University of Michigan Autism and Communication Disorders Center in Ann Arbor. ‘It was DPT, MMR, thimerosal and now the flu vaccine. ... Parents are understandably looking for an explanation.’”

Unlike Catherine Lord, this reviewer has, *for about two decades*, focused on finding the underlying medical causes for a variety of human health problems, including, *but not limited to*, studying the literature on the causes of human mercury poisoning (metallic mercury, Calomel, amalgam fillings, “methyl mercury” and Thimerosal).

From this reviewer’s study of mercury poisoning, it is clear that, *whenever the healthcare establishment has been behind the mercury poisoning*, the medical profession has concealed the mercury poisoning by calling/diagnosing it as some “causeless” disease rather than diagnosing the underlying mercury poisoning.

For example, when the mercury poisoning of babies was caused by Calomel, mercurous chloride, in teething powders and worming preparations, also represented as being safe without any proof thereof, those who survived the poisoning were diagnosed, in the US, as having “causeless” conditions, “Pink Disease” and “Acrodynia,” but not mercury poisoning.

At its peak, of those babies who survived, the US rate of “Pink Disease” was estimated at about 1 child in 500.

As Calomel was phased out of drug use in the 1940s, the incidence of these “causeless” medical conditions *coincidentally* declined and, when these Calomel-containing drugs ceased to be used, the diagnosis and the disease, “Pink

Disease,” “disappeared” without anyone being held accountable for knowingly mercury poisoning babies.

Coincidentally, at about the time the use of Calomel began to be questioned, Eli Lilly and Company developed, in the late 1920s and the 1930s, a series of organic mercurial compounds and, *from those that were water soluble*, chose to develop Thimerosal, *with a solubility of 1 gram of compound per milliliter of water*, one of the most toxic mercury compounds, and one that was not very stable in water, saline, and protein containing solutions, for use as an antiseptic and a preservative in serums and vaccines.

At no time did Eli Lilly carry out any *published* rigorous safety studies in any animals having a mercury-poisoning susceptibility similar to humans, by conducting scientifically sound and appropriate toxicological studies, *including short-term acute toxicity, intermediate-term chronic toxicity, multigenerational reproductive toxicity assessment, and long-term low-dose toxicity studies in such animals*, to establish that any level of Thimerosal in any of their products was safe (with at least a 100-fold safety margin) for human use.

In the early 1970s, it has been reported that they internally reported Thimerosal toxicity at the “1 ppm” level but the court sealed the documents, containing the details of their findings.

Coincidentally, in the mid-1970s, though a major player in the vaccines and serums business, Eli Lilly abruptly exited these product lines and licensed their “Thimerosal” technology to other pharmaceutical manufacturers.

Moreover, when fetuses and babies were being similarly mercury poisoned to varying degrees by Thimerosal, the healthcare establishment used other “causeless” symptom-based labels, including, “autism”¹⁵, instead of looking for and diagnosing the underlying disease, sub-acute cumulative mercury poisoning.

“Not all of them see the mercury-poison theory as the answer, adding a new layer of dissonance. ‘There is so much vitriol,’ says Kathleen Seidel, the mother of an autistic teen. She started Neurodiversity.com, an online site about autism and related issues. ‘It’s the lure of the jackpot that leads to the exploitation of parents.’”

Having examined this autism “diva’s” views and found little of science in them, this reviewer finds it “odd” that this writer, *implicitly claiming to support letting sound science decide the issues raised by the theory that bolus-dosed Thimerosal-preserved vaccines cause that form of cumulative, bolus-dose-based, sub-acute*

¹⁵ Based on personal communications from Dr. Mark R. Geier and David A. Geier, currently more than 85% of the cases (150+) presenting to them with a “causeless” diagnosis of autism or an autistic spectrum disorder, have, after differential diagnosis directed toward uncovering the underlying causes, been found to be *poisoned* by mercury and other heavy metals. Moreover, less than 10% have been found to have an identifiable genetic defect with no clinical evidence of poisoning by heavy metals. Further, those having poisoning by mercury and other heavy metals have been found to have low glutathione levels, high testosterone levels for their age and sex, and abnormal *heme* metabolism (as evidenced by the elevation of certain porphyrins in their urine).

mercury poisoning diagnosed as autism, would choose to quote Ms. Seidel's views here.

Some point to the recent media blitz as part of a bigger anti-vaccine movement, and others view upcoming federal vaccine court deadlines as possible reasons for the stepped-up visibility.

Factually, the reasons for the increased media exposure are:

- ❖ Theory that "*Thimerosal causes that form of mercury poisoning diagnosed as autism*" has been clearly established and confirmed by the recent epidemiological studies and
- ❖ The success of the theory-based case-study interventions (*in which the appropriate supportive medicines and dietary supplements coupled with heavy metal detoxification using oral chelating agents are used*) conducted by independent researchers and medical professionals using that theory and their understanding of the underlying biochemical interventions¹⁶ to guide their treatment of children medically diagnosed as being poisoned by mercury and other heavy metals.

"But Manning says that's not it. 'We are not anti- vaccine. What's driving the interest is so many children affected, and the CDC is not responding.' Manning led a small group in lobbying state attorneys general in an effort to get states to join in a lawsuit, similar to tobacco litigation, against the pharmaceutical companies that produced certain vaccines. 'These children are mercury-toxic.'"

This reviewer finds that Ms. Manning's "These children are mercury-toxic" statement to be a layperson's view of the apparent scientific/medical reality that, *when subjected to a proper differential diagnosis that examines the children's DNA and biochemical markers for poisoning by mercury and other heavy metals along with their markers for an impaired ability to excrete mercury*, more than 85% of those with a confirmed autism or autistic spectrum diagnosis are found to have been mercury poisoned (and, therefore, are now, "mercury toxic") by the bolus doses of Thimerosal injected into them when they were vaccinated with Thimerosal-preserved vaccines in addition to the background doses of mercury they receive from the other environmental mercury sources to which they were/are exposed.

"Detailing the science

For decades, accusations of vaccine-related maladies have surfaced. So when researchers at Columbia University in New York found a possible association between thimerosal and neurological disorders in early, small-scale studies, anti- vaccine groups took notice. But these results have not been replicated in subsequent research."

