

# Key realities about autism, vaccines, vaccine-injury compensation, Thimerosal, and autism-related research

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## Abstract

The propaganda dispensed by Public health care and vaccine apologists is, *at best*, a weak attempt to rationalize the healthcare establishment's positions using all the tools of doublespeak or, as George Orwell's called it in his book *1984*, "newspeak", to: (a) mislead, (b) distort reality, (c) pretend to communicate, (d) make the bad seem good, (e) avoid and/or shift responsibility, (f) make the negative appear positive, (g) create a false verbal map of the world, and (h) create dissonance between reality and what their narrative said or did not say.

Such propaganda often relies on half-truths and/or superficially logical, but foundationally flawed, phrasing. However, this propaganda is fundamentally flawed and based on pseudo-science or non-reviewable statistical studies of medical records, where, contrary to ethical science, the study design, data selection/rejection criteria, exact approach used to evaluate the data, and/or the original data set itself is kept confidential making independent evaluation/verification of the published findings impossible. A review of the statements from an article in the November 1, 2007 issue of the *Skeptical Inquirer* that is entitled "Vaccines and Autism: Myths and Misconceptions" by Steven Novella, MD (which was found online at <http://www.encyclopedia.com/doc/1G1-170731919.html>) triggered this presentation of the factual realities that rebut the myths/misconceptions presented in that article and/or in similar articles published and/or underwritten by the purveyors of vaccines and vaccination recommendations. Each myth/misconception is summarized in a short statement and then addressed by presenting the factual reality and when appropriate, providing peer-reviewed references that support this reality.

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**Keywords:** autism, mercury poisoning, vaccines, myths and misconceptions

## I. Fundamental Autism Realities

**Autism myth #1:** Autism is a disorder whose cause is unknown.

**Reality:** Autism is a disorder that is diagnosed by a defined set of symptoms/behaviors (according to the DSM-IV or Diagnostic and Statistical Manual 4<sup>th</sup> edition) that are known to have multiple causes, some of which are known (e.g., Thalidomide, alcohol consumption, and synthetic retinoids [synthetic Vitamin A derivatives] taken during pregnancy, and poisoning by heavy metals such as lead and mercury [most recently, via Thimerosal]).<sup>1</sup> In general, there are two recognized types of autism: congenital and regressive (or delayed-onset) autism. However, with the recommendations: a) to inoculate pregnant women with a potential Rh-factor blood incompatibility with a Thimerosal-preserved serum (a Rho(D) serum) at 28 weeks, during any amniocentesis or spotting episode in the late 1980s to early 2000s)<sup>2</sup> and b), starting in 2002, to vaccinate pregnant

women with influenza vaccines that are Thimerosal-preserved,<sup>3</sup> it has obviously become increasingly difficult to differentiate between these two types of autism.

**Autism myth #2:** Those having a diagnosis of autism or a diagnosis of mercury poisoning do not have the same symptoms.

**Reality:** The set of symptoms used to diagnose autism and other neurodevelopmental disorders are the same as or highly similar to the symptoms seen in individuals with sub-acute mercury poisoning.

In addition, other non-neurological symptoms (e.g. severe gastrointestinal dysfunction, dystonia) are exhibited by those who have a diagnosis of sub-acute (less than ultimately lethal) mercury poisoning because Thimerosal is an all-systems poison (e.g., cardiovascular, endocrine, dermal, etc.)

c. Bowman JM, Pollock JM. Antenatal prophylaxis of Rho isomunization: 28-weeks'-gestation service program. *Can Med Assoc J.* 1978; **118**:627–30.

d. American College of Obstetricians and Gynecologists (1981). The selective use of Rho(D) Immune Globulin (RhIG). *ACOG Tech Bull* 61.

e. Pollack W. Rh hemolytic disease of the newborn; its cause and prevention. *Prog Clin Biol Res* 1981; **70**:185–203.

f. American College of Obstetricians and Gynecologists (1990). Prevention of D isoimmunization. *ACOG Tech Bull.* 147.

3 Bridges CB, Fukuda K, Uyeki TM, Cox NJ, Singleton JA. Prevention and Control of Influenza Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 2002 Apr 12; **51**(RR03):1–31.

<sup>1</sup> April 2007 (PowerPoint Presentation) by Dr. Larry Needham, Chief, Organic Analytical Toxicology Branch, National Center for Environmental Health, Centers for Disease Control and Prevention, "Exposure (To Stressors) and Autism Spectrum Disorders" to the Institute of Medicine of the US National Academy of Sciences.

<sup>2</sup> a. American College of Obstetricians and Gynecologists (1976). Current uses of Rho immune globulin and detection of antibodies. *ACOG Tech Bull.* 35.

b. Bowman JM, Chown B, Lewis M, Pollock JM. Rh isoimmunization during pregnancy: antenatal prophylaxis. *Can Med Assoc J* 1978; **118**:623–7.

The reality of the preceding has been repeatedly established and discussed by Dr. King<sup>4</sup> who presents comparative listings of and references for the similarity between the symptoms of autism and related neurodevelopmental disorders and those of sub-acute mercury poisoning.

To aid the reader, a portion of the information provided in Dr. King's reference is presented in Table I below.

**Table I: Summary Comparison of "Traits" of Autism and Mercury Poisoning**

Where differences in typical language exist, "Autism/ASD" is designated by "(ASD)"; "Mercury Poisoning" by "(HgP)"

### **Psychiatric Disturbances**

Social deficits, social withdrawal, shyness.

Repetitive, preservative, stereotypic behaviors; obsessive-compulsive tendencies.

Depression/depressive traits, mood swings, flat affect; impaired face recognition.

Anxiety; schizoid tendencies; irrational fears.

Irritability, aggression, temper tantrums.

Lacks eye contact; impaired visual fixation (HgP). Problems in joint attention (ASD).

### **Speech and Language Deficits**

Loss of speech, delayed language, failure to develop speech.

Dysarthria; articulation problems.

Speech comprehension deficits.

Verbalizing and word retrieval problems (HgP). Echolalia, word use and pragmatic errors (ASD).

### **Sensory Abnormalities**

Abnormal sensation in mouth and extremities.

Sound sensitivity; mild to profound hearing loss.

Abnormal touch sensations; touch aversion.

Over-sensitivity to light; blurred vision.

### **Motor Disorders**

Flapping, myoclonal jerks, choreiform movements, circling, rocking, toe walking, unusual postures.

Deficits in eye-hand coordination; limb apraxia; intention tremors (HgP). Problems with intentional movement or imitation (ASD).

Abnormal gait and posture, clumsiness and incoordination; difficulties sitting, lying, crawling, and walking; problem on one side of body.

### **Cognitive Impairments**

Borderline intelligence, mental retardation - some cases reversible.

Poor concentration, attention, response inhibition (HgP). Shifting attention (ASD).

Uneven performance on IQ subtests; verbal IQ higher than performance IQ.

Poor short-term, verbal, and auditory memory.

Poor visual and perceptual motor skills; impairment in simple reaction time (HgP). Lower performance on timed tests (ASD).

Deficits in understanding abstract ideas & symbolism; degeneration of higher mental powers (HgP). Sequencing, planning & organizing (ASD); difficulty carrying out complex commands.

### **Unusual Behaviors**

Self-injurious behavior, e.g. head banging.

ADHD traits.

Agitation, unprovoked crying, grimacing, staring spells.

Sleep difficulties.

### **Physical Disturbances**

Hyper- or hypotonia; abnormal reflexes; decreased muscle strength, especially upper body; incontinence; problems chewing, swallowing.

Rashes, dermatitis, eczema, itching.

Diarrhea; abdominal pain/discomfort, constipation, "colitis."

Anorexia; nausea (HgP)/vomiting (ASD); poor appetite (HgP). Restricted diet (ASD).

Lesions of ileum and colon; increased gut permeability.

**Autism myth #3:** Evidence is accumulating that autism is largely a genetic disorder (Szatmari 2008).

**Reality:** Despite the large-scale genetic studies to pinpoint the "autism" genes, to date, only a small percentage of those with a diagnosis of autism have been found to have any identified genetic abnormalities (e.g., Fragile X, downs syndrome, Tay Sachs).

Even children with, for example, Fragile X, where some are diagnosed with an autism spectrum disorder, many do not have this diagnosis.<sup>5</sup>

Additionally, those with ties to public health and the pharmaceutical industry know that a growing body of scientific fact has established and supports the reality that vaccines and/or the mercury in some of them can and do, in many instances, cause the neurodevelopmental harm that generates the set of symptoms used to diagnose autism. To date, even the largest studies have failed to find any definitive genetic pattern that is always associated with autism.

Furthermore, public health officials and vaccine apologists ignore the genetic reality that Thimerosal is a proven teratogen and mutagen that, *for decades*, has been known to induce genetic harm.<sup>6</sup>

Given the preceding realities, it may be that many of the genetic anomalies appearing today may be the result of genera-

<sup>5</sup> Richard Lathe. *Autism, Brain, and Environment*, Jessica Kingsley Publishers, London, England, 288pp, 2006. Hardback, ISBN: 978-1-84310-438-4.

<sup>6</sup> a. Goncharuk GA. Experimental investigation of the effect of organomercury pesticides on generative functions and on progeny. *Hyg Sanit.* 1971; **36**:40–3. [Note: Paper shows second-generation effects even though the first-generation progeny were *not* given organic mercury-containing compounds—clearly showing teratogenic effects to the first-generation progeny's reproductive systems.]  
b. Verschaevae L, Kirsch-Volders M, Susanne C, *et al.* Genetic damage induced by occupationally low mercury exposure. *Environ Res* 1976; **12**:306–16.

<sup>4</sup> Appendix A, "Comparison Of: The Characteristics of 'Autism' To Those For Mercury Poisoning," in *Thimerosal Causes Mercury Poisoning I—A Rebuttal to Dr. Novella's Views* (30 Aug. 2005). Available online at [www.mercury-freedrugs.org/docs/Thimerosal\\_Causes\\_Mercury\\_Poisoning.pdf](http://www.mercury-freedrugs.org/docs/Thimerosal_Causes_Mercury_Poisoning.pdf)

tions of the *apparently knowing* mercury poisoning of babies – first by Calomel (in the late 1880s to the early 1940s in the U.S. and until the mid-1950s in Australia) and, *more recently* (from the 1930s onward), by Thimerosal in vaccines as well as by Thimerosal and other mercury compounds (e.g., phenyl mercuric salts) in other drugs.

Research scientists (not “Mercury alarmists”) know:

- The scientifically sound studies support the “Thimerosal in vaccines causes autism” hypothesis and
- The “*negative evidence*” of which vaccine apologists speak is derived from provably less-than-sound, improperly manipulated and/or intentionally misdesigned studies.

**Autism myth #4:** The families that have children who regressed into autism have always been anti-vaccine.

**Reality:** Often these families who have become resistant to the states’ recommended vaccinations and/or the CDC’s recommended vaccination schedules have adhered to the recommended childhood immunization schedule and only began to oppose the current vaccination program after they or their children have actually experienced a serious adverse reaction.

Thus, most of the families who have children who have regressed into autism have not always been anti-vaccine and, *in some cases*, still support the giving of some vaccines to children.

**Autism myth #5:** The autism “epidemic” does not represent a true increase in the disorder, but rather is an artifact of expanding the diagnosis (now referred to as autism spectrum disorder, ASD) and increased surveillance (Taylor 2006).

**Reality:** Since the 1990s, the number of children enrolled in special education classes has vastly increased for children in the autism spectrum.

Thus, it is clear that most of the increase is real and *not* related to “*expanding the diagnosis*” or “*increased surveillance*.” See, for example: California Department of Health and Human Services, Department of Developmental Services, “AUTISTIC SPECTRUM DISORDERS Changes In The California Caseload An Update: 1999 through 2002,” Sacramento, CA (April 2003).

**Autism myth #6:** The science involving vaccines and autism is complex, making it difficult for the average person to sift through all the misdirection and misinformation.

**Reality:** Ask the “*average person*” the fundamental question: “Do you think that injecting soluble organic mercury into babies mercury poisons them?” – most, pause for a moment, and then answer, “Yes!” “Yes, I do” or “Yes, of course.”

Since Thimerosal-derived mercury poisoning has been proven for many children with an autism diagnosis who have been tested for mercury poisoning, there is no longer any need for the “*average person to sift through all the misdirection and misinformation*” that has been and is still being put out by those with an overriding interest in maintaining the status quo.

The ever-increasing evidence shows that Thimerosal is a major causal factor for childhood behavioral and developmental

disorders, including ADHD and the autism spectrum disorders (ASDs).

**Autism myth #7:** Currently, the evidence leads to the firm conclusion that vaccines do not cause autism.

**Reality:** The proofs of causation given in this manuscript, and in particular **Section II. Vaccines, IV. Thimerosal, and V. Wakefield/Geier’s Research**, and the government’s concession in *Hannah Poling v. Sec. HHS* (case #: 02-1466V) discussed in **Section III. NVICP**, should provide the reader with scientifically sound evidence leading to the firm conclusion that Thimerosal-containing vaccines are a major causal factor in autism. Thimerosal in vaccines has been, and still is, a major causal factor that underlies most diagnoses of an autism spectrum disorder as well as many other developmental and childhood disorders. In addition, there is evidence that MMR vaccine is a causal factor in some cases where a child is subsequently diagnosed with regressive autism.

Thus, the reality is that, *when administered to developing children*, vaccines can and do “*cause autism*.”

## II. Key Vaccine Realities

**Vaccine myth #1:** Vaccines are one of the most successful programs in modern health care, reducing, and in some cases even eliminating, serious infectious diseases.

**Reality:** The vaccination programs for vaccines developed in the late 1800s and the early 1900s for highly infectious and/or deadly diseases (e.g., the vaccines for smallpox, rabies, diphtheria, tetanus, polio, and measles) have been very successful in minimizing the short- and long-term risks of Americans’ developing these diseases when Americans are exposed to the indigenous/“native”/“wild” disease strains of the organisms that can cause these diseases.

Moreover, since persons bitten by a rabid animal almost always die, post-bite vaccination for rabies is truly lifesaving.

Nevertheless, all is *not* perfect in “vaccine land” because some vaccines:

- Have caused more harm than they have protected those vaccinated (e.g., the now-withdrawn vaccine for Lyme disease),
- Are simply not truly effective in preventing those vaccinated from getting or spreading a disease (e.g., the human influenza vaccines and, apparently, the chickenpox vaccine),
- Are *neither* medically cost-effective *nor* provide the level of protection claimed and/or
- Have both short-term and longer-term risks that have been concealed from the American public by collusive actions between the vaccine makers and the federal officials charged with licensing, approving, recommending, and promoting the uses for these vaccines.

Among others, these collusive actions include:

- Allowing other than sterile saline to be used as the placebo in short-term vaccine adverse-reaction studies to suppress the relative incidence rates to the point that these relative

adverse-event rates show “no statistically significant” increase over the “placebo” (that, in some cases, has been allowed to be an experimental vaccine or the vaccine formulation without the biological antigens),

- Permitting vaccine safety studies to be restricted to a few days or, at most, a few months even though some severe adverse outcomes do not begin to emerge until several years after vaccination (e.g., childhood MS 4 years after vaccination),
- Consenting to reductions in the size and number of persons in the phase-III clinical trials that not only reduce the vaccine makers costs but also reduce the risk that the study will find the rare but deadly adverse effects that a vaccine may have,
- Allowing surrogate endpoints (e.g., the reactivity of the patient’s blood to animal anti-sera) for specific antibodies to be used to assess vaccine efficacy instead of requiring comprehensive testing to establish both general and specific immunity in those vaccinated that is comparable to the immunity found in those who have had the disease,
- Recommending widespread use of new vaccines long before the long-term (at least 10-year) outcomes can be assessed in the trial population, and
- Licensing vaccines and recommending their “universal” use in populations that have near-zero risk of contracting a disease (e.g., the hepatitis B vaccine in young children or the HPV vaccine in non-sexually-active children) or where the clinical cases of the disease occur at low rate and are virtually absent in most demographic segments of U.S. population (e.g., the rotavirus vaccine).

**Vaccine myth #2:** Public support for the vaccination program remains strong, especially in the United States where vaccination rates are currently at an all-time high of greater than 95% (CDC 2004).

**Reality:** First, there is no dispute that “*vaccination rates are currently at an all-time high of greater than 95%.*” However, one *cannot* accurately assess the public support for the vaccination program when the population is being coerced to vaccinate by state laws.

While state laws and regulations requiring vaccination for children to attend school do provide for medical, religious (48 of 50 states), and philosophical (20 of 50 states) exemptions, many states inappropriately erect barriers of varying difficulty, which impede their citizens from knowing about, or obtaining, any of the available exemptions should said citizens desire to do so.

**Vaccine myth #3:** Despite a long history of safety and effectiveness, vaccines have always had their critics: some parents and a tiny fringe of doctors question whether vaccinating children is worth what they perceive as the risks.

**Reality:** For some vaccines, there is a clear and growing body of peer-reviewed published evidence that, for these vaccines, the costs, the adverse-outcome risks, lack of effectiveness and/or the costs of even the reported adverse-outcomes out-

weigh the theoretical benefits from widespread vaccination with those vaccines.

For example, consider the following vaccines:

- The hepatitis B vaccines do not provide long-term immunity from contracting hepatitis B when the vaccinated children become sexually active or IV drug users, and increase their long-term risk for childhood MS and other autoimmune diseases. Addressing the hepatitis B issue, Dr. Jane Orient, director of The Association of American Physicians & Surgeons, writes, “For most children, the risk of a serious vaccine reaction may be 100 times greater than the risk of hepatitis B. Overall, the incidence of hepatitis B in the U.S. is currently about 4 per 100,000. The risk for most young children is far less; hepatitis B is heavily concentrated in groups at high risk due to occupation, sexual promiscuity, or drug abuse.”
- Influenza vaccines are *not* effective.<sup>7</sup>
- The chickenpox vaccine appears to cause more harm long-term than it prevents disease and, *even after a second dose*, it appears to have a reported efficacy that is less than 75%.
- Rotavirus vaccines, including the withdrawn one, gives everyone inoculated a case of rotavirus, when, in the U.S. population, the clinical cases of the disease occur at low rates and are mostly confined to those in the lowest-income population segments.
- The HPV vaccines appear to be causing significant harm, including death, to some of those vaccinated, but do *not* appear to provide long-term immunity to the HPV infection and may *not* provide any protection from cervical cancer 30 years in the future.
- The childhood pneumococcal vaccine (Prevnar<sup>®</sup>) has given rise (or caused a shift) to a strain that is resistant to treatment and is causing childhood deaths.
- A recent outbreak of mumps in 2006 occurred among some 6584 college students (aged 18 to 24 years) who had received two vaccine doses, indicates that the mumps vaccine did not provide protection (New England Journal of Medicine, 2008; 358:1580–9). Due to lack of effectiveness of the mumps vaccine, Japan no longer administers the mumps component of the MMR (measles, mumps and rubeolla) vaccine.

**Vaccine myth #4:** Vaccines, like most medical interventions, are not without risk; however, the benefits far outweigh those risks.

**Reality:** Here, the statement combines a general truth, “*vaccines are not without risk (no medical intervention is),*” with a *purposely* vague and unsubstantiated generalization, “*the benefits far outweigh those risks.*”

If nothing else, all of the vaccines that have been introduced and then withdrawn from the market when they caused significant harm (e.g., the RotaShield rotavirus vaccine, the LymeRix

<sup>7</sup> Geier DA, King PG, Geier MR. Influenza Vaccine: Review of effectiveness of the U.S. immunization program, and policy considerations. *J Am Phys Surg* 2006; 11(3):69–74 and the supporting studies referenced therein.

Lyme-disease vaccine, the vaccines containing whole-cell pertussis lysates [the DTaP vaccines] when the purified acellular pertussis vaccines were found to be much safer [the DTaP and Tdap vaccines], the tetravalent MMR-V vaccine which is producing significantly more adverse reactions than MMR and V [for Varicella] given separately, to name some) clearly indicate that, *for these vaccines*, the theoretical benefits did *not* even outweigh the risks – much less, *far outweigh those risks*”.

At the root of the problem are the words used to describe the risks and the benefits.

Typically, the risks are presented as “theoretical” when, in fact, they are real—all that is “theoretical” are the typically grossly underestimated rates for the risks.

Moreover, most of the severe risks are continually downplayed (e.g., the death risk to first providers in the recent smallpox vaccination program) or concealed (e.g., the anaphylactic shock risk from Thimerosal in vaccines) in most of the current pro-vaccination literature and advertising

Similarly, the benefits are inflated and presented as real when, in fact, they are what are theoretical. [Note: Unless and until a person is exposed to the microbe that causes the disease for which he or she is vaccinated, there is no benefit to vaccination against that agent.]

Moreover, even when exposed, there is no guarantee that any one of those who have been vaccinated will not get the disease.

Furthermore, the measurable immune-system responses after vaccination do not, in most cases, accurately predict a given person’s resistance to subsequent disease exposure.

Finally, vaccines that contain live viruses usually give those inoculated with one of them a mild case of the disease, which, *when the inoculation does not follow the native disease’s exposure mode*, induces incomplete immunity at best.

**Vaccine myth #5:** There are multiple independent lines of evidence that indicate vaccines do not cause autism.

**Reality:** The CoMeD website, <http://www.mercury-freedrugs.org/>, contains recent articles posted that present a rebuttal to this claim citing an ever-growing body of peer-reviewed published facts that support a vaccine/autism link.

Moreover, in light of the recent (9 November 2007) finding for the plaintiffs in *Poling v. Sec. HHS, a “Thimerosal causes autism” test case in Omnibus Autism Proceeding (OAP)*, even the federal government has conceded that Thimerosal in vaccines may be a causal factor for an autism-spectrum-disorder diagnosis (See docket text item 17, “Respondent’s Report, filed by SECRETARY OF HEALTH AND HUMAN SERVICES. Entered: 11/09/2007” [which found in favor of the plaintiffs] and item 18, “SCHEDULING ORDER: On or before 11/30/2007, the parties shall contact the undersigned’s chambers and propose three dates and times for the next status conference in this matter to discuss further proceedings to address damages. Signed by Special Master Patricia E. Campbell-Smith. (cc2,) Entered: 11/14/2007.”)

Given the preceding events as well as the test-cases petitioners’ attorneys’ having to request the OAP for time to choose another “Thimerosal causes autism” test case to replace one of the three in the second group, the “Thimerosal as a causal fac-

tor” group, it is clear that the “Respondent’s Report” (item 17), *though it did not mention Thimerosal or mercury*, found for the petitioners with respect to the original test case claim under which it was to be considered in OAP—namely that “Thimerosal in vaccines was a causal factor in the diagnosed autism spectrum disorder”—for the child in question even though the “Rule 4(c)” report focused on a “mitochondrial disorder” manifesting as “a regressive encephalopathy with features of autism spectrum disorder”—commonly diagnosed/labeled as regressive autism.

Interestingly, Hannah Poling’s father, a physician, had published a case study of his daughter’s case in February of 2006. [Poling JS, Fyre RE, Shoffner J, Zimmerman, AW. Developmental regression and mitochondrial dysfunction in a child with autism. *J Child Neurol* February 2006; **21**(2):170–2 (a Brief Communication)]

Moreover, since that case study reported that there “was no family history of autism or affective, neuromuscular, or hearing disorders,” and, *prior to the vaccines given to her at about 19 months of age*, her “development was progressing well . . .,” the lack of evidence of neuromuscular disorder prior to the 19-month vaccinations she received undermines the implicit claim in the government’s published “Rule 4(c)” case-concession report that the mitochondrial disorder diagnosed was fundamentally a genetic factor.

In addition, the published case study seems to support the reality that this child had a diagnosis of regressive autism:

- Associated with the vaccines, *including those childhood vaccines (hepatitis B, DTaP, and Hib) that were Thimerosal-preserved at the time she was given them*, she had received from birth (hepatitis B) onwards, and
- Precipitated (“significantly aggravated”) by the vaccinations she received at about 19 months of age.

Lest the reader think that “underlying mitochondrial disorder” has nothing to do with mercury poisoning by mercury/Thimerosal, the reader need only consult some of the papers linking Thimerosal to the poisoning of mitochondrial pathways:

- a. Yel L, Brown LE, Su K, Gollapudi S, Gupta S. Thimerosal induces neuronal cell apoptosis by causing cytochrome c and apoptosis-inducing factor release from mitochondria. *Int J Mol Med*. 2005 Dec; **16**(6):971–7.
- b. Humphrey ML, Cole MP, Pendergrass JC, Kiningham KK. Mitochondrial mediated Thimerosal-induced apoptosis in a human neuroblastoma cell line (SK-N-SH). *Neurotoxicology* 2005 Jun; **26**(3):407–16.
- c. Parys JB, Missiaen L, De Smedt H, Droogmans G, Casteels R. Bell-shaped activation of inositol-1,4,5-trisphosphate-induced Ca<sup>2+</sup> release by Thimerosal in permeabilized A7r5 smooth-muscle cells. *Pflugers Arch*. 1993 Sep; **424**(5-6):516–22.

**Vaccine myth #6:** The findings in the epidemiological studies relied upon by the 2004 IOM have been proven to be scientifically sound.

**Reality:** Attempts by independent researchers to obtain the underlying data sets from the original authors in the epidemiological studies touted by the CDC and other vaccine apologists (ex-

cept the 2004 Ip *et al.* study) as supporting the claims of “no link” have been repeatedly rebuffed. Interestingly, a November 2007 paper by Desoto and Hitlan, entitled *Blood Levels of Mercury Are Related to a Diagnosis of Autism: A Reanalysis of an Important Data Set*, independently reviewed the basis data from the previously published Ip *et al.* epidemiology study reporting no evidence of a link between the blood levels of mercury and autism. The reanalysis, with which the authors of the original epidemiological article agreed, found that the original article’s inaccurate conclusions were based on a significant calculation error and a less-than-appropriate choice of t-tail statistical test.

Thus, no independent analysis has been able to confirm the validity, or lack thereof, of the findings reported in the studies upon which the 2004 IOM committee relied.

In the case of the key U.S. study by Verstraeten *et al.*, CDC officials have claimed that the original data sets have been “lost.”

Until independent researchers can:

- Obtain the complete original data sets and study designs used in these “no link” papers, and
- Confirm: a) the study design and data sets used are appropriate for the study, b) the methods used for the evaluations are scientifically sound and appropriate, and c) the results reported are valid,

epidemiological studies that do not allow their data to be independently evaluated should be excluded from any consideration of the evidence linking Thimerosal or MMR to a diagnosis of any developmental disorder, including any neurodevelopmental disorders inside or outside of the autism spectrum.

**Vaccine myth #7:** Robert Kennedy Jr. and others point to dubious evidence, such as the myth that the Amish do not vaccinate and do not get autism. Both of these claims are not true, and the data RFK Jr. refers to is nothing more than a very unscientific phone survey (Leitch 2007).

**Reality:** There are the factual realities reported by Dan Olmsted while he was a senior editor for United Press International (UPI), including:

- <http://www.washtimes.com/upi-breaking/20050607-030036-7472r.htm>

**The Age of Autism: One in 15,000 Amish** by Dan Olmsted, UNITED PRESS INTERNATIONAL

“Washington, DC, Jun. 8 (UPI) [2005] -- The autism rate for U.S. children is 1 in 166, according to the federal government.

The autism rate for the Amish around Middlefield, Ohio, is 1 in 15,000, according to Dr. Heng Wang.”

- <http://www.washingtontimes.com/upi/20051204-060313-6829r.htm>

**The Age of Autism: 'A pretty big secret'** by Dan Olmsted, UPI Senior Editor, Dec. 7, 2005 at 2:08PM

“ It’s a far piece from the horse-and-buggies of Lancaster County, Pa., to the cars and freeways of Cook County, Ill.

But thousands of children cared for by Homefirst Health Services in metropolitan Chicago have at least two things in common with thousands of Amish children in rural Lancaster: They have never been vaccinated. And they don’t have autism.

‘We have a fairly large practice. We have about 30,000 or 35,000 children that we’ve taken care of over the years, and I don’t think we have a single case of autism in children delivered by us who never received vaccines,’ said Dr. Mayer Eisenstein, Homefirst’s medical director who founded the practice in 1973. Homefirst doctors have delivered more than 15,000 babies at home, and thousands of them have never been vaccinated.

The few autistic children Homefirst sees were vaccinated before their families became patients, Eisenstein said, ‘I can think of two or three autistic children who we’ve delivered their mother’s next baby, and we aren’t really totally taking care of that child -- they have special care needs. But they bring the younger children to us. I don’t have a single case that I can think of that wasn’t vaccinated.’

The autism rate in Illinois public schools is 38 per 10,000, according to state Education Department data; the Centers for Disease Control and Prevention puts the national rate of autism spectrum disorders at 1 in 166 -- 60 per 10,000.

‘We do have enough of a sample,’ Eisenstein said. ‘The numbers are too large to not see it. We would absolutely know. We’re all family doctors. If I have a child with autism come in, there’s no communication. It’s frightening. You can’t touch them. It’s not something that anyone would miss.’

No one knows what causes autism, but federal health authorities say it isn’t childhood immunizations. Some parents and a small minority of doctors and scientists, however, assert vaccines are responsible.

This column has been looking for autism in never-vaccinated U.S. children in an effort to shed light on the issue. We went to Chicago to meet with Eisenstein at the suggestion of a reader, and we also visited Homefirst’s office in northwest suburban Rolling Meadows. Homefirst has four other offices in the Chicago area and a total of six doctors.

Eisenstein stresses his observations are not scientific. ‘The trouble is this is just anecdotal in a sense, because what if every autistic child goes somewhere else and (their family) never calls us or they moved out of state?’

In practice, that’s unlikely to account for the pronounced absence of autism, says Eisenstein, who also has a bachelor’s degree in statistics, a master’s degree in public health and a law degree.

Homefirst follows state immunization mandates, but Illinois allows religious exemptions if parents object based either on tenets of their faith or specific personal religious views. Homefirst does not exclude or discourage such families. Eisenstein, in fact, is author of the book *Don’t Vaccinate Before You Educate!* and is critical of the CDC’s vaccination policy in the 1990s, when several new immunizations were added to the schedule, including Hepatitis B as early as the day of birth. Several of the vaccines—Hep B included—contained a mercury-based preservative that has since been phased out of most childhood vaccines in the United States.

Medical practices with Homefirst’s approach to immunizations are rare. ‘Because of that, we tend to attract families that have questions about that issue,’ said Dr. Paul Schattauer, who has been with Homefirst for 20 years and treats ‘at least’ 100 children a week.

Schattauer seconded Eisenstein’s observations. ‘All I know is in my practice I don’t see autism. There is no striking 1-in-166,’ he said.”

As far as the inadequacy of surveys, the CDC has used the same methodology to survey autism rates.

**Vaccine myth #8:** A victory for the anti-vaccination activists would undermine public confidence in what is arguably the single most effective public health measure devised by modern science.

**Reality:** The chief factors that are undermining the public's confidence in the current vaccination program are the growing number of vaccine-damaged children and the articles, which continually misrepresent Thimerosal's proven toxicity and/or its continuing presence in U.S. vaccines (**see Section IV. Key Thimerosal Facts**).

Vaccine apologists need to look into the mirror and see that the misleading statements and prevarications that they are publishing about the presence of Thimerosal in U.S.-licensed vaccines are doing more to undermine public confidence in the U.S. vaccination programs than the vaccine critics, the "*stubborn vocal minority*" of whom these apologists often speak.

As to vaccines being "*arguably the single most effective public health measure devised by modern science*," this claim is itself more of a myth and/or misrepresentation where the *apparent* success of a few vaccination programs is propagandized to obscure the net harm inherent in the current overall U.S. "no fault" vaccination programs that protect the vaccine makers, government officials and the healthcare providers, but *neither* adequately protect the American public *nor* provide truthful information about the risks and the theoretical benefits of the preventive vaccines to those who decide whether or not and when they and/or their children and/or wards should be vaccinated for a given disease for which there is a U.S.-licensed vaccine.

**Vaccine myth #9:** There is an anti-vaccination movement that threatens the effectiveness of public health programs.

**Reality:** If there truly were an "anti-vaccine movement" then, like the pro-life movement (often, cast as the anti-abortion movement), there would be vocal demonstrations by thousands and tens of thousands of Americans as well as pickets outside of every medical office that practices vaccination in the U.S.

Since neither of the preceding elements of a movement (vocal mass demonstrations of thousands or tens of thousands or nation-wide medical-office picketing) exists for vaccines and vaccination, there is no real "*anti-vaccination movement*."

However, there is a stubborn vocal minority of those who are pro-vaccine safety and, therefore, oppose use of Thimerosal in vaccines.

An unbiased review of all the recent peer-reviewed toxicological, case, and *reviewable* epidemiological studies published since 2000 demonstrates that it is plausible that vaccines, in general, and, in particular, those with a mercury preservative, Thimerosal, can cause autism.

The validity of this pro-vaccine-safety minority's position that, for some, the doses of Thimerosal in vaccines that some children received caused the symptoms that characterize autism was recently boosted when a test case for the theory that Thimerosal in vaccines causes autism scheduled for consideration in the Omnibus Autism Proceedings in 2008 was conceded by the government medical experts based on the medical records and affidavits submitted by the petitioners before the petitioners' experts' reports were even filed (*Hannah Poling v. Sec. HHS, vaccine-injury-compensation-program case 02-1466V*).

In addition, this vocal pro-vaccine-safety minority is exposing the lack of adequate safety data for: **a)** the long-term effects of each vaccine, **b)** the effects of multiple vaccinations at the

same time, **c)** the reproductive, mutagenic, and carcinogenic effects of each vaccine, and **d)** the preservatives and adjuvants used in vaccines as well as increasing evidence that the national immunization programs for many of the current vaccines are either: **i)** not effective (e.g., the chickenpox and human influenza vaccines) or **ii)** not medically cost-effective (e.g., Merck's RotaTeq, GlaxoSmithKline's Rotarix, and Merck's HPV vaccines).

How can the claims of any minority, vocal or otherwise, threaten the effectiveness of the national vaccination program if the vaccines are truly safe and effective, and no adverse reactions are occurring?

Moreover, *though they are significantly underreported*, serious adverse vaccine reactions, including those attributed to sudden-infant-death syndrome (SIDS), are occurring on a large scale.

**Vaccine myth #10:** The decrease in public confidence in the current U.S. national vaccination programs from the disclosure of the factual risks and harms inherent in each vaccine will lead, as it has before, to declining vaccination compliance and an increase in infectious disease.