Here, the writer again twists several realities to suit her ends.

¹⁶ Geier DA, Geier MR. A Clinical and Laboratory Evaluation of Methionine Cycle-Transsulfuration and Androgen Pathway Markers in Children with Autistic Disorders. *Horm Res*. 2006 May 9; **66**(1): 33-39. [Epub ahead of print.]

The writer's first statement, "For decades, accusations of vaccine-related maladies have surfaced," while factual, adds nothing of substance to the of the link between injecting Thimerosal (49.55% mercury by weight) into developing humans and observing significant clinical symptoms caused by mercury poisoning, in more than 15% of those so exposed because, *for whatever reasons*, the bolus doses given were magnitudes higher than their body's mercury detoxification mechanisms could handle – resulting in the clinical symptoms observed for these mercury-poisoned children.

Factually the studies to which the writer is alluding seem to be the experimental toxicology studies conducted by Hornig *et al.*¹⁷

While these experimental animal studies have *not* "been fully replicated" in subsequent experimental studies, the following animal studies have confirmed parts of the findings of the studies by Hornig *et al.* into the neurotoxic effects of postnatal Thimerosal exposure in several strains of mice:

1. Havarinasab S, Hultman P. Alteration of the spontaneous systemic autoimmune disease in (NZB x NZW)F1 mice by treatment with thimerosal (ethyl mercury). *Toxicol Appl Pharmacol.* 2006 Jan 26; [Epub ahead of print] [Note: This study found systemic deleterious autoimmune effects on the kidneys of female (NZB x NZW)F1 (ZBWF1) mice treated with Thimerosal similar to the autoimmune effects seen by Hornig *et al.* in the brain.]
2. Havarinasab S, Hultman P. Organic mercury compounds and autoimmunity. *Autoimmun Rev.* 2005 Jun; 4(5): 270-5. Epub 2005 Jan 5. [Note: "This review reported: At equimolar doses of Hg, MeHg has the weakest immunostimulating, autoimmunogen, and immune-complex-inducing effect, while the effect of thimerosal is similar to that of inorganic mercury. Immunosuppression is caused by the organic mercurials per se. Recent studies in mice with a susceptible genotype has revealed that the immunosuppressive effect of MeHg and EtHg will within 1-3 weeks be superseded by immunostimulation causing an Hg-induced-autoimmunity-like syndrome. Since these organic mercury compounds undergo fairly rapid transformation to inorganic Hg, studies are being undertaken to delineate the importance of the organic substances per se and the newly formed inorganic Hg for induction of autoimmunity."]
3. Havarinasab S, Haggqvist B, Bjorn E, Pollard KM, Hultman P. Immunosuppressive and autoimmune effects of thimerosal in mice. *Toxicol Appl Pharmacol.* 2005 Apr 15; 204(2):109-21. [Note: "In a study of A.SW (H-2s) mice using 10-ppm Thimerosal-water, the organic mercury compound thimerosal (EtHg) has initial immunosuppressive effects similar to those of methylmercury hydroxide (MeHg). However, in contrast to MeHg, thimerosal treatment leads, in genetically susceptible mice, to a second phase with strong immunostimulation and autoimmunity, which is T-cell dependent, H-2 linked and may at least partly be due to the inorganic mercury derived from the metabolism of ethyl mercury."]

¹⁷ Hornig M, Chian D, Lipkin WI. IMMEDIATE COMMUNICATION. Neurotoxic effects of postnatal Thimerosal are mouse strain dependent. *Molecular Psychiatry* Jun 8, 2004: 1-13.

In addition, the following studies confirmed the accumulation of mercury in the brain of the animals studied and elucidated the differences attributable to the mode of administration and the nature of the mercury compound being studied:

1. Burbacher TM, Shen DD, Liberato N, Grant KS, Cernichiari E, Clarkson T. Comparison of blood and brain mercury levels in infant monkeys exposed to methylmercury or vaccines containing thimerosal. *Environ Health Perspect.* 2005 Aug; **113**(8): 1015-21. [Note (with **bolding** added for emphasis): “Animal study in baby monkeys that confirmed both the ‘ethylmercury’ and the ‘methylmercury’ species studied crossed the animals’ blood-brain barrier and accumulated with metabolism into ‘inorganic mercury’ in the animals’ brains. A higher percentage of the total Hg in the brain was in the form of inorganic Hg for the thimerosal-exposed monkeys (34% vs. 7%).” “The results indicate that **ingested MeHg hydroxide** is not a suitable reference for risk assessment from exposure to [injected] thimerosal-derived Hg, **but** shed no light on [injected] MeHg thiosalicylate sodium salt as a suitable reference of [injected] Thimerosal-derived Hg.” Overall, the study confirms mercury poisoning is responsible for the alterations in the brain and behavior that Hornig *et al.* observed.]
2. Harry GJ, Harris MW, Burka LT. Mercury concentrations in brain and kidney following ethylmercury, methylmercury and Thimerosal administration to neonatal mice. *Toxicol Lett.* 2004 Dec 30; **154**(3): 183-9. [Note (with **bolding** added for emphasis): “The distribution of mercury to the brain following an injection of methylmercury (MeHg) or ethylmercury (EtHg) was examined in immature mice. **Postnatal day (PND) 16 CD1 mice received MeHg chloride either by IM injection or by gavage.** At 24 h and 7 days post-treatment, total mercury concentrations were determined in blood, kidney, brain, and muscle by cold vapor atomic fluorescence spectrometry. **At 24 h, an IM injection of MeHg chloride (17.4 microg) produced total mercury concentrations in the blood (6.2 +/- 0.9 microg/g), brain (5.6 +/- 1.3 microg; 0.6% delivered dose), and kidney (25.2 +/- 5.6 microg; 1.1%), that were approximately 35%, 35%, and 39%, respectively, of the levels obtained from oral administration** (blood: 17.9 +/- 1.0 microg; brain: 16.1 +/- 1.2 microg, 1.5%; kidney: 64.9 +/- 6.3 microg, 2.7%). **For comparison, PND 16 mice received an IM injection of concentrated dosing suspensions (2 microl dosing vol.) for EtHg chloride (6 microg) or Thimerosal (15.4 microg).** For EtHg, approximately 0.39 +/- 0.06% of the injected mercury was detected in the brain and 3.5 +/- 0.6% in the kidney at 24 h. **Thimerosal IM injection resulted in 0.22 +/- 0.04% in the brain, and 1.7 +/- 0.3% in the kidney. By 7 days, mercury levels decreased in the blood but were unchanged in the brain.** An acute IM injection to adult mice of each suspension at a 10-fold higher dose resulted an average 0.1% mercury in the brain, and higher levels in the blood, kidney, and muscle as compared to the young. In immature mice, MeHg delivered via oral route of administration resulted in significantly greater tissue levels as compared to levels from IM injection. Comparisons of tissue distribution following IM administration suggest that an oral route of administration for mercury is not comparable to an IM delivery and that MeHg does *not* appear to be a good model for EtHg-containing compounds. This study further confirmed mercury accumulation in the brain and shed light on the relative difference between the brain levels of mercury from oral gavage administration of an MeHg compound to the levels seen from the injection of a mole equivalent of thimerosal or the comparable EtHg compound, which Burbacher *et al.* reported finding subsequently.”]