**If** there is a decline in confidence in the implied national vaccination program, **then:**

- Vaccine apologists who continually falsely assert Thimerosal has been removed from all vaccines given to children (from before their birth until they reach 18 years of age), when it has not, will only have themselves to blame, and
- Should childhood diseases increase in the absence of vaccination, *given today's better medicines for treating infectious diseases*,
  1. Almost all of our children will recover and have long-term or life-long immunity that far exceeds that provided by most vaccines,
  2. The public will profit from the decrease in the rates for the long-term chronic diseases that the Thimerosal-containing vaccines and other vaccines (e.g., hepatitis B) can exacerbate, and
  3. Our children will probably be healthier overall.

Vaccine apologists, health officials, child healthcare providers, government officials and vaccine makers, who (*in the face of conclusive case studies and human toxicological evaluations showing sub-acute mercury poisoning from Thimerosal*) are continuing to misrepresent:

- The knowing failure of all these parties to keep their 1999 promise to remove Thimerosal from all vaccines, and
- The maximum total amount of vaccine-derived Thimerosal that, *absent banning Thimerosal from all vaccines*, a child born today may receive from conception to the age 18 years.

**Vaccine myth #11:** The anti-vaccination movement is largely based on poor science; and fear mongering has become more vocal and even hostile (Hughes 2007).

**Reality:** Here prejudicial terms, such as “*anti-vaccination movement*”, have been fabricated to weaken the legitimate criticism of some vaccines.

Moreover, the phrase “*poor science and fear-mongering*” and negative words: “*anti-vaccination*” and “*hostile*” are obviously designed to slander those with genuine substantiated criticisms for certain vaccines and/or particular U.S. national vaccination programs for some vaccines.

Factually, the pro-vaccine safety advocates simply point to an ever-growing body of peer-reviewed published scientifically sound evidence that clearly establishes that the current U.S. vaccination programs are less safe and the newer vaccines much less effective than the older vaccines (polio, measles, diphtheria, smallpox and tetanus) continually used as “vaccination success” examples in support of the benefits of vaccination.

### III. Key realities concerning the NVICP (National Vaccine Injury Compensation Program) and recent Poling Case

**NVICP myth #1:** Media from public health officials and others continually portray vaccination as virtually harmless and maintain there is no proof that Thimerosal, or any other part of any vaccine, has ever caused autism in any way.

**Reality:** In the scheduled *Poling* “Thimerosal-autism” case conceded on November 9, 2007, the HHS appears to have conceded that the vaccines administered to a child, Hanna Poling, significantly contributed to the underlying harm that caused the regressive neurodevelopmental harm that preceded this child’s being diagnosed with an autism spectrum disorder (ASD) as well as, more recently, to the onset of the seizure disorder that this child experienced some time after her autism diagnosis.

**NVICP myth #2:** One court case (such as the Poling case) is hardly significant and cannot properly be used to support that a vaccine-autism link exists.

**Reality:** The *Poling* Thimerosal/autism case was not a court case; it was an *administrative proceeding* that was conceded *before* it was heard and *prior* to the date the experts were to submit their reports.

Based on Hannah’s medical records and the parents affidavits, medical personnel in the Division of Vaccine Injury Compensation (DVIC), Department of Health and Human Services made the decision.

Thus, the *Poling* decision is historic since it is the first of 355-plus “Decided,” “Autism” cases that has been found to be compensable in the federal administrative vaccine dispute resolution system.

The other “355,” “Decided,” “Autism,” “Vaccine Court” cases were, for one reason or another, dismissed. [See [http://www.hrsa.gov/vaccinecompensation/statistics\\_report.htm](http://www.hrsa.gov/vaccinecompensation/statistics_report.htm) **Table II** “Adjudications,” last updated 1 Apr. 2008; last visited 2 Apr. 2008.]

Apparently, *since compensation has not yet been awarded*, the *Poling* case has *not* yet been added to the “Adjudications” table.

A CBS News investigation uncovered at least nine other cases dating back to 1990, where records show the court or-

dered the government compensate families whose children developed autism or autistic-like symptoms.

These cases included toddlers who had been called “very smart” and “impressed” doctors with their “intelligence and curiosity” until their vaccinations.

Based on an on-line report,<sup>8</sup> those nine cases were:

1. *Kleinert v. HHS* (Case 90-211V, 1991 U.S. Cl. Ct. LEXIS 69, February 20, 1991) DPT vaccine administered in February 1981. Seizure disorder in a child diagnosed with “overfocussing,” “similar in some respects to autism.” Michael Hugo, counsel for petitioner; Denis J. Hauptly, Special Master
2. *Underwood v. HHS* (Case 90-719V, 1991 U.S. Cl. Ct. LEXIS 373, July 31, 1991) DPT vaccine administered in 1974. Seizure disorder in a child diagnosed with autism. Curtis Webb, counsel for petitioner; Elizabeth Wright, Special Master
3. *Sanford v. HHS* (Case 90-2760V, 1993 U.S. Claims LEXIS 49, May 10, 1993) DPT vaccine administered in September 1979. Seizure disorder in a child with “autistic tendencies.” Mari Bush, counsel for petitioner; LaVon French, Special Master
4. *Bastian v. HHS* (Case 90-1161V, 1994 U.S. Claims LEXIS 196, September 22, 1994) DPT administered in December 1984. Seizure disorder in a child diagnosed with autism. Testifying doctors for petitioners and HHS all agreed that while he “exhibits some autistic symptomatology, [he] is not autistic.” Boyd McDowell, counsel for petitioner; Richard Abell, Special Master
5. *Lassiter v. HHS* (Case 90-2036V, 1996 U.S. Claims LEXIS 216, December 17, 1996) DPT vaccine administered in 1972. Seizure disorder in a young man diagnosed with autism. The court ruled that a diagnosis of idiopathic autism (i.e., autism of unknown origin) was not sufficient to establish a “factor unrelated” that might result in the dismissal of a claim. Clifford Shoemaker, counsel for petitioner; LaVon French, Special Master
6. *Suel v. HHS* (Case 90-935V, 1997 U.S. Claims LEXIS 210, September 22, 1997) DPT vaccine administered in the 1980’s. Aggravation of tuberous sclerosis in a child diagnosed with autism. Richard Gage, counsel for petitioner; Laura Millman, Special Master
7. *Freeman v. HHS* (Case 01-390V, 2003 U.S. Claims LEXIS 285, September 25, 2003) MMR vaccine administered in July 1999. Seizure disorder in a child displaying features of “atypical autism.” Ronald Homer and Sylvia Chin-Caplan, counsel for petitioner; George L. Hastings, Special Master
8. *Noel v. HHS* (Case 99-538V, 2004 U.S. Claims LEXIS 354, December 14, 2004) DpaT [sic; DTaP] and HiB vaccines administered in March 1997. Seizure disorder in a child diagnosed with autism. Clifford Shoemaker, counsel for petitioner; Laura Millman, Special Master
9. *Banks v. HHS* (Case 02-0738V, 2007 U.S. Claims LEXIS 254, July 20, 2007) MMR vaccine administered in March 2000. The child was diagnosed with PDD secondary to acute disseminated encephalomyelitis (ADEM). Michael McLaren, counsel for petitioner; Richard Abell, Special Master

In some of these cases (e.g., *Lassiter*), the government actually attempted to use the child’s autism diagnosis as a reason to deny compensation for the child.

<sup>8</sup> <http://neurodiversity.com/weblog/article/148/>, last visited on 12 Mar. 2008.



**NVICP myth #3:** The Poling case is an isolated case that involves a rare, underlying mitochondrial disorder that is not relevant to other vaccine-autism injury cases and this disorder was likely present from birth.

**Reality:** A recently published study entitled, “Developmental Regression and Mitochondrial Dysfunction in a Child with Autism,” indicates that mitochondrial dysfunction was found in 38% of patients with autism and therefore is not unique to the **Poling** case (Poling JS, Frye RE, Shaffner J, Zimmerman AW. *J Child Neurol* 2006; **21**:170–2).

Also, it is possible to distinguish congenital mitochondrial disorders from other forms that derive from vaccinations.

Moreover, vaccine-derived mitochondrial disorders appear less severe than those clinically diagnosed at, or close to, birth. [See: Rossignol DA, Bradstreet JJ. Evidence of Mitochondrial Dysfunction in Autism and Implications for Treatment. *Am J Biochem and Biotechnol* 2008; **4**(2):208–17].

**NVICP myth #4:** The nine test cases before the vaccine courts will likely determine the fate of 4,800 other claims made over the past eight years for compensation for injuries allegedly due to childhood vaccines.

**Reality:** Since the National Vaccine Injury Compensation Program (NVICP) currently requires each case to be administered “de novo” (from scratch), the outcomes may influence the views of the Special Masters who hear the “Thimerosal as a causal factor” vaccine cases but they will *not* “determine the fate” of these cases unless the applicable statute is amended to permit the decision in a decided case (specifically, **Hannah Poling v. Secretary of HHS**) to be directly considered as a controlling precedent in future cases.

Even then, given the logistics of hearing each case and the number of Special Masters available to hear the cases individually, it will take decades for all of the cases to be heard unless the current NVICP statutes were to be amended to permit appropriately consolidated groups of cases to be heard together.

However, in cases where the petitioners can establish that their neurodevelopmentally damaged child was mercury poisoned (by a valid urine porphyrin-profile-analysis [UPPA] test, chelation challenge, or other means) through administration of Thimerosal-containing vaccines, rather than have the full case presented in the vaccine court, **Poling** has clearly shown that the federal government has implicitly conceded that injecting such vaccines can mercury poison some children causing brain function damage leading to a neurodevelopmental disorder that manifests as an ASD.

**NVICP myth #5:** The Federal Government maintains that vaccines do not cause autism and that the single Poling case does not change their position.

**Reality:** Public health officials and other vaccine apologists are obviously playing with words here.

Vaccines cause brain impairment, and brain impairments cause the symptoms of autism.

The symptoms of autism are used to diagnose autism.

Moreover, Hannah Poling was given an autism diagnosis and medical professionals, and not the administrative “vaccine

court,” decided that vaccinations she received were causative factors.

Therefore, how can anyone continue to think that the “*Federal Government*” has concluded vaccinations do not cause autism?

**NVICP myth #6:** Because vaccines are somewhat compulsory in the United States, a National Vaccine Injury Compensation Program was established to streamline the process for compensation for those who are injured due to vaccines (USDOJ 2007).

**Reality:** Regardless of the information provided by the reference cited, this statement is at odds with the history of the “*National Vaccine Injury Compensation Program*” (NVICP).

Factually, Congress established the NVICP on November 14, 1986 (Pub. L. 99-660), because the federal government, *instead of nationalizing the production of vaccines as the public health statutes in Title 42 of the U.S. Code permit*, gave in to the vaccine makers’ demands for protection from being directly sued for the harm that their vaccines, principally the DTWP vaccines and some lots of the polio vaccines, were causing to some who were vaccinated, rather than forcing the vaccine makers to either: **a)** improve the safety of their vaccines or **b)** turn over the manufacture of and facilities for the making of vaccines to the federal government.

In return for the legal protections afforded to the vaccine makers, *among other things*:

- ❑ The vaccine makers were supposed to improve the safety of their vaccines,
- ❑ The Secretary of HHS was mandated to do all that the applicable statutes and laws allow to make certain vaccine safety was improved (**see: 42 U.S.C. Sec. 300aa-27 Mandate for safer childhood vaccines**),
- ❑ A fair, non-adversarial, and speedy administrative claims system (the “Vaccine Court”) was established,
- ❑ A vaccine tax was provided to obtain the revenues required to maintain the Vaccine Court, and
- ❑ Statutes requiring certain recordskeeping practices by the vaccine providers and a vaccine adverse events reporting system (VAERS) were established to provide:
  - The feedback required to provide the records needed for the vaccine court to judge whether or not the vaccine may have harmed those vaccinated and
  - The information required to:
    - Determine the “in use” safety of vaccines and
    - Direct the efforts of the responsible HHS agencies in managing the vaccine licenses and approvals to increase vaccine safety.

Almost immediately after the NVICP was enacted, both the Congress, *driven by its own federal interests and special interests*, and those who were responsible for administering the NVICP systems and for overseeing the licensing and approval of vaccines, *driven by similar forces*, began to modify the statutes and the regulations and policies required to implement the NVICP in ways that made the NVICP less fair, increasingly adversarial, and less than rapid.

The first change (**Pub. L. 100-203, title IV, Sec. 4303(d)(2)(B)**, Dec. 22, 1987, **101 Stat. 1330-222**) repealed the

provision for automatic cost-of-living adjustment from the NVICP by striking **42 U.S.C. Sec 300aa-18** which “provided for annual increases for inflation of compensation under subsections (a)(2) and (a)(4) of section 300aa-15 of this title and civil penalty under section 300aa-27(b) of this title” – making the compensation provided increasingly less fair for those injured and the civil penalties provided for those who break these laws less punitive.

Administratively, as the cases began to be heard, the government administrators, *without even a public hearing*, unilaterally removed several of the “automatic” compensable injury indications from the original vaccine injury tables set forth in **42 U.S.C. Sec. 300aa-14. Vaccine Injury Table** – making the NVICP more adversarial.

Moreover, the lawyers of the U.S. Department of Justice who were assigned to represent the federal government as respondent in the vaccine injury cases, *driven by the policies of their appointed administrators*, became increasingly adversarial in contesting every aspect of these cases—making cases more adversarial and their administration anything but rapid.

Thus, *as the backlog and the Omnibus Autism Proceeding demonstrate*, though the NVICP may have been “*established to streamline the process for compensation for those who are injured due to vaccines (USDOJ 2007)*,” today’s NVICP is anything but streamlined.

**NVICP myth #7:** The lawyers for those claiming that vaccines caused their children’s autism put on pathetic performances with transparently shoddy science, while the other side marshaled genuine experts and put forth an impressive case.

**Reality:** The causal link has been established between Thimerosal exposure and sub-acute mercury poisoning that manifests as symptoms and the set of symptoms that are used in the diagnosis of neurodevelopmental disorders, including the autism spectrum disorders and others (e.g., tics and stuttering).

Moreover, the federal government, in *Hannah Poling v. Sec. HHS*, has directly conceded that the vaccinations Hannah Poling received at about 19 months of age were significant causal factors in Hannah’s diagnosed autism disorder as well as the medical mitochondrial dysfunction and seizures that these vaccinations caused and/or triggered.

In addition, there exist a body of non-autism vaccine-injury cases where the award was for neurodevelopmental harm characterized as encephalopathies (see **Poling/NVICP myth #2**).

Thus, it should be obvious that reality is the opposite of the myth; and the myth’s anonymous “*genuine experts*” used medical cant rather than medical science to support their assertions.

**NVICP myth #8:** If the petitioners win these test cases despite the evidence, it will open the floodgates for the rest of the 4,800 petitioners. This will likely bankrupt the Vaccine Injury Compensation Program and will also risk our vaccine infrastructure. Pharmaceutical companies will be reluctant to subject themselves to the liability of selling vaccines if even the truth cannot protect them from lawsuits.

**Reality:** Factually, if “*the petitioners win these test cases*,” then, *as in the conceded “Thimerosal” test case*, the petitioners will win because of the evidence and not “*despite the evidence*.”

Moreover, since the National Vaccine Injury Compensation Program requires each case to be heard individually and there are only a limited number of special masters and court rooms available for all claims, this reviewer finds that, unless the controlling statutes are changed or the vaccine court is greatly expanded, no more than about 50 cases in the pending “autism” backlog could be heard each year.

Given the current hearing limitations, it is obvious that the phrasing “*will open the floodgates*” is a misrepresentation because no more than 50 cases a year is more of a “trickle” than a “flood.”

Since: a) the Vaccine Compensation fund is so large that even the paltry interest the federal government pays is currently more than adequate to pay all existing settled claims, the cost of operating the vaccine court, and costs of the cases settled in a given year on each vaccine, b) no more than 50 “autism” cases a year would be “settled,” and c) the vaccine tax can easily be increased, the bankruptcy concern expressed in this misrepresentation is, at best, misplaced.

With respect to the statement: “*Pharmaceutical companies will be reluctant to subject themselves to the liability of selling vaccines if even the truth cannot protect them from lawsuits*,” consider these observations:

- When the truth comes to light, and the vaccine makers are proven to have *knowingly* failed to prove their vaccines were safe as required by law and were *knowingly* distributing adulterated vaccines and other drugs, then, when the applicable criminal RICO statutes are invoked, as they should be, the federal government should:
  - Seize these vaccine makers and all their assets, and
  - Then operate these vaccine makers as not-for-profit firms where the profits are used to pay for the harm done until all claims are paid

In addition, the federal government should also appropriately prosecute all of those who participated in this racket (including government officials, health officials, and vaccine apologists).

As those who were engaged in, assisting, or a party to, this racket are convicted they should be permanently debarred from working in any capacity in any FDA-regulated industry or in the federal government, and, as restitution, *in addition to any fines levied*, all those persons convicted of actively participating in any aspect of this racket should be sentenced to tend to those institutionalized individuals who have been directly harmed by this racket for an appropriate number of years.