In addition, numerous recent tissue and cell studies have confirmed and elucidate the pathways for the immune and autoimmune effects seen in the studies on susceptible mice conducted by Hornig *et al.*

Thus, contrary to the writer's statements, others have conducted experimental studies in animals, tissues, and cells that support, broaden, and elucidate the mechanisms for the studies conducted by Hornig *et al.*

“Even large epidemiological studies in Denmark failed to show a connection.”

First, this reviewer is compelled to note that the findings of epidemiological are only inferential, epidemiological studies *cannot* prove a link or disprove a link—they can only establish the probability of a link.

Moreover, *because such studies are prone to design bias and variable confusion and confounding*, the findings of an epidemiological study can be no better than the validity of the study design and the accuracy with which the “raw” data sets are constructed.

Further, *for a comparison of the level of exposure to the displaced incidence rate for the outcomes being evaluated to be valid between two populations*, the populations must have comparable causal exposure levels and timings and the case data must be properly assigned to the person's birth cohort and not his or her diagnosis or case inclusion dates.

Unfortunately, the large Danish epidemiological study (*of which the writer seems to be speaking*) conducted by Hviid A, Stellfeld M, Wohlfahrt J, Melbye M, and titled, “Association between thimerosal-containing vaccine and autism,” which was published in the Journal of the American Medical Association [**JAMA**. 2003 Oct 1; **290**(13):1763-6], violated all the preceding precepts.

Moreover, the researchers failed to fully disclose the conflict-of-interests that so obviously (*to this reviewer*) contributed to the design flaws and dataset errors that permeated this study.

Based on all of the preceding, the conclusions reached are **not**:

- Applicable to the US population because the maximum Thimerosal level and duration of the Thimerosal exposures in Denmark were much lower (less than a third of) than the maximum Thimerosal level for the US exposure, and
- Scientifically sound because the study design, database and data sets apparently were seriously flawed.

Further undermining this study was the refusal of the study's authors to allow independent researchers to examine the details of the design and independently evaluate the datasets used.

Based on all of the preceding, this epidemiological study's findings should be ignored until the issues raised by this reviewer have been fully addressed.

“By 2004, the Institute of Medicine proverbially put the issue to bed in its final report.”

Factually, all that the 2004 report on Thimerosal and autism by the Institute of Medicine (IOM) did was state:

- a. The narrow body of epidemiological evidence they chose to examine did *not* support a legally significant statistically probable link between Thimerosal level and the incidence of autism, and
- b. All research into the link between Thimerosal and neurodevelopmental disorders should stop.

Since clinical/toxicological evidence is required to prove a link and, *because it was presented but not yet published*, the findings of Hornig *et al.*, *though valid*, were simply dismissed along with the several published peer-reviewed epidemiological studies that had found clear significant statistical probable links between Thimerosal exposure and several neurodevelopmental disorders as well as the body of published supportive clinical/toxicological evidence supporting clinical mercury poisoning of tissues and systems at mercury levels below 0.1 ppm that has been accumulating since the 1930s, the IOM's report was, *on its face*, obviously biased and scientifically unsound.

Not only did the IOM's report fail to "proverbially put the issue to bed," their final report was the catalyst for David Kirby's researching the issues and, *based on what he was able to find*, publishing **EVIDENCE OF HARM ◀ MERCURY IN VACCINES AND THE AUTISM EPIDEMIC: A MEDICAL CONTROVERSY ▶** in 2005 and, in 2006, issuing an updated paperback version of this book, because of the additional evidence he had found and the ongoing demand for the book.

"The American Medical Association has also made clear its support for vaccination. 'It's critically important for parents to know that numerous scientific studies show no connection between thimerosal in vaccines and autism,' said AMA Trustee Robert M. Wah, MD, in a speech delivered last summer. 'We need more research to investigate the actual causes of autism, yet it would be a shame and a disservice to the health of our children if we let vaccines take the blame for this tragic and little-understood disease.'"

Contrary to AMA Trustee Wah's views about the connection between Thimerosal and neurodevelopmental disorders, including autism, it is "critically important for parents to know" the truth about the link between injecting bolus doses of Thimerosal (49.55% mercury by weight) *indirectly* into developing fetuses and *directly* into developing children.

That truth is that injecting 0.01% levels of Thimerosal in Thimerosal-preserved vaccines and other drugs mercury poisons all so treated.

While the majority may be sub-clinically transiently mercury poisoned, the rest of the children (more than 15%) exhibit delayed clinical mercury poisoning to the degree that most exhibit one or more of the clinical symptoms of mercury poisoning (including the set of symptoms used to diagnose autism) or, *in some cases*, are mercury poisoned to death.

Moreover, contrary to Wah's view, vaccines *per se* are *not* being blamed for autism, Wah's "this tragic and little-understood disease."

In about 85% of the "autism" cases, bolus-dosed mercury poisoning (*from the increased injection of Thimerosal-preserved serums and vaccines*) appears, *in those cases that have been fully diagnosed*, to be the underlying cause for the epidemic of autism and other autism spectrum disorder (ASD) cases being observed today.

In a small percentage of the ASD cases, the live-virus measles component may be a factor in causing the neurological harm observed in those children who have a severe reaction to the M-M-R II vaccine but do *not* die, *as some do each year*, from this severe and, apparently abnormal, "reaction" to being infected simultaneously by the live measles, mumps, and rubella viruses in the live-virus M-M-R II vaccine.

Having witnessed "healthcare establishment" professionals deliberately oversell the benefits of vaccination and fail to disclose all of the risks and/or their true incidence rates, and, *when challenged*, claim that their dissembling was for the good of the public, this reviewer knows that such behaviors have done more to undermine the public's confidence in vaccines and vaccination than the truth, coupled with real root-cause corrective action, ever could.

"But still, the issue stays in the limelight."

Until the "healthcare establishment":

- a. Stops claiming, *without proof of safety*, that it is "safe" to inject Thimerosal-preserved vaccines into developing humans because "they say it is,"
- b. Removes Thimerosal from all vaccines and other drugs, and
- c. Tells the public the truth about the harm that Thimerosal-preserved vaccines have caused,

this issue will not only stay in the proverbial "limelight" and but also continue to poison the public's trust in the "healthcare establishment" and the current vaccination programs.

"Pediatrics professor Paul Offit, MD, chief of infectious diseases at Children's Hospital in Philadelphia, believes early public education could have quelled flames.

'If we would have simply educated the public at the time. If we had said it's been used safely for 70 years.'"

Contrary to the stated views of vaccine apologist Offit, had the "health-care establishment" conducted the appropriate toxicology studies and, *based on what those studies would have found*, replaced the Thimerosal with another, non-bioaccumulative preservative, then, there would have been no need to "educate" the public, the "healthcare establishment" could have told the truth and avoided the Thimerosal-based mercury-poisoning epidemic with which, *in different ways*, both the "healthcare establishment" and the public are currently dealing.

“‘If we explained that ethyl mercury is structurally different,’ Dr. Offit says. ‘But we didn’t. Instead, we started to take it out of the vaccines ... and even though we assured people thimerosal was safe; taking it out it made it seem unsafe.’”

Since the scientific evidence has clearly established that “ethyl mercury” compounds are more toxic to humans than the corresponding “methyl mercury” compounds,¹⁸ this reviewer is at a loss to see how explaining “that ethyl mercury is different” will help the current situation.

Moreover, *given the preceding reality and the lack of proof of safety for Thimerosal at any level in a vaccine*, this reviewer would suggest that Dr. Offit and others of his ilk:

- ❖ Get busy getting Thimerosal and all other mercury species out of medicine entirely,
- ❖ Strongly advocate for the reduction of mercury emissions in industrial processes, and
- ❖ Support outlawing the use of mercury in dental fillings, that is, if the medical profession is truly interested in improving the health of the American public.

Rather than attempting to assure “people thimerosal was safe” when there is no scientific proof to support such a claim, the “healthcare establishment” should stop trying to support the unsupportable and get mercury out of all medicines!

“‘People started asking, ‘Why are they taking it out if it’s perfectly safe?’ ... The CDC opened the door, and the anti-vaccine people ran with it.’”

Based on this statement, this reviewer must conclude that Offit has lost touch with reality and believes the “healthcare establishment” is above the laws that require concrete proof of safety (**21 CFR Sec. 610.15(a)** and **21 U.S.C. Sect. 351(a)(2)(B)**), *not* mere statements that Thimerosal is “perfectly safe.”

“Dr. Offit blames a confluence of forces. ‘There are the anti- vaccine people, the parents of kids with autism, the lawmakers and the media.’”

In his arrogance, Offit seeks to blame others for his own and the “healthcare establishment’s” failures to insist that all vaccines fully comply with the law.

“‘In the current culture there is a belief in cover-ups and conflicts of interest. Thimerosal is out, so why now?’ His opinion is clear: ‘It’s the same as the breast-implant litigation. It’s a directed, coordinated campaign to educate the jury. This is about lawsuits, about going to court.’”

Again, *blinded by arrogance*, Offit seeks to ignore the millions that have been harmed by the Thimerosal-preserved vaccines and the hundreds that have died from being injected with these vaccines and, *instead*, to focus on transferring the

¹⁸ Harry GJ, Harris MW, Burka LT. Mercury concentrations in brain and kidney following ethylmercury, methylmercury and Thimerosal administration to neonatal mice. *Toxicol Lett.* 2004 Dec 30; 154(3): 183-9.

blame to other than himself and his fellows who: **a)** failed to ensure that Thimerosal-preserved vaccines were sufficiently nontoxic (as required by law) and **b)**, *when clear evidence of their harm to some began to grow*, attempted to deny the truth – ensuring that even more children would be harmed.

Contrary to Offit's views, this reviewer knows that the Thimerosal issue is really about:

- ❖ The millions of harmed children,
- ❖ The trillions of dollars that will be needed to pay for their care, and,
- ❖ Like asbestos, who will be forced to pay the costs for this care:
 - The “healthcare establishment” (who “*knowingly*” caused the problem and is currently in the stonewalling mode), or
 - The public (who currently is directly and indirectly bearing the costs for this care while the “healthcare establishment” continues to profit from the harm that it has done and is still doing).

Hopefully, the public will wake up, take back the government from the oligarchs, who currently control it, and make the “healthcare establishment” pay for this harm since it is currently being knowingly inflicted and the Thimerosal-preserved vaccines are clearly adulterated, and have been adulterated for decades, since 1973¹⁹, if not 1962²⁰.

“Between 2001 and 2006, 5,005 claims have been filed in the federal vaccine court established through the National Vaccine Injury Compensation Program to consider thimerosal-autism related cases. Because litigants must prove injury, the steering committee for the petitioners requested a stay until this fall to develop expert witnesses and the theory for their cases.”

While the writer has stated the facts, the writer has failed to disclose that the monies used to pay the claims are taxpayer dollars – the public's dollars and *not* the vaccine maker's or the government's monies because the government collects a tax on each dose of each vaccine component and, supposedly, puts that money in a trust fund for future claims.

Moreover, though the government has turned the “vaccine court” into an adversarial venue where each litigant must prove their case, the “vaccine court” was sold to the public as a non-adversarial, no-fault, rapid-decision venue.