#### IV. Key Thimerosal Facts

**Thimerosal myth #1:** It is the quantity of a substance that establishes whether or not it is toxic. There is little doubt, and no controversy, that mercury, the major component of Thimerosal, is a powerful neurotoxin, or poison to the brain. However, toxicity is always a matter of dose. Everything becomes toxic in a high enough dose; even too much water or vitamin C can kill you. So the real question is whether the amount of mercury given to children in vaccines containing Thimerosal was enough to cause neurological damage.

**Reality:** Overall toxicity is a matter of the specific dose and its persistence in the parts of the body in a form that is toxic to those organs, tissues, and/or fluids in which it is present at a level high enough to exert its toxic effects.

Thimerosal (49.55 wt.-% mercury) is a highly toxic mercury compound that, *at levels below 1 part-per-million*, is also teratogenic, mutagenic, carcinogenic and an immune system disruptor in humans unless, which has not been done, that Thimerosal-containing formulation has been proven safe to the applicable federal standard minimum (“sufficiently nontoxic...” [as set forth in **21 C.F.R. Sec. 610.15(a)**]).

Vaccines with “trace” amounts of Thimerosal, by definition, “contain less than 1 microgram of mercury (Hg) per dose (<http://www.fda.gov/cber/vaccine/thimerosal.htm>).” For example, consider that the reduced-Thimerosal flu vaccine with 0.0002% mercury is equivalent to 1 microgram [ $\mu\text{g}$ ] of Hg per 0.5 mL, or 2  $\mu\text{g}$  of Hg per mL, which is the same as 2000  $\mu\text{g}$  per liter; or 2000 parts per billion [ppb].

0.5 parts per billion (ppb) mercury has been shown to kill human neuroblastoma cells (Parran *et al.*, Toxicol Sci 2005; 86:132–40).

2 ppb mercury is the U.S. EPA limit for drinking water (<http://www.epa.gov/safewater/contaminants/index.html#mcls>).

20 ppb mercury destroys neurite membrane structures (Leong *et al.*, Neuroreport 2001:12733–7).

200 ppb mercury is the level in liquid that the EPA classifies as hazardous waste (<http://www.epa.gov/epaoswer/hazwaste/mercury/regs.htm#hazwaste>).

25,000 ppb mercury is the concentration of mercury in multi-dose, Hepatitis B vaccine vials, administered at birth from 1991–2001 in the U.S.

50,000 ppb mercury is the concentration of mercury in multi-dose DTP and Haemophilus B vaccine vials, administered 8 times in the 1990’s to children at 2, 4, 6, 12 and 18 months of age and currently “preservative” level mercury in multi-dose flu, meningococcal and tetanus (7 and older) vaccines.

In *in vitro* studies, Thimerosal has been found to be toxic to rapidly dividing human neurons at levels below 0.01 ppm—levels that are more than 10,000 times lower than the 100 ppm level in most Thimerosal-preserved influenza vaccines.

In reality, Thimerosal’s ethylmercury solvolysis products are probably the compounds that carry Thimerosal’s toxicity throughout the human body because the discoverer of Thimerosal noted that the toxic properties of aqueous solutions of Thimerosal increase as the Thimerosal solution stands and as the relative concentration of the ethylmercury solvolysis products concomitantly increased.<sup>9</sup>

Moreover, Thimerosal’s bioaccumulative metabolites<sup>10</sup> are tissue-bound “inorganic” mercury species, which collectively have an estimated half-life of about two (2) decades in the human brain.<sup>11</sup>

<sup>9</sup> Kharasch, MS. 1932. Stabilized Bactericide and Process of Stabilizing it. US Patent 1,862,896.

<sup>10</sup> Metabolites are the things (compounds and complexed ions) into which the body converts Thimerosal.

<sup>11</sup> Sugita M. The biological half-time of heavy metals. The existence of a third, “slowest” component. *Int Arch Occup Environ Health* 1978; **41**(1):25–40.

From the published work of Burbacher *et al.* in developing baby monkeys,<sup>12</sup> the data indicates that, *on average*, up to about 10% of the initial mercury from the overall dose of Thimerosal ended up in the baby monkey’s brains when they were sacrificed and the level of mercury (total and “inorganic”) was measured on brain tissue.

Moreover, because:

- Thimerosal (49.55 weight-% mercury), Thimerosal’s primary mercury-containing solvolysis products (ethylmercury chloride [75.66 weight-% mercury] and ethylmercury hydroxide [81.28 weight-% mercury]), and its final metabolites (tissue-incorporated “inorganic” mercury [bio-complexed  $\text{Hg}^{2+}$ ]) have been proven to be highly toxic in short-term ( $\leq 2$  days) studies using various human tissues and cells even at mercury levels in the range from  $< 0.0001$  ppm to about 0.01 ppm,
- Recent peer-reviewed published research studies<sup>16</sup> have clearly established that some young children with a diagnosis in the autism spectrum are mercury poisoned and their principal mercury exposure was from the Thimerosal-preserved vaccines and other drugs that they and, *in some cases*, their mothers received and passed to them during pregnancy and breast feeding, and
- Apparently, in *Hanna Poling v. Sec. HHS* (02-1466V), a “Thimerosal as a causal factor” test case in the vaccine court’s Omnibus Autism Proceeding, the federal government has *indirectly* conceded that the Thimerosal in the vaccines Hannah Poling received was a causal factor in the neuroencephalopathy-generated autism spectrum disorder symptoms that characterize Hannah Poling’s vaccine injuries. Thus, there is no question that Thimerosal can cause sub-acute mercury poisoning in some children injected with Thimerosal-containing vaccines to the point that the mercury-poisoned child will exhibit mercury-poisoning symptoms that include that set of symptoms used to diagnose autism spectrum disorders that include mitochondrial dysfunction (including hypotonia).

Moreover, a November 2007 paper<sup>13</sup> by Desoto and Hitlan (entitled “Blood Levels of Mercury Are Related to a Diagnosis of Autism: A Reanalysis of an Important Data Set”):

- Independently reviewed the basis data from a *previously* published Ip *et al.* epidemiology study<sup>14</sup> that had reported no evidence of a link between the blood levels of mercury and autism and
- Found that the original article’s inaccurate conclusions were based on a significant calculation error and a less-than-appropriate choice of t-tail statistical test.

<sup>12</sup> Burbacher TM, *et al.* Comparison of blood and brain mercury levels in infant monkeys exposed to methylmercury or vaccines containing Thimerosal. *Environ Health Persp* 2005; **113**(8):1015–21.

<sup>13</sup> DeSoto MC, Hitlan RT. Blood levels of mercury are related to a diagnosis of autism: A reanalysis of an important data set. *J Child Neurol* 2007; **22**(11):1309–11.

<sup>14</sup> Ip P, Wong V, Ho M, Lee J, Wong W. Mercury exposure in children with autism spectrum disorder. *J Child Neurol* 2004; **19**:431–4.

[**Note:** The authors of the original epidemiological article have agreed that the calculation in question was in error.]

Thus, the real question is when are vaccine apologists going to cease raising questions that have been answered and start admitting that Thimerosal-containing vaccines have mercury poisoned and are continuing to mercury-poison our children and ourselves to the point that some children and some adults are sub-acutely mercury poisoned and exhibit those symptoms that are used to in the diagnosis of a wide variety of neurodevelopmental (e.g., the autistic disorder, pervasive developmental disorder – not otherwise specified [PDD-NOS], Asperger’s, attention deficit disorder [ADD] and attention deficit hyperactivity disorder [ADHD]) and other disorders (asthma, diabetes, obesity, multiple sclerosis (MS), and food allergies) in our children, and, *for those old enough to miss the prenatal and early childhood Thimerosal-poisoning*, “dementias” (e.g., Alzheimer’s) in ourselves.

In addition, these significant differences in the findings of the independent reanalysis of:

- The underlying data sets in a study assessing the link between blood mercury level and the diagnosis of an autism spectrum disorder (see footnote 14, where the original researchers provided the data) as well as
- The underlying MMR and autism cases data from Denmark (see footnote 30, where the data was obtained from governmental officials and *not* the original authors)

points to a fundamental problem with the epidemiological studies touted by public health officials and other vaccine apologists as evidence of “no link” between Thimerosal (or MMR) and neurodevelopmental disorders, including autism.

Individuals should be critical of those vaccines that have *not* been proven safe, are *not* truly effective, and/or are *not* truly, *at least*, societally cost-effective when the costs of the harm caused by these vaccines are included in the cost calculations.

**Thimerosal myth #2:** Those in the anti-vaccination movement believe that it was the use of Thimerosal in childhood vaccines that led to the apparent autism epidemic beginning in the 1990s.

**Reality:** Factually, the pro-drug-safety group understands that the toxicological and case-control evidence has established<sup>15</sup> that the use of Thimerosal (in vaccines, serums and some other drugs) and phenyl mercuric salts or other mercury compounds in some serums and other drugs are collectively a major causal factor in childhood behavioral and developmental disorders.

Thus, mercury poisoning has been and is a major causal factor in those who have been diagnosed with an autism spectrum disorder (ASD), as well as in several disorders and diseases that, prior to 1970, were virtually non-existent in children (e.g., childhood asthma and type-II diabetes) or rare (an ASD, where

reported incidence rate estimates were on the order of 1 to 5 in 10,000), and have since become epidemic (occurring at a rate > 1 in 1,000 children).

These now-epidemic childhood diseases include, *but are not limited to:* asthma, type-I and type-II diabetes, obesity, gastroenteritis, ulcerative colitis, leukemia, MS, severe food allergies, ADHD, ADD, and the ASDs, including autism, pervasive developmental disorder – not otherwise specified (PDD-NOS) and Asperger’s.

These are all childhood medical conditions where mercury poisoning has been shown to be an actual or a probable causal factor.

However, *based on the current data*, the onset of these childhood disease epidemics occurred in the late 1980s—though, the healthcare establishment may have “missed” these epidemic increases until the 1990s and, in some cases, has continued to deny the fact that these increases are both epidemic and vaccination related into the mid-2000s.

Furthermore, autism and its related conditions are complex disorders that are defined by a set of abnormal behaviors and social-skill deficits that are mistakenly represented to be solely neurological impairments (neurodevelopmental disorders) when most having such diagnoses also have other comorbidities.

Finally, in the 1990’s, the number of autism-spectrum diagnoses significantly increased, from between one and three to more than fifteen cases per ten thousand, though the U.S. underascertainment-corrected maximum incidence is/was probably between one and three per hundred (1 to 3%).

**Thimerosal myth #3:** During the 1990s, the number of vaccines given in the routine childhood schedule increased. This led some to assume, or at least speculate, causation from correlation--perhaps the vaccines or something in them created this ‘epidemic’ of autism.”

**Reality:** This assertion understates the change because not only did the “*number of vaccines given*” increase but also the number of doses of vaccines containing Thimerosal more than tripled and, *in addition*, a second dose was added for the MMR vaccine.

Consider

- The epidemiological evidence that has clearly shown that there is a Thimerosal-autism link when the population statistical probability studies (epidemiological studies) are scientifically sound,
- The clear evidence of Thimerosal’s toxicity at levels below 1 ppm in developing children, and
- The correspondence between the symptoms of sub-acute mercury poisoning as well as the symptoms exhibited by children with a diagnosis in the autism spectrum<sup>16</sup>

<sup>15</sup> FDA citizen petition, titled “Citizen Petition to Ban Use of Mercury in Medicine, UNLESS Proven Toxicologically Safe to the CGMP Standard ‘Sufficiently Nontoxic ...’” by the FDA, filed by CoMeD, Coalition for Mercury-free Drugs, with the FDA Division of Dockets Management on 24 August 2007 and, *on that day*, assigned FDA Docket # 2007P-0331 by the FDA.

[See: The pertinent references in [http://www.mercury-freedrugs.org/docs/070824\\_CoMeDCitizenPetitionPart2.pdf](http://www.mercury-freedrugs.org/docs/070824_CoMeDCitizenPetitionPart2.pdf).]

<sup>16</sup> a. Nataf R, *et al.* Porphyrinuria in childhood autistic disorder: implications for environmental toxicity. *Toxicol Appl Pharmacol* 2006; **214**:99–108.

b. Geier DA, Geier MR. A prospective assessment of porphyrins in autistic disorders: a potential marker for heavy metal exposure *Neurotox Res* 2006; **10**:57–64.

c. Geier DA, Geier MR. A case series of children with apparent mercury toxic encephalopathies manifesting with clinical

– issues addressed, *in detail*, in [http://www.mercury-freedrugs.org/docs/Thimerosal\\_Causes\\_Mercury\\_Poisoning.pdf](http://www.mercury-freedrugs.org/docs/Thimerosal_Causes_Mercury_Poisoning.pdf) (visited last on 5 Mar. 2008) of the primary author's 2005 article, "FEAR NOT Vaccinations don't give children autism. They save children from disease."

**Thimerosal myth #4:** The dose of mercury in Thimerosal-preserved vaccine with a Thimerosal level of 0.01% does not exceed Environmental Protection Agency (EPA) limits.

**Reality:** First of all, no safe dose has been established by any agency or published toxicological study for the level of Thimerosal that is safe to inject into a developing child.

Moreover, since some are allergic to Thimerosal to the degree that very small doses can induce anaphylactic shock, it is clear that there is no dose of Thimerosal that is safe ("sufficiently nontoxic ...") to inject into all developing children.

With respect to the EPA limit for ingested mercury, this claim could only be true when the administer dose or doses were averaged over several months.

The problem with this approach can be illustrated by the following example: "You can take two Tylenol® a day for 60 days and you will be fine. But if you took 120 Tylenol in one day, that's a lethal dose and you'll probably die."

Finally, even government officials have conceded that the amount of mercury in a 0.25-mL dose of a Thimerosal-preserved vaccine (delivering 12.5 micrograms of mercury) exceeds the EPA's recommended daily ingestion intake maximum (0.1 microgram of mercury per kilogram of body weight) *unless* the baby receiving this dose weighs more than 125 kilograms (275.6 pounds) or, for children receiving a 0.5-mL dose of such vaccines, 250 kilograms (551.2 pounds)!

**Thimerosal myth #5:** In addition to the mercury contained in vaccines, the load of mercury in the mother from other environmental sources as well as from seafood should also be considered.

**Reality:** While it is agreed that the post-natal *load of mercury should be considered with* other mercury-containing drugs taken by the child's mother, however, this consideration should more specifically focus on the mercury dose that is transferred from the mother to the fetus (which, during pregnancy, has been estimated, based on animal studies, to be about 80% of the dose given to the mother<sup>17</sup> and depends on the developing child's weight at the time the mother is given a Thimerosal-containing vaccine or any other Thimerosal-containing drug (e.g., until the late 1990s, RhoGAM [a Rho-D serum given to Rh-negative mothers where the father is or may be Rh positive to protect the developing child from the adverse effects of Rh incompatibility], or some nasal sprays, eye and ear drops [and topical anti-septics solutions, creams, and gels until 2002].)

*Except for a heavy fish eater*, fish consumption is not a major contributor because, *if it were a major factor*, then autism

symptoms of regressive autistic disorders. *J Toxicol Environ Health A* 2007; **70**:837–51.

<sup>17</sup> The monitoring of mercury in maternal human hair during pregnancy has found that the fetus absorbs mercury from the mother.

would have been "discovered" at least 100 years earlier than it was.

Moreover, the other sources of mercury exposures available to children developing *in utero* and to newborns include, *in order of importance*, the mercury from their mother's amalgam fillings, the mercury in breast milk for nursing children, and the mercury in the air (for babies living down plume from coal-fired power plants, crematoriums, cement plants, diaphragm-cell chlor-alkali plants, and/or exposed to rooms where there is metallic mercury from a previously broken thermometer and/or a broken fluorescent fixture), and water (in instances where there is a non-zero level of mercury and/or methylmercury hydroxide).

Furthermore, a published study<sup>18</sup> reviewing the mercury exposures of developing children born in the late 1990s and early 2000s estimated that about 50% of all the mercury to which fully vaccinated infants were exposed came from routinely recommended Thimerosal-containing childhood vaccines.

Worse, the vaccine-mercury exposures were from bolus doses directly injected into the child in a manner that bypasses the mercury-sequestering compounds (metallothioneins) found in the gut that reduce the absorption of ingested mercury by the body.

Thus, absent Thimerosal and other mercury compounds in vaccines and other drugs, the incidence for "autism" would be in the <1 in 10,000 range, as it was *before* Thimerosal-preserved serums and vaccines and other drugs containing Thimerosal and other mercury compounds were marketed without the requisite proofs of safety.

As evidence of the reality of the proceeding, one need only review the literature for Pink disease that appeared in the U.S. the late 1800s, reached epidemic levels in the early 1900s (with a reported peak incidence rate of about 1 in 500), and, coincidentally, "disappeared" after the Calomel-laced teething powders<sup>19</sup> were withdrawn from the U.S. market in the early 1940s.<sup>20</sup>

Like the neurodevelopmental disorders, *including those in the autism spectrum*, that are linked to the sub-acute mercury poisoning by Thimerosal in some who are administered vaccines and other drugs containing it, Pink disease was a "cause unknown" disease, according to the U.S. healthcare establishment's steadfast claims, when Calomel-containing drugs were being sold in America.

In the late 1950s, *a decade after it was removed from the U.S. market*, the medical establishment finally began to admit, what the toxicologists had been finding for decades: Calomel is

<sup>18</sup> Bingham M, Copes R. Thimerosal in vaccines Balancing the risks of adverse effects with the risk of vaccine-preventable disease. *Drug Safety* 2005; **28**(2):89–101.