However, *as soon as the public “looked away,”* this administrative court was stripped of key provisions that made it non adversarial and fair, and tilted in the government's favor at the expense of the public to the point that, *today*, cases take many years to be addressed and most cases are dismissed in any technicality or denied based on a failure to adequately prove that the damaged person was damaged by the vaccines administered.

¹⁹ Under the vaccine-specific regulations set forth in 21 CFR Section 610.15(a).

²⁰ Under general drug safety requirements set forth in 21 U.S.C. Section 351(a)(2)(B) including meeting “the requirements of this chapter [Chapter 9 – The Federal Food, Drug and Cosmetic Act as amended] as to safety.”

“In addition, thousands of civil actions against manufacturers are under way.”

As far as this reviewer can ascertain, the writer’s alleged number of civil suits seems to be inflated because those reviewer doubts that there are thousands of attorneys and litigants who can afford the costs of a civil trial where the chance of a favorable outcome is, *at best*, less than 50:50 and the testing required to prove probable vaccine-related-mercury poisoning is fairly expensive (in the range of US\$ 10,000.00 to US\$ 20,000.00) for each child harmed.

When this reviewer discussed this issue with someone involved in such cases, that person thought that the current number of active civil vaccine actions was less than a ten.

“In order to quiet conflict-of-interest charges, the CDC transferred vaccine safety activities from the National Immunization Program to the Immunization Safety Office's Office of the Chief Science Officer, giving thimerosal research priority.”

Given the failure of the CDC to:

- ❖ Provide independent researchers unfettered access to usable integrity-verified VSD database datasets,
- ❖ Preserve the data sets used in all of the “Verstraeten” studies as directed by Congress, and
- ❖ Take legal action against all government officials who profited from the apparent “selling” of the VSD to the government through the payments paid to dummy corporations and/or were simultaneously full-time paid employees of both the National Immunization program (NIP) and the private “Brighton Collaboration,”

it will take more than the CDC’s transferring “vaccine safety activities from the National Immunization Program to the Immunization Safety Office's Office of the Chief Science Officer” and claiming to give “thimerosal research priority” to quite the ongoing conflict-of-interest charges pending against the CDC, the US FDA, and the Secretary of Health and Human Services.

“Ongoing studies there include:

- A study of more than 1,000 thimerosal-exposed children evaluated with standardized neuropsychological assessments. Results will be published later this year.”

Since, under today’s schedule, millions of children are exposed to Thimerosal each year:

- a. Any serious population study would have to study not less than 1,000,000 randomly selected Thimerosal-exposed children between the ages of 5 (to ensure getting those diagnosed with autism) and 14, with 100,000 in each age group along with a matched control cohort of children without any exposure to Thimerosal (serum, vaccine or other drug) for each year of not less than 25,000 children, and

- b.** Standardized neuropsychological assessments would need to be developed and validated for children who are totally non verbal – otherwise, this “screen” will only be able to assess those with mild to moderate damage.

*Unless the preceding changes are effected, the study risks not finding a sufficient number of children who have been significantly harmed, the statistical power for the results obtained in the proposed study are insufficient to extrapolate from the results for the set tested to the entire population, and the “screen” will *not* be able to assess those most adversely affected by Thimerosal (who *cannot*/do *not* speak at all).*

Based on the preceding, the study, as described, will deliberately weed out those most harmed by the Thimerosal and have insufficient statistical power to extrapolate to the entire US population of those who, though damaged by Thimerosal, can still communicate sufficiently to take the “standardized neuropsychological assessments” used.

- “• A case-control study involving a follow-up of a clinical trial of acellular pertussis vaccine performed in Italy. Two different acellular pertussis vaccines were evaluated – one with thimerosal, one without.”

This study is problematic because: **a)** it is *not* being conducted on American children **and b)** it fails to follow up on the findings in the published US studies evaluating these differential outcomes observed for the US-licensed Pertussis vaccines – with and without Thimerosal.

- “• A study exploring autism risk associated with thimerosal exposure by reviewing children from the prenatal period to the first seven months of life.”

Again another dangerous and flawed study that appears to require Thimerosal, a *known human teratogen*, to be injected into pregnant women at various stages in their pregnancy and then, at birth, and 1, 2, 4, 6, and 7 months, to inject the appropriate Thimerosal-containing vaccines into the baby while continually monitoring all levels of the known mercury-poisoning markers as well as all key health-indicating parameters before and after each mercury dose.

In addition, two matched control group will be needed, one given only Thimerosal-free serums and vaccines and the other totally unvaccinated, in order to recognize any differences attributable to the Thimerosal-preserved vaccines and those attributable to the vaccines without Thimerosal, at least 1,000 males and 1,000 females should be in each vaccine arm, and 250 males and 250 females in the unvaccinated control set so that, *if any*, sex-related differences will more easily identified and tracked.

“Some say these and more findings will clear the air.”

Given the manner in which the studies are presented, this reviewer understands that such underpowered and biased studies will do little “clear the air” and, indeed, may actually “muddy the waters.”

In addition, this reviewer notes that the requisite Thimerosal toxicity studies are still *not* being conducted.

Until the requisite toxicological studies (as outlined previously in this rebuttal) are properly conducted and the findings published, this reviewer understands that the outlined studies *cannot* truly “clear the air.”

“Mady Hornig, MD, associate professor of epidemiology at Columbia University Mailman School of Public Health in New York, says the complexity of the thimerosal-autism story is part of the problem. She published early studies citing mercury-induced autoimmune outcomes in mice that suggested a genetic basis underlying developmental thimerosal neurotoxicity.”

This reviewer agrees with Dr. Hornig and understands that there are genetic factors, which affect the absorption, transport, metabolism, storage, and transport of mercury species in the human body, as well as possible genetic factors that affect the body’s resistance to mercury damage and/or ability to recover from intermittent mercury bolus dosings.

However, *given the reality of the bolus dosings of mercury from Thimerosal-preserved vaccines, the science indicates that, as with the mice Hornig studied, the harm was inflicted by the bolus mercury doses from the Thimerosal-preserved vaccines given to “susceptible” humans.*

“The literature reports a subset of children with immune disruption. Whether this is solely genetic or triggered by environmental contributors that set the stage for an immune disturbance, we don’t know,” she says. ‘A connection is not strongly made on the basis of these few studies alone. We need much more coordinated [research] efforts.’”

Actually, given the millions of mercury-poisoned human cases the “healthcare establishment” has created, the studies would better serve the public if the “healthcare establishment” studied those injured, and their parents and siblings.

“Anti-vaccine and no-mercury groups frequently point to Dr. Hornig's early findings.”

This reviewer, a scientist in a “no-mercury” group, finds that the writer appears to be naive about: **a)** the early animals studies dating from the 1930s that have shed more light collectively on the complexity of organic-mercury-based mercury poisoning than recent work reported in the paper by Hornig *et al.*, and **b)** the others who have already stepped in and begun elucidating the mechanisms associated with some of “Hornig's early findings.”

Moreover, as the references in this rebuttal indicate, this reviewer points to the works of others as much or, in several cases, more than he points to the paper by Hornig *et al.*

Thus, the writer's statement here is, at best, an overly broad generalization.

“But there are too many variables that oversimplification does not address, she says. ‘It will be valuable to have a continued dialogue. I'd like to see the research continue and expand. [Current] studies are not adequate, and more are sorely needed.’”

This reviewer agrees with Dr. Hornig here and notes that, *as outlined previously*, additional research in the area of animal models and mercury poisoning, immunogenicity, and autoimmunogenicity has already been conducted and, in many cases, published.

“Particularly heartening, she says, is the Columbia-led Autism Birth Cohort study in which scientists will follow 100,000 Norwegian babies and their parents for at least five years, beginning during the mother's pregnancy. The goal is to identify biological and environmental factors that could combine to cause autism and other developmental disorders. ‘We are learning all the time,’ Dr. Hornig says.

While this reviewer has no problem with a Norwegian study *per se*, he understands that a similar study in the US would provide information that is more applicable to the US realities than a comparable Norwegian study.

This study is also suspect because these Norwegian babies have no comparable exposure to injected Thimerosal.

Underimmunization

“For public health experts, the potential impact of this movement on vaccination coverage rates is a matter for anxiety. In general, the CDC reported in 2004 that each year 2.1 million children ages 19 months to 35 months are undervaccinated while 17,000 children are unvaccinated.”

Since there are about 6 million children between 19 month and 35 months of age each year, the data presented indicate:

- ❖ Only about 0.3 % of families do *not*, for whatever reason, medical, religious, or philosophical, vaccinate their children at all and,
- ❖ Based on general vaccine uptake percentages in the low to mid 90s range, that, in general, the “Thimerosal” in vaccines issue is only turning the public toward insisting on “Thimerosal free” vaccines in all cases.

“Additionally, nearly three-fourths (71%) of parents who choose not to vaccinate say doctors have little influence over their decisions. Almost half (48%) of these parents expressed a concern about vaccine safety, the CDC's National Immunization Survey found.”

This reviewer sees these statistics as indicators that the public is becoming increasingly aware of the realities that, *at best*, vaccine benefits are over-hyped and vaccine risks are understated.

When the percentage expressing concern about vaccine safety exceeds 95%, this reviewer will be satisfied that the public has been adequately informed about the

benefits and risks associated with each vaccine and will, *if mentally competent*, be qualified to give “informed consent”

“‘With vaccines, there is no such thing as 100% safe or 100% effective, so we go by the weight of the evidence,’ says UTMB's Dr. Myers, former director of the Dept. of Health and Human Services National Vaccine Program Office. But changing risk perceptions also have an impact on parents' decisions.”

While this reviewer generally agrees with Dr. Myers' statement and the writer's remark here, this reviewer understands that the “healthcare establishment” currently is *neither* providing the public with accurate safety risk and effectiveness data *nor* trying to accurately capture and investigate all vaccine adverse events reports.

Until these deficiencies in the vaccine programs can be and are corrected, the “healthcare establishment” should *not* expect public confidence in the current vaccine programs to increase.

Finally, until the true cost effectiveness of each vaccine is assessed and vaccines that are *not* truly cost effective for the public discontinued, the “healthcare” establishment will face increasing resistance to “booster vaccines” and added vaccine doses for vaccines whose justification for licensing was barely cost-effective for one dose of the vaccine.

This vaccine pushback will be led by knowledgeable vaccine activists who are pro-vaccine only when the vaccine

- ❖ Fully complies with all applicable statutes and laws governing drugs, in general, and vaccines, in specific, and
- ❖ Has been proven to be:
 - Sufficiently safe long term,
 - Long-term effective, and
 - Truly cost effectivefor the public.

“Pediatric medicine is a victim of its own success, says Douglas S. Diekema, MD, MPH, an associate professor of pediatrics at the University of Washington School of Medicine and interim director of the Center for Pediatric Bioethics at Children's Hospital and Medical Center in Seattle. ‘Fifty years ago people died of measles, and lots of babies were born with malformations from rubella,’ he says. ‘When you get that successful, people forget [about these horrors], and that changes the equation for parents. To them, the diseases don't exist anymore.’”

First, this reviewer finds it odd that Dr. Diekema would couple the success of “Pediatric medicine” to the vaccine program since the improvements in hygiene, water and air quality, and nutritional health in the early 1900s contributed more to the decline in these diseases than the vaccines cited, which were generally not introduced until the disease death rate were well below epidemic rates.

Moreover, this reviewer finds that Diekema seems to be a “victim” of his own hubris here.

This the case because his remarks indicate that he has forgotten that some babies still die from the measles virus in the M-M-R II vaccine and many more are severely harmed and some babies are still born with “malformations from rubella.”

In addition, this reviewer finds that he has ignored the epidemic rise in neurodevelopmental disorders, asthma, type II diabetes, obesity, MS, some cancers, idiopathic dilated cardiomyopathy (IDCM), severe food allergies, and other diseases that may have been, *in large part*, caused by components (like Thimerosal, aluminum salts, antibiotics, viral contaminants, and genetically engineered viral fragments) currently in some vaccines.

Finally, this reviewer must remind this commenter and the writer’s employer, the AMA, that they seem to have forgotten some vaccines have caused more harm than the good they were “purported” to do (e.g., the now-withdrawn LYMERix [or LymeRx] vaccine, marketed by SmithKline Beecham [now, a merged into GlaxoSmithKline], and the RotaShield vaccine, marketed by Wyeth-Lederle [part of Wyeth-Ayerst]).