<sup>19</sup> These teething powders contained up to 25% Calomel (chemically, mercurous chloride, Hg<sub>2</sub>Cl<sub>2</sub>; 84.98% mercury by weight) and, "coincidentally" like Thimerosal in the organic-mercury realm, was also marketed as a "special" form of inorganic mercury and claimed to be safe without any toxicological proof of safety.

<sup>20</sup> In Australia, Pink disease continued to be diagnosed until the late 1950s when the Calomel-containing teething powders were finally withdrawn from the Australian market.

a poisonous mercury compound that was the causal agent in Pink disease.

Though the characteristic visual symptoms that gave the Pink disease its name, bright pinkish gray palms of the hand and soles of the feet, are uncommon in those with a diagnosis in the autism spectrum, the general symptoms for Pink disease are similar in nature to those for the autism spectrum.

Moreover, were today's children who have an autism diagnosis and "pink" palms and "soles" to be seen by a physician practicing in the early 1920s, the odds are good that many of such children would have been diagnosed with Pink disease.

Interestingly, how coincidental was it that, just as there was a public furor building over the Calomel in teething powders in the 1930s and shortly before the manufacturers "decided" to withdraw the Calomel-laced teething powders and other medicines, Thimerosal was introduced in antiseptics and as a "preservative" in serums and vaccines – also without any real proof of safety and with specious proof of effectiveness as an antiseptic.<sup>21</sup>

Such marketing coincidences (Thimerosal in/Calomel out) seem to be events orchestrated by those who also stood to gain from the continuing the sub-acute mercury-poisoning of babies, which increases not only the short-term medical customer base in the affected children but also, *because it causes many of them to develop life-long "chronic" diseases*, increases the number of times these customers will need to be seen, treated, and, *in most cases*, prescribed medicines.

**Thimerosal myth #6:** Those who support a Thimerosal/autism link argue that some children may have a specific inability to metabolize mercury, and perhaps these are the children who become autistic.

**Reality:** The above statement is much too simplistic.

Factually, those children:

- Who have an innately reduced capability to excrete mercury, and/or
- Whose capability to excrete mercury has been impaired by other factors, including drugs (e.g., acetoaminophen and many antibiotics)—children who often have some evidence of illness, like irritability, or have some other diagnosed infection (e.g., an ear infection) when the Thimerosal-containing vaccines and other drugs were administered—and/or malnutrition (e.g., a diet that contains little or no cysteine)

have a greater risk of being mercury poisoned to the point that they exhibit the set of symptoms that are used to diagnose these children with:

- A neurodevelopmental disorder, like autism,
- Another disorder (e.g., type II diabetes),
- A behavioral problem (e.g., ADD),
- A food allergy (e.g., peanut allergy), and/or

<sup>21</sup> a. Morton HE, North LL, Engley FB. The bacteriostatic and bactericidal actions of some mercurial compounds on Hemolytic streptococci: in vivo and in vitro studies. *J. Am. Med. Assoc.* 1948; **136**:37–41.

b. Engley FB. Evaluation of mercurial compounds as antiseptics. *Ann. N. Y. Acad. Sci.* 1950; **53**:197–206.

- A food intolerance (e.g., gluten intolerance).

**Thimerosal myth #7:** Fear over Thimerosal and autism was given a huge boost by journalist David Kirby with his book *Evidence of Harm* (Kirby 2005).

**Reality:** Most vaccine apologists use the word "Fear" when the word "Concern" is clearly the appropriate choice.

Factually, David Kirby's 2005 book, *Evidence of Harm: Mercury in Vaccines and the Autism Epidemic: A Medical Controversy*, has raised and is raising public awareness and concern about the link between Thimerosal in vaccines and autism.

However, the recent *Poling* case and the publicity it has received as well as the recent efforts by celebrities with mercury-poisoned children (e.g., Jenny McCarthy and Jim Carey) appear to have done more to raise the general public's interest and have attracted widespread interest in the mainstream media to a greater extent than David Kirby's book.

**Thimerosal myth #8:** *Evidence of Harm* is an example of reporting that grossly misrepresents the science and the relevant institutions. Moreover, in the last two years, the evidence has been piling up that Thimerosal does not cause autism.

**Reality:** As the preceding references clearly indicate, the unbiased evidence has been accumulating since the 1930s that Thimerosal-containing serums and other drug products, including vaccines, do cause the sub-acute mercury poisoning, which manifests as a neuroencephalopathy and, in some cases, produces clinical symptoms that are characteristic of autism spectrum disorders.

Moreover, this evidence has "piled up" to the point that even the Secretary of Health and Human Services conceded one of the three "Thimerosal in vaccines causes autism" test cases originally scheduled to be heard in the Omnibus Autism Proceeding in 2008 (see *Hannah Poling v. Sec. HHS* [02-1466V], case entries "17" and "18") in 2007, before the case was heard and even before the experts' reports were scheduled to be filed.

Since the government's reasons for conceding this vaccine injury case cite mitochondrial dysfunction, a condition for which Thimerosal is a proven causative factor<sup>22</sup> (see also footnote 4), either the government is conceding that Thimerosal in vaccines was a causal factor or, *worse for the current vaccination programs*, that all of the many vaccines that Hannah Poling received were causal factors.

**Thimerosal myth #9:** There have now been a number of epidemiological and ecological studies that have all shown no correlation between Thimerosal and autism (Parker 2004 and Doja 2006). The current consensus holds that there is no real autism epidemic, just an artifact of how the diagnosis is made. If there is no epidemic, there is no reason to look for a correlation between Thimerosal and autism. This has been backed up by The Institute of Medicine, which has also reviewed all the available evidence (both epidemiological and toxicological) and con-

<sup>22</sup> Yel L, Brown LE, Su K, Gollapudi S, Gupta S. Thimerosal induces neuronal cell apoptosis by causing cytochrome c and apoptosis-inducing factor release from mitochondria. *Int J Mol Med.* 2005 Dec; **16**(6):971–7.

cluded that the evidence does not support the conclusion that Thimerosal causes autism (IOM 2004).”

**Reality:** Since the “*number of epidemiological and ecological studies*” and “*the current consensus*” are not scientifically sound proofs of causation or of the lack of causation, it is suggested that the reader study the case-control studies (see footnote 8) that have established that, *in a majority of cases*:

- Mercury poisoning from Thimerosal is the major causal factor in autism and
- There is a fairly good, statistically valid correlation between the degree of mercury poisoning found and the degree of neurodevelopmental damage that a child with the diagnosis in the autism spectrum has as well as the severity of the harm.

Moreover, toxicological studies in animals and monkeys as well as, *more recently*, in children with a diagnosis in the autism spectrum have confirmed the role of mercury poisoning in these disorders.

**Thimerosal myth #10:** Especially damning for the Thimerosal hypothesis are the recent studies that clearly demonstrate that early detection of autism is possible long before the diagnosis is officially made. Part of the belief that vaccines may cause autism is driven by the anecdotal observation by many parents that their children were normal until after they were vaccinated—autism is typically diagnosed around age two or three years. However, more careful observations indicate that signs of autism are present much earlier, even before twelve months of age, before exposure to Thimerosal (Mitchell 2006).

**Reality:** Since the 2002 CDC recommendation<sup>23</sup> to vaccinate women pregnant during the flu season, *when feasible*, Thimerosal-containing vaccines have been being *indirectly* given to the developing child *in utero* whenever the child’s mother is injected with a Thimerosal-containing flu-shot vaccine, which today starts during the first trimester of pregnancy when the fetus may weigh only a few grams.

Moreover, *until recently*, Thimerosal-containing vaccines were being given to some children at birth (e.g., the first dose hepatitis B shot—as of January 30, 2007 GlaxoSmithKline was issued an FDA license for a no-Thimerosal formulation; previously, the trace Thimerosal EnergixB by GlaxoSmithKline had <0.5µg mercury per 0.5mL dose or <1 ppm, equivalent to <1000 ppb) and, *even if the mother chooses the current “no Thimerosal” early childhood vaccines for her child*,

- The CDC, *by issuing recommendations that do not ban the use of Thimerosal-preserved vaccines in children of any age* (e.g. Tetanus toxoid, meningococcal), and
- The FDA, *by continuing to approve Sanofi-Aventis’ Thimerosal-preserved Fluzone formulation for use in children as young as 6 months*,

<sup>23</sup> Bridges CB, Fukuda K, Uyeki TM, Cox NJ, Singleton JA. Prevention and Control of Influenza Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 2002 Apr 12; **51**(RR03):1–31. “The 2002 recommendations ... influenza vaccination of healthy children aged 6–23 months ...”

permit Thimerosal-preserved influenza shots to be given to children at 6 and 7 months of age—delivering a total of 50 micrograms of Thimerosal (25 micrograms of mercury).

Thus, even today’s child can easily be exposed to 100 micrograms of Thimerosal (50 micrograms of mercury) from vaccines by 7 months of age.

Moreover, because the developing child being exposed to a 50-microgram dose of Thimerosal *in utero* (from the mother’s being given a Thimerosal-preserved flu shot) may weigh less than 1% of the weight of full-term child, the potential for harm may easily exceed that by the post-partum child by a factor greater than 100.

In addition, recent studies starting with evaluations at 18 months lost three quarters of those initially classified as possible being in the autism spectrum by the time of their third evaluation.<sup>24</sup>

Since:

- These early evaluations only see “*signs of autism*” but, *as the article cited shows*, do not reliably diagnose autism until months later, and
- Thimerosal exposure can begin at up to 8+ months before birth,

it is obvious that writer’s “*before exposure to Thimerosal*,” *as taken from “Mitchell, S., J. Brian, L. Zwaigenbaum, W. Roberts, P. Szatmari, I. Smith, and S. Bryson. 2006,”* is a blatant misrepresentation of the current realities vis-à-vis Thimerosal exposure.

**Thimerosal myth #11:** Some have argued that the Thimerosal in prenatal vaccines may be to blame, but recent evidence has shown a negative correlation there as well (Miles 2007).

**Reality:** The quoted study is confounded by significant biases such as: a) the exclusion, *on one pretext or another*, of most of those with the most significant adverse effects and b) the inclusion of Rh-negative mothers who received “no Thimerosal” Rho(D) serum injections (all receiving Rho(D) after 2001) combined with the group of mothers who did receive Thimerosal-preserved Rho(D) injections.

As with any research that lacks a sound foundation, this study has been thoroughly discredited by several independent researchers.<sup>25,26</sup>

**Thimerosal myth #12:** What we have are the makings of a solid scientific consensus. Multiple independent lines of evidence all point in the same direction: vaccines in general, and Thimerosal in particular, do not cause autism, which rather likely has its roots in genetics. Furthermore, true autism rates are probably static and not rising.

<sup>24</sup> VanDenHeuvel A, Fitzgerald M, Greiner B, Perry IJ. Screening for autistic spectrum disorder at the 18-month developmental assessment: a population-based study. *Ir Med J.* 2007 Sep; **100**(8):565–7.

<sup>25</sup> www.safeminds.org/pressroom/pres\_releases/Review\_Miles\_Takas\_hashi\_6-20-07.pdf

<sup>26</sup> Geier DA, Geier MR. A prospective study of Thimerosal-containing Rho(D)-immune globulin administration as a risk factor for autistic disorders. *J Maternal-Fetal and Neonatal Med.* 2007 May; **20**(5):385–90.

**Reality:** This statement is again a classic example of double-speak where it is asserted:

- “*What we have are the makings of a solid scientific consensus,*” which, *like having the makings (ingredients) for a cherry pie*, actually means there is no scientific consensus because *having the ingredients does not make a cherry pie*,
- “*Multiple independent lines of evidence all point in the same direction:*” when all of the evidence cited is generally from only one line of evidence—statistical analysis of heavily pruned and/or intentionally misdesigned epidemiological and/or ecological studies of the medical records of some group of individuals,
- “*vaccines in general, and Thimerosal in particular, do not cause autism, which rather likely has its roots in genetics,*” which is a classic example of misstatement and misdirection because the toxicological and clinical studies, *previously cited*, have clearly shown that the symptoms caused by the sub-acute mercury poisoning of children by Thimerosal in vaccines include the set of symptoms used to diagnosis autism in children in the autism spectrum.

Factually, the estimated rates that do exist:

- Are for: disjoint groups (e.g., the CDC’s 8-year olds in 6 sites and then in 14 sites) and/or times (e.g., the CDC’s 8-year olds surveyed in 2000 and 2002) or,
- Are *not* corrected for underascertainment and the population change (in children) in the area from which the data is being reported (e.g., the California data where all that is routinely reported is cases by age group and not cases per number of children by birth year).

However, *from these retrospective estimates*, it is clear that a disorder that had an estimated “<3 in 10,000” rate in the mid-1970s has increased until the current retrospective estimates for the rates in the early 1990s are at least “66 in 10,000” and may easily have been more than “100 in 10,000” (> 1%).

Moreover, since:

- Thimerosal has not been removed from all vaccines and medicines,
- *Contrary to the 1999 promise*, the FDA has approved more Thimerosal-preserved vaccines, and
- The CDC has recommended administering one of those Thimerosal-preserved vaccines, the Thimerosal-preserved influenza vaccine, for pregnant women and babies,

federal officials have continued the *knowing* mercury poisoning of children and adults while touting the removal of Thimerosal as a preservative from most of the other early childhood vaccines and proclaiming these removals as if they were the removal of Thimerosal from all vaccines – classic examples of misdirection and deceit.

**Thimerosal myth #13:** With the scientific evidence so solidly against the mercury hypothesis of autism, proponents maintain their belief largely through the generous application of conspiracy thinking.

**Reality:** Here, *as the clinical and case evidence previously cited shows*, this statement begins with a misrepresentation,

*“With the scientific evidence so solidly against the mercury hypothesis of autism.”*

Compounding this distortion, the statement then opines: *“proponents maintain their belief largely through the generous application of conspiracy thinking.”*

Factually, those who have and are investigating the interactions among government agencies, elected officials, health officials, academics, the vaccine manufactures, their consultants, and those who continue to defend the use of Thimerosal as a preservative *without* the requisite proof of safety have determined that there is clear evidence of prior and continuing collusion among those parties to directly or indirectly violate applicable federal laws (regulations) and statutes that place an absolute, non-dischargeable duty upon the vaccine makers to prove that the Thimerosal used as a preservative is safe to the legal standard minimum.

To the extent that this collusion exists, it appears to this reviewer that all those involved are knowingly participating in a racket and may, therefore, be subject to the applicable criminal provisions of the RICO (Racketeering, Influencing, and Corrupt Organizations) statutes as set forth in **18 U.S.C.A. Sec 1961 et seq.**

In addition, because these vaccines and other drug products have *not* been appropriately proven to be safe, all of these are adulterated drugs under **21 U.S.C. Sec. 351(a)(2)(B)**.

Because these are adulterated drugs, shipping them into commerce is a prohibited act (**21 U.S.C. Sec. 331 Prohibited acts**) and subjects the drugs to removal from the market and the drug manufacturers and other accountable persons to the sanctions set forth in **21 U.S.C. Sec. 333. Penalties**.

Thus, many individuals have come to the conclusion that the evidence appears to establish, *at a minimum*, collusion among the parties.

**Thimerosal myth #14:** Despite the lack of evidence for any safety concern, the FDA decided to remove all Thimerosal from childhood vaccines, and by 2002 no new childhood vaccines with Thimerosal were being sold in the U.S. This was not an admission of prior error, as some mercury proponents claimed; instead, the FDA was playing it safe by minimizing human exposure to mercury wherever possible. The move was also likely calculated to maintain public confidence in vaccines.

**Reality:** No part of this myth is factually accurate.

Factually, in July of 1999, the federal government issued a press release<sup>27</sup> (entitled *Thimerosal in Vaccines: A Joint Statement of the American Academy of Pediatrics and the Public Health Service*, which was posted on the CDC’s *Morbidity and Mortality Weekly Reporter [MMWR]* web site), and, *in part*, states:

“... because any potential risk is of concern, the Public Health Service (PHS), the American Academy of Pediatrics (AAP), and vaccine manufacturers agree that Thimerosal-containing vaccines should be removed as soon as possible. Similar conclusions were reached this year in a meeting attended by

<sup>27</sup> *Morbidity Mortality Weekly Report* 1999 July 9; **48**(26):563–5. [Note: The original press release issued July 7, 1999] This announcement can be found searching <http://www.cdc.gov/mmwr/>.



European regulatory agencies, European vaccine manufacturers, and FDA, which examined the use of Thimerosal-containing vaccines produced or sold in European countries.”

First, all the parties agreed there was a “potential risk”—since Thimerosal is known to be toxic to humans at tissue levels below 1 ppm.

Second, the decision to remove the Thimerosal-containing vaccines was a decision that only the manufacturers of vaccines could implement.

Third, under the Public Health Act (42 U.S.C.), the FDA, acting on behalf of the Secretary of HHS, could have (and, by 2007, should have) revoked the U.S.-licenses for the manufacturing of all Thimerosal-containing vaccines, but, *as far as this reviewer can ascertain*, the FDA has yet to revoke any of these manufacturing licenses.

Fourth, as of *today, about 9 years later*, Thimerosal-containing vaccines can be, and are still being, given to children without proof of safety to the applicable safety standard, “sufficiently nontoxic ...” (21 C.F.R. Sec. 610.15(a)) as any careful review of “Table 3” on the appropriate FDA webpage, <http://www.fda.gov/cber/vaccine/Thimerosal.htm> (last visited on 5 April 2008) will show, and the permissible age ranges for the use of each vaccine will confirm.

Fifth, with respect to the myth’s claim, “*by 2002 no new childhood vaccines with Thimerosal were being sold in the U.S.*,” this is also false because, among other Thimerosal-containing vaccines that could be given to children in 2002, the Thimerosal-preserved influenza vaccine, *which, by its nature, is a new vaccine every year*, was effectively *knowingly* added to the recommended vaccination schedule for pregnant women as well as to the recommended childhood vaccination schedule in April of 2002<sup>28</sup> at a time when all doses of the influenza vaccine approved for “healthy children aged 6–23 months” were Thimerosal preserved.

Sixth, *compounding the harm*, in April of 2002, the CDC’s recommendation that the Thimerosal-preserved influenza vaccine be given to pregnant women who would be in their second and third trimesters of their pregnancies during the influenza season, thereby knowingly recommending the Thimerosal and mercury poisoning the developing child in utero when the risk of harm is even greater than it is postpartum and the results published in 1977<sup>29</sup> clearly found that Thimerosal-preserved flu vaccines that were given to pregnant women significantly increased (with a hospital-standardized relative risk of 2.0 or higher) their children’s risk of serious birth defects (cleft palate [RR=7.1], microcephaly [RR=2.3], and pyloric stenosis [RR=2.0]).

If, *as the statement asserts*, the FDA were “*playing it safe by minimizing human exposure to mercury wherever possible*,” then, the FDA would have acted to ban the use of Thimerosal

and any other mercury compounds in all medicines and medical procedures, since all such uses are unnecessary because other compounds can be, have been, and are being used as an in-process sterilants and/or a finished-packaged-product preservative, the only areas where the FDA has authorized the use of Thimerosal.

Furthermore, had the U.S. government truly wished to safeen U.S.-licensed vaccines, as the National Vaccine Injury Compensation Program (NVICP) mandates (see 42 U.S.C. Sec. 300aa-27. **Mandate for safer childhood vaccines**), then the use of a preservative in vaccines would have been outlawed and all vaccines would have been required to be packaged in unit-dose containers.

However, except to ban the use of Thimerosal and other mercury compounds in over-the-counter topical antiseptics and vaginal contraceptives, the FDA has steadfastly refused to:

- Ban the use of Thimerosal and other mercury compounds in any medicine, or
- Provide or demand from the vaccine manufacturers, scientifically sound and appropriate toxicological proof that all uses of Thimerosal in medicine are “sufficiently nontoxic ...” as required by law.

Since, *regardless of who made the promise to remove Thimerosal-containing vaccines from the U.S. market*, this promise has not been kept, if the move to minimize human exposure to mercury “*was also likely calculated to maintain public confidence in vaccines*,” then, the failure to keep the 1999 promise and the continual false claims that the 1999 promise has been kept have most certainly undermined, and are undermining, “*public confidence in vaccines*.”

When such misleading statements are made by public health officials and others about any aspect of drug safety, including the removal of Thimerosal from vaccines, and then published, these statements contribute to the lessening of public confidence in vaccines as, *in the current instance*, the truth is revealed.

**Thimerosal myth #15:** Removing Thimerosal in vaccines created the opportunity to have the ultimate test of the Thimerosal-autism hypothesis. If rising Thimerosal doses in the 1990s led to increasing rates of autism diagnosis, then the removal of Thimerosal should be followed within a few years by a similar drop in new autism diagnoses. If, on the other hand, Thimerosal did not cause autism, then the incidence of new diagnoses should continue to increase and eventually level off at or near the true rate of incidence.

**Reality:** Since:

- Thimerosal has *not* been removed from all vaccines,
  - *For many U.S. children*, the specific-dose received has significantly increased, and
  - The total *maximum* dose of Thimerosal that any U.S. child may receive has *not* decreased by at least a factor of 100,
- this myth speaks to some future event or to some alternative population (nation), where:
- The promise has been kept and

<sup>28</sup> Bridges CB, Fukuda K, Uyeki TM, Cox NJ, Singleton JA. Prevention and Control of Influenza Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 2002 Apr 12; 51(RR03): 1-31. [“The 2002 recommendations include five principal changes or updates, as follows: ..., influenza vaccination of healthy children aged 6–23 months is encouraged when feasible. ...”]

<sup>29</sup> Heinonen OP, Slone D, Shapiro S. 1977. Birth Defects and Drugs in Pregnancy. Littleton: Publishing Sciences Group, Inc.

- The maximum total dose of Thimerosal from vaccines that a child may receive from conception to 18 years of age is near “zero” (< 0.001 ppm).

To support this assertion about the presence of Thimerosal in vaccines, consider the list of U.S.-licensed vaccines containing Thimerosal that are currently being distributed as shown in Table II.

Factually, *at the beginning of 2008*, this list still includes 8 vaccines (in 5 “Vaccine” categories) with a preservative level of Thimerosal and 7 listed vaccines (in 6 “Vaccine” categories) with a reduced level of Thimerosal.

After reviewing the facts shown here, hopefully, readers will stop talking about the absence of Thimerosal in vaccines and start working to:

- Remove Thimerosal from all marketed vaccines, and
- Ban any use of Thimerosal, all other organic mercury compounds, inorganic mercury compounds, and mercury in any aspect of medicine or dentistry.

Unlike today’s other complex scientific issues,

- The proven general toxicity, teratogenicity, carcinogenicity, mutagenicity, and immune-system poisoning effects of mercury, *in all forms*, at levels well-below 1 part-per-million (ppm) and
- The long-half-lives for the end-metabolite, the bioaccumulative, tissue-retained “inorganic mercury” from these mercury sources in the human body,

clearly indicate that urgent and immediate reforms are necessary because these established realities have proven that there is no justification for continuing to permit mercury, *in any form, at any level*, to be used in medicine and dentistry since there are, *and have been*, suitable less toxic, non-bioaccumulative alternatives that can be used.

**Thimerosal myth #16:** Five years after the removal of Thimerosal, autism diagnosis rates have continued to increase (IDIC 2007). That is the final nail in the coffin in the Thimerosal-vaccine-autism hypothesis. The believers, however, are in full rationalization mode. David Kirby and others have charged that although no new vaccines with Thimerosal were sold after 2001, there was no recall, so pediatricians may have had a stockpile of Thimerosal-laden vaccines--even though a published inspection of 447 pediatric clinics and offices found only 1.9 percent of relevant vaccines still had Thimerosal by February 2002, a tiny fraction that was either exchanged, used, or expired soon after (CDCP/ACIP 2002).

**Reality:** As shown in Table II, the truth is that Thimerosal is still in vaccines at preservative and lower levels; and these Thimerosal-containing vaccines are being administered indirectly to the fetus (*in utero*) and directly (postpartum) to developing children. The reader is urged to check the reference provided and verify that Thimerosal is still present in some of the vaccines approved for use in children as well as in most doses of the influenza vaccines that are approved for administration to children and pregnant women.

**Table II. Current (March 14, 2008) FDA-listed Vaccines that Contain Thimerosal**

Vaccine	Trade Name	Manufacturer	Thimerosal Concentration <sup>1</sup>	
DTaP	Tripedia	Sanofi Pasteur, Inc	≤ 0.00012%	
DT	---	Sanofi Pasteur, Inc	< 0.00012% (single dose)	
		Sanofi Pasteur, Ltd	<b>0.01%</b>	
Td	Decavac	Mass Public Health	<b>0.0033%</b>	
		Sanofi Pasteur, Inc	≤ 0.00012%	
TT (Tetnus Toxoid)	---	Sanofi Pasteur, Inc	<b>0.01%</b>	
Hepatitis B	Engerix-B Pediatric/adolescent	GlaxoSmithKline Biologicals	< 0.0002 %	
HepA/HepB	Twinrix	GlaxoSmithKline Biologicals	< 0.0002 %	
		Fluzone	Sanofi Pasteur, Inc	<b>0.01%</b>
	Fluvirin (Preservative Free)	Fluvirin	Novartis Vaccines and Diagnostics Ltd	<b>0.01%</b>
		Novartis Vaccines and Diagnostics Ltd	< 0.0004 %	
Influenza	Fluarix	GlaxoSmithKline Biologicals	< 0.0004 %	
	FluLaval	ID Biomedical Corporation of Quebec	<b>0.01%</b>	
	Afluria	CSL Ltd, (Approved 28 Sept. 2007)	<b>0.01%</b>	
Japanese Encephalitis	JE-VAX	Research Foundation for Microbial Diseases of Osaka University	<b>0.007%</b>	
Meningococcal	Menomune A, C, AC & A/C/Y/W-13	Sanofi Pasteur, Inc	<b>0.01%</b> (multidose)	

<sup>1</sup> The values in bold are levels of Thimerosal that are considered to be preservative levels.

Thimerosal-preserved and Thimerosal-containing vaccines are still being given to developing children under conditions that, in 2002 and afterwards:

- Significantly increased the specific toxicity exposure (specific dose; dose per kg of body weight) since the *in-utero* child is being exposed to up to 50 micrograms of Thimerosal (25 micrograms of mercury) when that child’s mother is administered a Thimerosal-preserved flu shot, and
- Progressively added to maximum Thimerosal exposure by: Adding a 0.25-mL flu shot for infants 6 to 23 months of age in 2002,
- Increasing the exposure by recommending two 0.25-mL flu shots, 1 at 6 months and 1 at 7 months and increasing the age range to 6 months – 35 months in 2003,
- Further increasing the exposure risk for some by recommending that all children get two flu shots a month a part the first time they are vaccinated and extending the age range to 59 months in 2005,
- Additionally increasing the exposure risk for some by increasing the age range to 107 months and suggesting all children would benefit from a flu shot in 2007, and

- Increasing the exposure risk for all by increasing the age range for all children to 18 years of age (potentially resulting in a total dose of more than 5,000 micrograms (5 milligrams) of injected Thimerosal-mercury from vaccines.

**Thimerosal myth #17:** Thimerosal still exists as a necessary preservative in multi-shot vaccines outside the United States, especially in poor third-world countries that cannot afford stockpiles of single-shot vaccines. Anti-Thimerosal hysteria therefore also threatens the health of children in poor countries.”

**Reality:** The preceding begins with a false premise—namely that Thimerosal is “a necessary preservative.”

While the FDA regulations for some multi-dose (“multi-shot”) vaccines do require a preservative, they do not require that Thimerosal be that preservative. Factually, there are other safer (non-bioaccumulative poisons, non-teratogens, and non-immune-system disruptors) compounds that can be, have been, and are being used as a preservative in vaccines.

In addition to Thimerosal, the FDA currently allows several compounds or compound mixtures to be used as preservatives in U.S.-licensed vaccines (see Table III).

**Table III. Preservative compounds and compound mixtures in U.S.-licensed vaccines**

Preservative	Vaccine examples (Tradename; Manufacturer)
2-phenoxyethanol and formaldehyde	IPV (IPOL; Sanofi Pasteur, SA) DTaP (Daptacel; Sanofi Pasteur, Ltd)
Phenol	Typhoid Vi Polysaccharide (Typhim Vi; Sanofi Pasteur, SA) Pneumococcal Polysaccharide (Pneumovax 23; Merck & Co, Inc)
Benzethonium chloride Phemerol)	Anthrax (Biothrax; BioPort Corporation)
2-phenoxyethanol	DTaP (Infanrix; GlaxoSmithKline Biologicals) Hepatitis A (Havrix; GlaxoSmithKline Biologicals) Hepatitis A/Hepatitis B (Twinrix; GlaxoSmithKline Biologicals)

Thus, vaccine formulations using another preservative could be developed and deployed so that “poor third-world countries that cannot afford stockpiles of single-shot vaccines” could stockpile multi-dose vaccines using these non-Thimerosal preservatives.

Furthermore, if the U.S. experience teaches us anything, it is this: The long-term chronic-disease harm from the poisoning of children by injecting them with Thimerosal and, thereby, mercury poisoning all of those so injected to some degree, outweighs any cost-benefits currently attributed to the short-term protection from administering these Thimerosal-containing vaccines.

**V. Key realities concerning Wakefield/Geier’s Research**

**Wakefield/Geier’s research myth #1:** In 1998, researcher Andrew Wakefield and some of his colleagues published a study in the prestigious English medical journal *Lancet* that claimed to show a connection between the MMR vaccine and autism (Wakefield 1998). Wakefield’s theory was that the MMR vaccine, which contains a live virus, can cause in susceptible children a chronic measles infection. This in turn leads to gastrointestinal disturbances, including what he calls a “leaky gut” syndrome, which then allows for certain toxins and chemicals to enter the bloodstream where they can access and damage the developing brain. Investigative reporter Brian Deer has uncovered greater depths to Wakefield’s apparent malfeasance. Wakefield had applied for patents for an MMR vaccine substitute and treatments for his alleged MMR vaccine-induced gut disorder (Deer 2007). So, not only was he allegedly paid by lawyers to cast doubt on the MMR vaccine, but he stood to personally gain from the outcome of his research.”

**Reality:** Dr. Wakefield is a competent and recognized doctor and researcher (see Appendix C) whose accomplishments seem to support the general validity of the findings in his published studies.

Moreover, it is less than ethical to attack the findings of scientific studies by repeating *unsubstantiated* claims (e.g., “paid by lawyers to cast doubt on the MMR vaccine”) and attacking the ethics and motives of the researchers who have published, and stood by, their study’s findings.

Interestingly, in this discussion of ethics and motives of those involved in the MMR controversy “in Great Britain,” no mention is made regarding potential British conflicts of interest, which have recently surfaced, among: a) a key presiding court jurist, b) a management official for a British-based vaccine maker, and c) a *Lancet* management official.

Furthermore, from a scientifically sound interpretation<sup>30</sup> of the Danish epidemiological data for the introduction of the MMR vaccine and its delayed acceptance by the Danes<sup>31</sup>, it is clear that, *in some cases*, the MMR vaccine, *known to induce neurological encephalopathies in some vaccinated with it*, is a causal factor in some diagnosed neurodevelopmental disorder cases where the children were diagnosed as having an ASD.

As shown in footnote 30’s **Figure 4**, the prevalence of Danish autism cases increased statistically significantly from 0.34 per 1,000 children age <15 years in the period 1993-1994 to about 1.4 per 1,000 such children in 2000-2002, a “4-fold” increase.<sup>32</sup>

<sup>30</sup> Goldman GS, Yazbak FE. An investigation of the association between MMR vaccination and autism in Denmark. *J Am Physicians and Surgeons* 2002 Fall; 9(3):70–5.

<sup>31</sup> The removal of the Thimerosal-preserved DTP vaccine resulted in an ever-increasing percentage of the doses of MMR administered to children under age 15 during the period from 1994 through 2002 being given to children, except those born after 1994, who had received the Thimerosal-preserved DPT vaccine series.

<sup>32</sup> By way of comparison, the comparable U.S. autism rates in the late 1990s and early 2000s are estimated to be roughly “10” per 1,000 or roughly 4.5 times the rate in Denmark.

However, based on the two recent published<sup>33</sup> U.S. CDC survey-based estimates (from 2000 and 2002), where the CDC's publishing of both articles was inexplicably delayed until 2007, the two ASD rate estimates (for 8-year-old U.S. children: a) born in 1992 at six sites and b) born in 1994 at fourteen sites) are both about 6.7<sup>34</sup> (or nominally 20 times the Danish rate for children up to 15 years of age in the 1993-1994 period as well as about 4.6 times the peak rate in Denmark for the 2000-2002 period<sup>35</sup>).

**Wakefield/Geier's research myth #2:** Stephen Bustin, a world expert in the polymerase chain reaction (PCR), testified that the lab Wakefield used to obtain the results for his original paper was contaminated with measles virus RNA. It was therefore likely, Bustin implied, that the PCR used by Wakefield was detecting this contamination and not evidence for measles infection in the guts of children with autism who had been vaccinated, as Wakefield claimed. And finally, Nicholas Chadwick testified that the measles RNA Wakefield found matched the laboratory contamination and did not match either any naturally occurring strain or the strain used in the MMR vaccine—a fact of which he had informed Wakefield (USFCF 2007)."

**Reality:** Other researchers have apparently independently confirmed and extended Wakefield's original findings.<sup>36</sup>

<sup>33</sup> a. Rice C, et al. Prevalence of Autism Spectrum Disorders --- Autism and Developmental Disabilities Monitoring Network, Six Sites, United States, 2000. *MMWR* 2007 February 9; **56**(SS01):1–11.

b. Rice C, et al. Prevalence of Autism Spectrum Disorders --- Autism and Developmental Disabilities Monitoring Network, 14 Sites, United States, 2002. *MMWR* 2007 February 9; **56**(SS01):12–28.

<sup>34</sup> Though the overall averages were about the same on the 2 papers, the ASD survey rates for the 6 original sites increase from 6.7 per 1,000 in 2000 to 7.4 per 1,000 in 2004, an unexplained 10+ % increase. See: [http://www.safeminds.org/pressroom/press\\_releases/09Feb2007Press\\_Release.html](http://www.safeminds.org/pressroom/press_releases/09Feb2007Press_Release.html): "A calculation by SafeMinds, however, shows that while the rate for children born in 1992 was 6.7 per 1,000, the comparable 1994 rate for time trend purposes is 7.4 per thousand, a 10% increase in just two years. The survey of children born in 1992 was conducted at 6 sites. The survey of children born in 1994 was conducted at 14 sites, including the 6 sites of the 1992 survey. ... When the prevalence rate of the same 6 sites is calculated for the children born in 1994 – an apples-to-apples comparison – the rate is 7.4 per 1,000, or 10% more than in 1992"

<sup>35</sup> Presuming the 20-fold rate for the early 1990s applies for 8-year olds in 2000, then, the U.S. autism rate for 8-year olds born in 2000 could reach about 29 per 1,000 (2.9%) for that cohort.