“A recent mumps outbreak, blamed at least in part on underimmunization, is showing how close to the surface these threats remain. The CDC says the U.S. outbreak, which featured the same genotype responsible for more than 70,000 cases in the United Kingdom, continues to spread, with seven states and more than 2,400 cases.”

Contrary to the views expressed here, the culprit was *not* so much “underimmunization” as it was the failure of the vaccine to provide sufficiently long-term immunity to the disease.

Given the decision by the Japanese *not* to recommend the mumps vaccine but to provide it as an optional vaccine where needed, this reviewer finds that it would be better to let children have the mumps when they are young and acquire lifetime (typically, > 70-year) immunity, and only vaccinate those preteen boys found *not* to have developed an immunity to mumps.

Moreover, *given the problems observed with universal chickenpox vaccination program*, this program should be summarily abandoned and a voluntary program (similar to the program in Japan) should be phased in to replace it – if this were done: **a)** the costs of the program would decline and **b)**, *with reboosting from exposures to the circulating virus*, varicella immunity would increase, maternal antibodies would be replenished in females, the need for a varicella booster vaccine or for repeated shingles vaccinations would be greatly reduced, and the people’s financial and medical health would improve..

“This drama comes up a lot in exam rooms, Dr. Lord says. ‘We try to get parents to think about what they are doing – about what’s safe and what the risks are. If they aren’t going to vaccinate, we ask them how they will protect their child on airplanes, in a big shopping center. We have them think it through.’”

As long as the parents in Dr. Lord's scenarios are given accurate "take," effectiveness and adverse-effects data, this reviewer has no problem with the scenarios presented.

However, this reviewer finds that today's parents are *not* being accurately or fully informed about all of the preceding aspects of vaccines.

"A few family physicians and pediatricians will not accept patients if vaccinations are refused, a position the American Academy of Pediatrics discourages."

Since the decision to vaccinate or not to vaccinate belongs to the parents, family physicians and pediatricians who will not accept patients if vaccinations are refused should be strongly counseled to accept their patient's decisions in these matters.

"This issue needs to be handled with understanding, Dr. Diekema says. 'Parents' concern about the autism issue seems to go up or down with what's in the press, and they don't have a good way of judging opinions. But the reality is most are seeking guidance from their physician. These families are scared, and from what we see, most physicians are trying to have respectful conversations with families coming in with all kinds of [views].'"

Again Dr. Diekema's hubris seems to be intruding in these remarks.

As an informed consumer of vaccines, this reviewer resents the glib "Father knows best" approach and the attempt to cast families as less than capable "of judging opinions" and/or "scared," when, *in many cases*, the issues raised by the physician boil down to the underlying unstated issue of the revenue he or she won't get if the child is *not* vaccinated.

ADDITIONAL INFORMATION:

Key dates (revised)

1962: Oct. 10, 1962, Pub. L. 87-781, title I, Sec. 101, 76 Stat. 780, added:

"(B) if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess; ..."

after the existing **21 U.S.C. Section 351(2)**, which was redesignated as 21 U.S.C. Section 351(2)(A).

1973: 38 FR 32056, Nov. 20, 1973, added:

"PART 610--GENERAL BIOLOGICAL PRODUCTS STANDARDS" to the FDA's binding regulations set forth in **"TITLE 21--FOOD AND DRUGS, CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES,"** including at **21 CFR Sec. 610.15 Constituent materials**, which includes at "(a)," a requirement that preservatives on vaccines must be proven to be:

“sufficiently nontoxic so that the amount present in the recommended dose of the product will not be toxic to the recipient.”

- 1986: The National Childhood Vaccine Injury Act establishes the National Vaccine Injury Compensation Program, including a special court to consider vaccine -related claims.
- 1997: The Food and Drug Modernization Act requires the Food and Drug Administration to compile a listing of mercury in food and drugs.
- 1999: As a precaution, after having conferred with government healthcare researchers and officials in an illegally closed-to-the-public meeting in the Lister Hill auditorium on the campus of the National Institutes of Health, vaccine manufacturers begin removing thimerosal from their US-licensed childhood vaccines.”

Vaccine Safety Datalink (VSD) database is used by the NIP in the CDC to study possible Thimerosal-related safety problems initially using datasets purchased from several California managed care organizations (the so-called “Phase ‘0’ Study” by the NIP group headed by Dr. Verstraeten who now works for GlaxoSmithKline).

- 2000: Thimerosal-free/reduced-Thimerosal vaccines for hepatitis B and bacterial meningitis are widely available; organizations such as Safe Minds take form to press grassroots educational efforts regarding the obvious connection between Thimerosal and the mercury poisoning symptoms that are used to diagnose autism and autism spectrum disorders (ASDs) after “noticing” the clear parallels between the Thimerosal form of organic mercury poisoning diagnosed as ASDs, and the prior Calomel form of inorganic mercury poisoning diagnosed as Pink Disease and Acrodynia.

In October, vaccine industry representatives and consultants, government researchers and public health officials again held an illegally closed-to-the-public meeting at the Simpsonwood Retreat to discuss the “Feb 2000” draft epidemiological findings from the VSD database studies assessing the link between Thimerosal and neurodevelopmental disorders. Those at the meeting agreed to embargo the draft report and to work together to “manage” the clear links found in that draft. The lead government researcher, Dr. Verstraeten was hired by a vaccine manufacturer and relocated to Europe.

- 2001: An Institute of Medicine (IOM) Safety Review Committee report: a) concludes that, while the link us scientifically plausible, there is insufficient clinical and experimental evidence to prove the Thimerosal/“neurodevelopmental disorder” theory and recommends that additional studies should be conducted. [Note: The draft VSD epidemiological study findings were apparently not presented to this IOM.]
- 2002: In a University of Rochester (New York) study published in the *Lancet*, researchers conclude that mercury levels in the blood of infants receiving vaccines with thimerosal are below concentrations potentially associated with toxic effects in the blood. However, the researchers failed to take blood samples until several days after the test subjects were vaccinated and did not collect samples for hair and tissue evaluations or monitor the level of Thimerosal in urine and feces to track clearance of Thimerosal and mercury from the babies’ bodies.
- 2002: “Class” Thimerosal/autism claims proceedings begin in the vaccine court.
- 2003: Most of the Thimerosal-preserved lots of vaccines (except the Thimerosal-preserved flu vaccine that was “inexplicably” added to the recommended childhood vaccination schedule in

December of 2003) for young children begin to expire. However, lots with expiration dates into 2005 and, possibly, beyond were allowed to be used to vaccinate children!

The final “re-revised” VSD study was published in *Pediatrics*.²¹ By again massaging the data used and expressing the results in terms of the “Odds Ratio per 25-micrograms of mercury exposure,” the obvious links between Thimerosal and neurodevelopmental disorders in the “Phase 0” data and Simpsonwood “draft VSD” report were made to disappear. In addition, the article failed to disclose that Verstraeten was no longer a government employee and had *not* been one for more than a year before the final article was accepted for publication.

The **less-than-relevant and flawed**, Danish **epidemiological** study was published²² and it also discounted a link between thimerosal in vaccines and neurological disorders. Though touted by the vaccine apologists, this Danish study is a misleading and flawed epidemiological study because: **a)** Danish children received a much lower maximum dose of Thimerosal, **b)** the cases included in the database used dramatically changed over time and **c)** reporting rates were confused with occurrence rates. In addition, the CDC’s role in shaping the study design and the financial conflicts of the authors were *not* disclosed.

2004: In January 2004, Department of Health and Human Services, the CDC and the American Academy of Pediatrics issued an **Autism A.L.A.R.M. to medical professionals**. This **“A.L.A.R.M” counseled:**

“Autism is prevalent:

- 1 out of 6 children are diagnosed with a developmental disorder and/or behavioral problem
- 1 in 166 children are diagnosed with an autism spectrum disorder
- Developmental disorders have subtle signs and may be easily missed

Listen to parents

- Early signs of autism are often present before 18 months
- Parents usually DO have concerns that something is wrong
- Parents generally DO give accurate and quality information
- When parents do not spontaneously raise concerns, ask if they have any

Act early

- Make screening and surveillance an important part of your practice (as endorsed by the AAP)
- Know the subtle differences between typical and atypical development
- Learn to recognize red flags
- Use validated screening tools and identify problems early
- Improve the quality of life for children and their families through early and appropriate intervention

Refer

- To Early Intervention or a local school program (do not wait for a diagnosis)
- To an autism specialist, or team of specialists, immediately for a definitive diagnosis
- To audiology and rule out a hearing impairment
- To local community resources for help and family support

Monitor

- Schedule a follow-up appointment to discuss concerns more thoroughly
- Look for other features known to be associated with autism
- Educate parents and provide them with up-to-date information
- Advocate for families with local early intervention programs, schools, respite care agencies, and insurance companies
- Continue surveillance and watch for additional or late signs of autism and/or other developmental disorders”

²¹ Thomas Verstraeten, Robert L. Davis, Frank DeStefano, Tracy A. Lieu, Philip H. Rhodes, Steven B. Black, Henry Shinefield and Robert T. Chen; for the Vaccine Safety Datalink Team, “Safety of Thimerosal-Containing Vaccines: A Two-Phased Study of Computerized Health Maintenance Organization Databases,” *Pediatrics*. 2003; **112**(5): 1039-1048.

²² Anders Hviid, Michael Stellfeld, Jan Wohlfahrt and Mads Melbye, “Association Between Thimerosal-Containing Vaccine and Autism,” *Journal of the American Medical Association (JAMA)*. 2003; **290**(13): 1763-1766.

An early 2004 Institute of Medicine final report, "Vaccines and Autism," concluded: **a) the narrow body of epidemiological evidence they chose to use in their deliberations does not support a causal relationship between thimerosal-containing vaccines and autism and b) no additional research should be conducted into this relationship.**

Later in 2004, the American Academy of Pediatrics, American Academy of Family Physicians, the CDC vaccination advisory committee, and the Public Health Service issued a joint statement, maintaining that there is no convincing evidence of harm.

In August 2004, the Coalition for Mercury-free Drugs (CoMeD) filed a "Citizen Petition" with the FDA seeking to compel the FDA and the Secretary of HHS to comply with and enforce the laws governing vaccines (**see: FDA Public Docket: 2004P-0349**).

2005: On 4 February 2004, FDA issues its legally mandated 180-day interim response to the CoMeD that simply states they need more time to study the complex issues raised in the CoMeD petition.

On 23 February 2004 (posted to the FDA docket 2004P-0349 on 2 March 2005), CoMeD responded by putting the FDA and the Secretary of HHS on notice that, *should the FDA fail to act in the next 90 days on the straightforward compliance issues*, that CoMeD will consider taking action to compel the FDA and the Secretary of HHS to comply with the law.

Vaccine Safety Datalink (VSD) **database, paid for by the CDC with taxpayer funds, was placed under the control of a private firm by the CDC to further impede independent researchers' attempts to use the VSD database to study possible vaccine safety problems** David Kirby published his book, "**EVIDENCE OF HARM**"

2006: Anti- vaccine and anti-thimerosal groups sponsor *USA Today* ad accusing the CDC of covering up an autism epidemic; the CDC reports that at least 300,000 school-aged children had autism in 2003-04.

On 5 May of 2006, the CDC published survey results indicating that the current rate of autism in the US remains at epidemic levels with about 1 reported autism case in every 175 children.²³

Reacting to a continuing demand, David Kirby publishes an updated paperback of his "**EVIDENCE OF HARM**" book.

On 29 June 2006, autism and ASD activists held a demonstration in Atlanta, Georgia outside the CDC's headquarters over the ongoing failure of the CDC to come clean on their cover up of the dangers of mercury in vaccines other drugs and demanding Thimerosal be removed from all vaccines and drugs, and the CDC admit its attempted cover up of the causal link between Thimerosal and those forms of sub-acute mercury poisoning that generate the symptoms used to diagnose autism, other ASDs, and other neurodevelopment and behavioral disorders.

²³ Mental Health in the United States: Parental Report of Diagnosed Autism in Children Aged 4–17 Years — United States, 2003–2004. *Morbidity and Mortality Weekly Report*. May 5, 2006; **55**(17): 481-486