<sup>36</sup> a. Horvath K, Papadimitriou JC, Rabsztyan A, Drachenberg C, Tildon JT. Gastrointestinal abnormalities in children with autism. *J. Pediatrics*, 1999 November; **135**(5):559–63.

b. Wakefield AJ, Anthony A, Murch SH, Thomson M, Montgomery SM, Davies S, et al. Enterocolitis in children with developmental disorder. *Am. J. Gastroenterology*, Sept 2000; **95**(9):2285–95

c. Furlano RI, Anthony A, Day R, Brown A, McGaverty L, Thomson MA, Davies SE, Berelowitz M, Forbes A, Wakefield AJ, Walker-Smith JA, Murch SH. Colonic CD8 and T-Cell Infiltration With Epithelial Damage in Children with Autism. *J. Pediatrics*, 2001; **138**(3):366–72

d. Ashwood P, Murch SH, Anthony A, Pellicer AA, Torrente F, Thomson M, Walker-Smith JA, Wakefield AJ. Intestinal

**Wakefield/Geier's research myth #3:** Believers in the MMR-autism hypothesis dismiss the larger and more powerful epidemiological studies that contradict a link. Instead, they have turned Andrew Wakefield into a martyr, dismissing the evidence of his wrongdoing as a conspiracy against him designed to hide the true cause of autism from the public. (Gorski 2007)

Lymphocyte Populations in Children with Regressive Autism: Evidence for Extensive Mucosal Immunopathology, *J. Clin. Immunol.* 2003 November; **23**(6):504–17

- e. Torrente F, Anthony A, Heuschkel RB, Thomson MA, Ashwood P, Murch SH. Focal-Enhanced Gastritis in Regressive Autism, With Features Distinct from Crohn's and Helicobacter Pylori Gastritis. *Am. J. Gastroenterol.* 2004 April; **99**(4):598–605.
- f. Ashwood P, Anthony A, Torrente F, Wakefield AJ. Spontaneous Mucosal Lymphocyte Cytokine Profiles in Children with Autism and Gastrointestinal Symptoms: Mucosal Immune Activation and Reduced Counter-Regulatory Interleukin-10. *J. Clin. Immunol.* 2004 November; **24**(6):664–73.
- g. Jyonouchi H, Geng L, Ruby A, Zimmerman-Bier B. Dysregulated Innate Immune Responses in Young Children with Autistic Spectrum Disorders - Their Relationship in Gastrointestinal Symptoms and Dietary Intervention. *Neuropsychobiology*, February 2005, **51**(2):77–85.
- h. Balzola F, Barbon V, Repici A, Rizzetto M, Clauser D, Gandione M, Sapino A. Pan-Enteric IBD-Like Disease in a Patient with Regressive Autism Shown for the First Time by the Wireless Capsule Enteroscopy – Another Piece in the Jigsaw of this Gut/Brain Syndrome? *Am. J. Gastroenterol.* 2005; **100**(4):979–81.
- i. Balzola F, et al. Autistic Enterocolitis – Autistic Enterocolitis: Confirmation of a New Inflammatory Bowel Disease in an Italian Cohort of Patients, paper presented to the American Gastroenterological Association, May 2005 and published in *Gastroenterology* 2005;**128**(Suppl 2):A-303
- j. Wakefield AJ, Ashwood P, Limb K, Anthony A. The Significance of Ileo-Colonic Lymphoid Nodular Hyperplasia in Children with Autistic Spectrum Disorder, *Eur. J. Gastroenterol. Hepatol.* 2005 August; **17**(8):827–36.
- k. Martin CM, Uhlmann V, Killalea A, Sheils O, O'Leary JJ. Detection of measles virus in ileo-colonic lymphoid nodular hyperplasia, enterocolitis and developmental disorder. *Mol. Psychiatry* 2002; **7**(Suppl. 2):S47–48.
- l. Kawashima H, Mori T, Kashiwagi Y, Takekuma K, Hoshika A, Wakefield AJ. Detection and sequencing of measles virus from peripheral mononuclear cells from patients with inflammatory bowel disease and autism. *Dig. Dis. Sci.* 2000 Apr; **45**(4):723–9.
- m. Singh VK, Lin SX, Newell E, Nelson C. Abnormal measles-mumps-rubella antibodies and CNS autoimmunity in children with autism. *J Biomed Sci.* 2002 Jul-Aug; **9**(4):359–64.
- n. Bitnun A, Shannon P, Durward A, Rota PA, Bellini WJ, Graham C, Wang E, Ford-Jones EL, Cox P, Becker L, Fearon M, Petric M, Tellier R. Measles Inclusion-Body Encephalitis Caused by the Vaccine Strain of Measles Virus, *Clin. Infectious Dis. J.* 1999 October; **29**:855–61.
- o. Bradstreet JJ, El Dahr J, Anthony A, Kartzinel JJ, Wakefield AJ. Detection of Measles Virus Genomic RNA in Cerebrospinal Fluid of Children with Regressive Autism: a Report of Three Cases, *J. Am. Phys. Surg.* 2004 Summer; **9**(2):38–45.
- p. Wakefield AJ, Stott C, Limb K. Gastrointestinal comorbidity, autistic regression and measles-containing vaccines: Positive re-challenge and biological gradient. *Medical Veritas* 2006 Apr; **3**(1):796–802.

**Reality:** As most scientists know, statistics-based epidemiological studies cannot “*contradict a link*”; they can only assess the probability that there may be a link.

Moreover, epidemiological studies, *by their population-based nature*, cannot generally find statistical significance when the effect (link) is confined to some small segment of that population.

This sub-population reality seems to be the case for the possible link between: **a)** MMR vaccination in children who generally have also received Thimerosal-containing vaccines and **b)** neuroencephalopathies that manifest with the set of symptoms used to diagnose autism spectrum disorders.

The reader should keep an open mind when it comes to the possibility of a causal link between MMR and autism until the appropriate viral clinical toxicology studies, *which have not been done*, are conducted and the results of these studies establish that such a link is not possible.

The reader should focus on the apparent validity of Wakefield’s published findings and ignore the attack on Wakefield’s alleged actions and motives until and unless they are substantiated.

Thus, *lacking the requisite specific medical case evidence to refute Andrew Wakefield’s findings*, the above misconception attacks the messenger, Dr. Wakefield, in an attempt to undermine the validity of the message: giving the MMR vaccine, or the MMR vaccine with (and/or after) a Thimerosal-containing vaccine can cause post-MMR-vaccination-related neurodevelopmental disorders in some children.

**Wakefield/Geier’s research myth #4:** The only researchers who are publishing data that contradicts the “consensus” that vaccines in general, and Thimerosal in particular, do not cause autism are the father-and-son team of Mark and David Geier. They have looked at the same data as other scientists and have concluded that Thimerosal does correlate with autism.

**Realty:** Though the Geiers have probably been the most active independent researchers investigating the possible causative role of Thimerosal and other mercury compounds in the mercury poisoning of children developing *in utero* and postnatally, others have also published in this area as the previously cited references and the references in the recent citizen petition filed by the Coalition for Mercury-free Drugs in 24 August 2007 (FDA Docket # 2007P-0331) clearly show.<sup>37</sup>

<sup>37</sup> This FDA citizen petition, titled “Citizen Petition to Ban Use of Mercury in Medicine, UNLESS Proven Toxicologically Safe to the CGMP Standard ‘Sufficiently Nontoxic ...’” by the FDA, was filed by CoMeD, Coalition for Mercury-free Drugs, with the FDA Division of Dockets Management on 24 August 2007 and, on that day, was assigned FDA Docket # 2007P-0331 by the FDA. [See: [http://www.mercury-free-drugs.org/docs/070824\\_CoMeDCitizenPetitionPart2.pdf](http://www.mercury-free-drugs.org/docs/070824_CoMeDCitizenPetitionPart2.pdf)]

Searches of PubMed<sup>38</sup> for indexed articles published in the last 3 years and omitting the Geiers’ indexed publications as well as any publications that were underwritten by the health-care establishment, this reviewer finds 27 papers by other authors that support: a) the human toxicity of Thimerosal and mercury in vaccines and b) the reality that, *in some children*, Thimerosal-containing vaccines have been, and are, a major cause of the sub-acute mercury-poisoning symptoms that are exhibited by those diagnosed with an autism spectrum disorder:

1. Lopez-Hurtado E, Prieto A. Microscopic Study of Language-Related Cortex in Autism. *Am J Biochem Biotechnol.* 2008; **4**: 130–45. In press.
2. Park EK, Mak SK, Kültz D, Hammock BD. Evaluation of cytotoxicity attributed to Thimerosal on murine and human kidney cells. *J Toxicol Environ Health A.* 2007 Dec; **70**(24):2092–5.
3. Liu SI, Huang CC, Huang CJ, Wang BW, Chang PM, Fang YC, Chen WC, Wang JL, Lu YC, Chu ST, Chou CT, Jan CR. Thimerosal-induced apoptosis in human SCM1 gastric cancer cells: activation of p38 MAP kinase and caspase-3 pathways without involvement of [Ca<sup>2+</sup>]<sub>i</sub> elevation. *Toxicol Sci.* 2007 Nov; **100**(1):109–17. Epub 2007 Aug 13.
4. Dórea JG. Exposure to mercury during the first six months via human milk and vaccines: modifying risk factors. *Am J Perinatol.* 2007 Aug; **24**(7):387–400. Epub 2007 Jun 12.
5. Lawton M, Iqbal M, Kontovraki M, Lloyd Mills C, Hargreaves AJ. Reduced tubulin tyrosination as an early marker of mercury toxicity in differentiating N2a cells. *Toxicol In Vitro.* 2007 Oct; **21**(7):1258–61. Epub 2007 Apr 14.
6. Hagele TJ, Mazerik JN, Gregory A, Kaufman B, Magalang U, Kuppusamy ML, Marsh CB, Kuppusamy P, Parinandi NL. Mercury activates vascular endothelial cell phospholipase D through thiols and oxidative stress. *Int J Toxicol.* 2007 Jan-Feb; **26**(1):57–69.
7. Marques RC, Dórea JG, Fonseca MF, Bastos WR, Malm O. Hair mercury in breast-fed infants exposed to Thimerosal-preserved vaccines. *Eur J Pediatr.* 2007 Sep; **166**(9):935–41. Epub 2007 Jan 20.
8. Yole M, Wickstrom M, Blakley B. Cell death and cytotoxic effects in YAC-1 lymphoma cells following exposure to various forms of mercury. *Toxicology* 2007 Feb 28; **231**(1):40–57. Epub 2006 Nov 25.
9. Havarinasab S, Björn E, Ekstrand J, Hultman P. Dose and Hg species determine the T-helper cell activation in murine autoimmunity. *Toxicology* 2007 Jan 5; **229**(1-2):23–32.
10. Orct T, Blanusa M, Lazarus M, Varnai VM, Kostial K. Comparison of organic and inorganic mercury distribution in suckling rat. *J Appl Toxicol.* 2006 Nov-Dec; **26**(6):536–9.
11. Agrawal A, Kaushal P, Agrawal S, Gollapudi S, Gupta S. Thimerosal induces TH2 responses via influencing cytokine secretion by human dendritic cells. *J Leukoc Biol.* 2007 Feb; **81**(2):474–82. Epub 2006 Nov 1.
12. Walker SJ, Segal J, Aschner M. Cultured lymphocytes from autistic children and non-autistic siblings up-regulate heat shock protein RNA in response to Thimerosal challenge. *Neurotoxicology* 2006 Sep; **27**(5):685–92.
13. Woo KJ, Lee TJ, Bae JH, Jang BC, Song DK, Cho JW, Suh SI, Park JW, Kwon TK. Thimerosal induces apoptosis and G2/M phase arrest in human leukemia cells. *Mol Carcinog.* 2006 Sep; **45**(9):657–66.

<sup>38</sup> <http://www.ncbi.nlm.nih.gov/sites/entrez>

14. Nataf R, Skorupka C, Amet L, et al. Porphyrinuria in childhood autistic disorder: implications for environmental toxicity. *Toxicol Appl Pharmacol* 2006 July 15; **214**:99–108.
15. 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 Jul 1; **214**(1):43–54. Epub 2006 Jan 27.
16. Koch M, Trapp R. Ethyl mercury poisoning during a protein A immunoadsorption treatment. *Am J Kidney Dis*. 2006 Feb; **47**(2):e31–4. Review.
17. Cohly HH, Panja A. Immunological findings in autism. *Int Rev Neurobiol*. 2005; **71**:317–41. Review.
18. Yel L, Brown LE, Su K, Gollapudi S, Gupta S. Thimerosal induces neuronal cell apoptosis by causing cytochrome c and apoptosis-inducing factor release from mitochondria. *Int J Mol Med*. 2005 Dec; **16**(6):971–7.
19. 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.
20. Havarinasab S, Hultman P. Organic mercury compounds and autoimmunity. *Autoimmun Rev*. 2005 Jun; **4**(5):270–5. Epub 2005 Jan 5.
21. Marn-Pernat A, Buturoviá-Ponikvar J, Logar M, Horvat M, Ponikvar R. Increased ethyl mercury load in protein A immunoadsorption. *Ther Apher Dial*. 2005 Jun; **9**(3):254–7.
22. Mádi A. Being on the track of Thimerosal. *Review. Acta Microbiol Immunol Hung*. 2005; **52**(1):95–103. Review. PMID: 15957237
23. Humphrey ML, Cole MP, Pendergrass JC, Kiningham KK. Mitochondrial mediated Thimerosal-induced apoptosis in a human neuroblastoma cell line (SK-N-SH). *Neurotoxicology* 2005 Jun; **26**(3):407–16.
24. Parran DK, Barker A, Ehrich M. Effects of Thimerosal on NGF signal transduction and cell death in neuroblastoma cells. *Toxicol Sci*. 2005 Jul; **86**(1):132–40. Epub 2005 Apr 20.
25. Havarinasab S, Häggqvist B, Björn E, Pollard KM, Hultman P. Immunosuppressive and autoimmune effects of Thimerosal in mice. *Toxicol Appl Pharmacol*. 2005 Apr 15; **204**(2):109–21.
26. James SJ, Slikker W 3rd, Melnyk S, New E, Pogribna M, Jernigan S. Thimerosal neurotoxicity is associated with glutathione depletion: protection with glutathione precursors. *Neurotoxicology* 2005 Jan; **26**(1):1–8.
27. 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.

With respect to the oft-stated claim, “*They have looked at the same data as other scientists,*” the Geiers actually examined different data sets or, *in a few cases,* similar data sets – not the same data.

Moreover, the Geiers’ studies have found that the level of Thimerosal exposure from vaccines “*does correlate with autism*” and/or other common neurodevelopmental disorders (e.g., tics).

For example, the previous search found seven (7) recent peer-reviewed publications:

1. Geier DA, Sykes LK, Geier MR. A review of Thimerosal (merthiolate) and its ethylmercury breakdown product: specific historical considerations regarding safety and effectiveness. *J Toxicol Environ Health B Crit Rev*. 2007 Dec.; **10**(8):575–96.

2. Geier DA, Geier MR. A case series of children with apparent mercury toxic encephalopathies manifesting with clinical symptoms of regressive autistic disorders. *J Toxicol Environ Health A*. 2007 May 15; **70**(10):837–51.
3. Geier DA, Geier MR. A prospective study of Thimerosal-containing Rho(D)-immune globulin administration as a risk factor for autistic disorders. *J Matern Fetal Neonatal Med*. 2007 May; **20**(5):385–90.
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Thus, more than finding that there is a statistically significant correlation between the level of Thimerosal exposure and certain neurodevelopmental disorders, including autism (**see:** articles “3,” “5,” “6,” and “7”), the Geiers have conducted case studies (**see:** articles “2” and “4”) that have proven that some groups of children with a diagnosed autism spectrum disorder are mercury poisoned (where the principal bolus-dose exposures to mercury were from Thimerosal-containing vaccines given to these children indirectly *in utero* and/or directly beginning just after they were born).

Furthermore, they have published a comprehensive review (**see:** article “1”) of the available historical literature, *scientific and otherwise*, which clearly establishes the *knowing* mercury poisoning of developing children by the healthcare establishment through Thimerosal-containing vaccines and other drugs containing a preservative level of Thimerosal or another organic mercury compound.

Finally, though many of the cited “*consensus*” studies failed to find statistically significant evidence of a Thimerosal-autism link at a “by chance” probability value of less than 0.05, they did find some statistical evidence of this link and, in those papers, the researchers found a statistically significant or near statistically significant Thimerosal-tics link that agreed with the “tics” findings reported by the Geiers’ papers.

Taken together, when the overwhelming majority of epidemiological studies have statistical correlations in the same direction, as is the case for the Thimerosal-autism link, then this collective finding greatly exceeds the expectations of chance and confirms that there is strong epidemiological evidence of a Thimerosal-autism link.

This is the case because, if there were no link, about half of the studies should have found a near-zero or negative “dose” correlation and not the consensus of “dose” positive correlations reported by almost all of the pertinent studies.

**Wakefield/Geier's research myth #5:** Peer-reviewers have criticized the Geiers' methods and declared them fatally flawed, thus rendering their conclusions invalid or uninterpretable (Parker 2004).

**Reality:** The cited study, *Parker 2004*, simply adds to the unsubstantiated allegations used by the 2004 Institute of Medicine's (IOM's) CDC-paid committee to reject the Geiers' early epidemiological papers by nitpicking at the details of:

- The approaches the Geiers used to evaluate the data, and
- The data that was or, *in many cases*, was not published in the Geiers' paper –

without consulting with the Geiers' to see if the questioned information was available.

Moreover, Parker *et al.* failed to note that the approaches the Geiers were using were the same approaches, or approaches similar, to the epidemiological and ecological study practices used by the CDC.

Thus, this paper, *published in September of 2004*, by Parker *et al.* was written to give substance to the unsupported allegations that the CDC's tool, the IOM committee, had used early in 2004 to reject the Geiers' papers because, *unlike those papers this IOM committee chose to include in their review*, the Geiers' studies found statistically significant causal links between Thimerosal exposure and autism (or other neurodevelopmental disorders) in developing children.

Moreover, none of the few valid criticisms raised in Parker could have had the effect of reducing the significance of the causal linkages that the Geiers reported.

To their credit, *rather than attacking the Parker et al. article*, the Geiers simply responded by furnishing additional study-design information as well as the data values, to the extent they were able,<sup>39</sup> in their publications.

The result appears to be that these criticisms have not been raised for the Geiers' subsequent published studies.

Moreover, since these articles were published in rigorously peer-reviewed journals, it is clear that unbiased peer-reviewers supported the Geiers' methods and conclusions.

Therefore, the reality is that these pre-publication peer-reviewers had examined the Geiers methods and their conclusions and found both to be scientifically sound and appropriate for publication.

Thus, it is obvious that criticism of the Geiers' published articles are simply an attack on the outcomes because their findings are at odds with the healthcare establishment's unsubstantiated views.

**Wakefield/Geier's research myth #6:** The Geiers (like Wakefield) have made something of a career out of testifying for lawyers and families claiming that vaccines caused their child's autism, even though the Geiers' testimony is often excluded on the basis that they lack the proper expertise (Goldacre 2007).

<sup>39</sup> Federal officials had given the Geiers with confidential data on the number of vaccine doses for a significant period of time with the understanding that they would not publish them. Since the CDC authors in Parker *et al.* (2004) knew that this was the case, the questioning of the denominators was, *at best*, inappropriate.

The Geiers were not even called as experts in the Autism Omnibus hearings.

**Reality:** The Geiers have not made a career out of testifying in autism cases because

- Too few legal autism cases have been brought to any court, vaccine or other, for any expert to make something of a career out of testifying in such cases,
- Only Dr. Mark R. Geier, and not David A Geier, could have been called to testify as a causation expert, and
- In most cases, Dr. Geier has declined to be the lawyers' expert.

Since, in general, only Dr. Geier testifies in vaccine injury cases and the source "*(Goldacre 2007)*" is an editorial piece in a U.K. newspaper, this unsupported allegation should be ignored.

Moreover, while some vaccine court presiding administrators and some federal court judges have rejected Dr. Geier's testifying as a qualified expert, most vaccine-court administrators (special masters) and federal and state judges have recognized Dr. Geier as an expert in vaccine cases dealing with damage from the DPT, MMR and some other vaccines in most cases when he was an expert for the petitioners.

In addition, Dr. Geier is a distinguished medical practitioner, geneticist, epidemiologist and researcher with impeccable credentials (**see Appendix A**).

Similarly, David A. Geier, *Dr. Geier's son*, is a recognized research scientist and medical historian (**see Appendix B**).

Factually, Dr. Geier was *not* called as an expert witness in the three test cases where the theory of causation is "Thimerosal exposure with, or followed by, the MMR vaccine."

Since the Geiers have only two peer-reviewed publications where the live-virus measles/mumps/rubella vaccine was addressed,<sup>40</sup> understandably other experts were chosen to testify in the first three test cases.

However, because the cases for the other two theories of causation, "Thimerosal exposure causes" and "MMR exposure causes," have not yet been considered by the Vaccine court's special masters and the list of experts for the "Thimerosal exposure causes" theory of causation has not yet been finalized, it remains to be seen whether or not Dr. Geier will be scheduled to testify as an expert in other than the *conceded Poling* case – though it is clear he probably will be testifying in other autism cases where the developing child has also been proven to be mercury poisoned.

**Wakefield/Geier's research myth #7:** The Geiers are now undertaking an ethically suspect study in which they are administering chelation therapy to children with autism in conjunction with powerful hormonal therapy allegedly designed to reduce testosterone levels."

**Reality:** Here, the statement begins by impugning the ethics of the Geiers with an unsupported claim that the "*Geiers are now undertaking an ethically suspect study.*"

<sup>40</sup> Geier DA, Geier MR. A comparative evaluation of the effects of MMR immunization and mercury doses from Thimerosal-containing childhood vaccines on the population prevalence of autism. *Med Sci Monit.* 2004; **10**:PI33–9

### **Chelation Therapy**

With respect to the Geiers' "administering chelation therapy to children with autism," the facts are that the Geiers are giving medically appropriate "chelation therapy to children" who have been proven to be mercury poisoned (by either chelation challenge or, better, by a valid urine porphyrin profile analysis [UPPA] test) and have an autism spectrum diagnosis.

Whenever children are found to be mercury poisoned, chelation therapy is the medically recognized treatment regimen to reduce the mercury level in these children until the residual level is "safe" (where the proven safe level of mercury in humans is close to zero (0) because no safe level has been established).

Thus, the Geiers' administration of chelation therapy is clearly both ethical and medically indicated.

### **Hormonal Therapy**

Factually, the Geiers are using proven androgen-suppressing therapies to treat some children with an autism diagnosis who have, *by clinical testing*, been found to have abnormally elevated androgen levels in their blood.

Medically, these children have recognized endocrine conditions that are labeled as "precocious puberty" and/or "hyperandrogyny."

Accurately, *when they are properly prescribed, given, and monitored*, these androgen-suppressing therapies have been found to be effective in reducing the over-production of androgens, including testosterone, in children.

Thus, the only truth in this misconception's phrasing, "*in conjunction with powerful hormonal therapy allegedly designed to reduce testosterone levels*," is that some of the Geiers' patients, who have been found to: **a**) be mercury poisoned and **b**) have abnormally elevated androgen levels, are concomitantly treated for both these abnormal conditions, as they should be.

**Wakefield/Geier's research myth #8:** Chelation therapy removes mercury, and so it is dependent upon the mercury hypothesis, which is all but disproved.

**Reality:** The chelation therapy used by the Geiers typically employs DMSA (meso-2,3-Dimercaptosuccinic Acid, Sodium salt) in oral capsules and/or anal suppositories or DMPS (2,3-Dimercapto-1-propanesulfonic Acid, Sodium salt) in anal suppositories to remove mercury from their mercury-poisoned patients.

Thus, the chelation therapy offered by the Geiers is offered independent of the actual causal theory "Thimerosal exposure is causally linked to neurodevelopmental disorders, including the autism spectrum disorders," because this chelation therapy would be offered to any of the Geiers' patients who:

- Have been shown to be mercury poisoned by appropriate testing and
- Do not have any contraindications (e.g., mercury-amalgam dental filings) that must be addressed before initiating any solid-dosage-form DMSA-based or DMPS-based chelation therapy to remove stored mercury from their bodies.

So the statement "... *mercury hypothesis, which is all but disproved*" appears to be Orwellian in which the opposite of the truth is again presented as the truth.

**Wakefield/Geier's research myth #9:** There is no clinical evidence for the efficacy of chelation therapy. Such treatment is far from benign and is even associated with occasional deaths (Brown 2006).

**Reality:** Based on a review of peer-reviewed publications, "*the efficacy of chelation therapy*" has long been recognized.<sup>41</sup>

The most aggressive chelation treatment that the Geiers use, intermittent oral capsules and/or anal suppositories of DMSA or DMPS with interlaced replacement of the beneficial minerals that the administered chelating compound removes, is benign and has not been associated with any deaths caused by this treatment approach.

Furthermore, the reference given in this misrepresentation, "(Brown 2006)" ["Brown MJ, Willis T, Omalu B, Leiker R. 2006. Deaths resulting from hypocalcemia after administration of edetate disodium: 2003-2005. *Pediatrics*. 118(2): e534-36"], is for a wrongful death case where the *wrong form* of a *different* chelating agent, "edetate disodium", was administered to the patient, and an *unapproved* administration procedure, push IV chelation, was used to deliver this chelating agent.

In this case, the death was caused by medical negligence and *not* by chelation per se.

Thus, the reality is that there is clinical evidence of the efficacy of the chelation therapy used by the Geiers and no evidence that the chelation therapy used by the Geiers has been "*occasional deaths*."

**Wakefield/Geier's research myth #10:** With respect to the transient decline in autism rates reported in Geier, D.A., and M.R. Geier. 2006. An assessment of downward trends in neurodevelopmental disorders in the United States following removal of Thimerosal from childhood vaccines. *Medical Science Monitor* 12(6):CR231-9. Epub 2006 May 29, the Geiers simply reinterpreted the data using bad statistics to create the illusion of a downward trend where none exists.

**Reality:** To substantiate this statement, independent researchers would have to request the raw data from the Geiers, find errors in it, and/or reanalyze the published data the Geiers used, and find a different result.

Apparently, no one has done this.

Moreover, the peer reviewers, who did review "Geier, D.A., and M.R. Geier. 2006. An assessment of downward trends in neurodevelopmental disorders in the United States following removal of Thimerosal from childhood vaccines. *Medical Science Monitor* 12(6): CR231-9. Epub 2006 May 29" for the journal, having no issues with the data or the standard statistical procedures used in its analysis, recommended the article be published.

Finally, visually, the graphs provided for the data used appear to show a decline and apparently have plotted the data points appropriately.

<sup>41</sup> See, for example: H.V. Aposhian, "Biological Chelation: 2,3-Dimercaptopropanesulfonic Acid and Meso-Dimercaptosuccinic Acid" in *Adv. Enzyme Reg.* 20, G. Weber, Ed. (Permagon Press, Oxford, 1982).



Based on all of the preceding facts, there is no truth to this myth/misconception.

## Conclusion

The propaganda dispensed by Public health care and vaccine apologists is, *at best*, a weak attempt to rationalize the health-care establishment's positions using all the tools of doublespeak to: (a) mislead, (b) distort reality, (c) pretend to communicate, (d) make the bad seem good, (e) avoid and/or shift responsibility, (f) make the negative appear positive, (g) create a false ver-

bal map of the world, and (h) create dissonance between reality and what their narrative said or did *not* say.

Vaccine apologists, health officials, child healthcare providers, government officials and vaccine makers, who (*in the face of conclusive case studies and human toxicological evaluations showing sub-acute mercury poisoning from Thimerosal*) are continuing to misrepresent: 1) the knowing failure of all these parties to keep their 1999 promise to *remove* Thimerosal from all vaccines, and 2) the maximum total amount of vaccine-derived Thimerosal which a child born today may receive from conception to the age 18 years.

## APPENDICES

Appendix	Title
A	Curriculum Vitae of Mark R. Geier, MD, PhD, ABMG, DABFM, FACE
B	Curriculum Vitae of David A. Geier, BA
C	Curriculum Vitae of Andrew J. Wakefield, MB, BS, FRCS, FRCPath

### Appendix A. Curriculum Vitae of Mark R. Geier, MD, PhD, ABMG, DABFM, FACE

**Full Name:** Mark Robin Geier

#### Education

1970	B.S. George Washington University, Washington, D.C.
1970-1971	Graduate Student Department of Human Genetics and Development, Columbia University, New York, NY
1973	Ph.D. Genetics, George Washington University, Washington, D.C.
1978	M.D. George Washington University, Washington, D.C.

#### Work Experience

1969-1970	Research (Student) at the National Institutes for Health, Bethesda, MD
1970-1971	NIH Traineeship at Columbia University, Department of Human Genetics and Development, New York, NY
1971-1973	Research Geneticist, Laboratory of General and Comparative Biochemistry, NIMH, NIH, Bethesda, MD
1973-1974	Staff Fellow, Laboratory of General and Comparative Biochemistry, NIMH, NIH, Bethesda, MD
1974-1978	On Professional Staff Laboratory of General and Comparative Biochemistry NIMH, NIH, Bethesda, MD
1978-1979	Intern and Fellow, Department of Obstetrics and Gynecology, the Johns Hopkins Hospital, Baltimore, MD
1979-1982	Assistant Professor, Department of Gynecology and Obstetrics, the Johns Hopkins School of Medicine, Baltimore, MD
1980-1982	Guest worker Laboratory of General and Comparative Biochemistry, NIMH, NIH, Bethesda, MD
1981-1984	Assistant Research Professor, Psychiatry Department, Uniformed School of the Health Sciences, Bethesda, MD
1988-1994	Director of Genetics of Maryland Medical Laboratory, Inc. Baltimore, MD
1989-1994	Member of the Substance Abuse and Doping Committee and the Sports Medicine and Science Committee of the United States Bobsled and Skeleton Federation (Olympic Committee)

#### Other Training

2002-2003	Foundation for Advanced Education in the Sciences, National Institutes of Health, Bethesda, MD
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#### Courses:

- Emerging Infections: A Global Threat to Human Health
- Vaccines 2002

#### State Licensures

- Maryland, September 1979-Present
- Virginia, October 1992-Present

#### Board Certifications

- American Board of Medical Genetics (ABMG), 1987-Present
- Associate Member of the American College of Medical Genetics, 1993-Present
- Board Certified by the American Board of Forensic Examiners, 1996-Present
- Diplomate of the American Board of Forensic Medicine (DABFM), 1996-Present
- Fellow of the American College of Epidemiology (FACE), 2007

#### Other Positions

1980-2003	Laboratory Director Molecular Medicine, MD
1980-Present	Co-director of Genetic Consultants, Bethesda, MD
1981-Present	Director of Institute of Immuno-Oncology and Genetics, MD
1986-Present	President of Genetic Counseling and Research, Inc., T/A The Genetic Center, Baltimore, MD
1997-Present	President of Genetic Counseling and Research, Inc. T/A The Ultrasound Institute of Baltimore
1997-Present	President of the Genetic Centers of America
2001	Host of one-hour weekly medical talk show "The Dr. Mark Geier Show" on KFNX in Phoenix, Arizona, WALE in Provident, Rhode Island, and on the World Wide Web.

**Journal Peer-Reviewer for**

- *Vaccine*
- *Expert Review of Vaccines*
- *Expert Opinion on Emerging Drugs*
- *Clinical and Experimental Rheumatology*
- *Environmental Health Perspectives*
- *Annals of Internal Medicine*
- *Drug Safety*
- *Journal of Toxicology & Environmental Health, Part A*
- *European Journal of Pediatrics*
- *American Journal of Perinatology*
- *Pediatrics International*
- *International Journal of Experimental Pathology*

**Professional Societies**

- Sigma Psi
- American Association for Advancement of Science National Board of Medical Examiners, Diplomate
- American Society of Human Genetics
- Montgomery County Medical Society
- American Fertility Society
- Who's Who in America

**Major Presentations**

- Addressed United States' State Department, Foreign Service Institute (Washington, DC) on Contemporary Genetics
- Addressed the Institute of Medicine of the U.S. National Academy of Sciences (Washington, DC) on Vaccine Safety & Vaccine Policy Issues
- Addressed the Government Reform Committee of the United States' House of Representatives (Washington, DC) on Vaccine Safety Issues
- Addressed the Food and Drug Administration's Vaccine Advisory Committee (Silver Spring, MD) on Vaccine Safety Issues

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84. Geier DA, Geier MR. Neurodevelopmental disorders following Thimerosal-containing childhood immunizations: a follow-up analysis. *Int J Toxicol* 2004;23:369-376.
85. Geier MR, Geier DA. The potential importance of steroids in the treatment of autistic spectrum disorders and other disorders involving mercury toxicity. *Med Hypotheses* 2005;64:946-954.
86. Geier DA, Geier MR. A two-phased population epidemiological study

of the safety of Thimerosal-containing vaccines: a follow-up analysis. *Med Sci Monit* 2004;11(4):CR160-CR170.

87. Geier MR, Geier DA. Reply. *Clin Immunol* 2003;109:360-361.
88. Geier MR, Geier DA. Vaccine causation of selected adverse reactions: Epidemiology of the Vaccine Adverse Event Reporting System (VAERS). *Thimerosal & Vaccines* 2002;1(1):32-42.
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90. Arranga E, Geier MR, Geier DA, Small T. Interview with Dr. Mark Geier and David Geier concerning Thimerosal, testosterone, and autism treatment hypothesis. *Medical Veritas* 2005;2:465-471.
91. Geier DA, Geier MR. A case-control study of serious autoimmune adverse events following hepatitis B immunization. *Autoimmunity* 2005;38:295-301.
92. Abrams DJ, Augustyn AM, Geier MR. Prenatally diagnosed mosaic trisomy 17: a case report with two-year follow-up. *Prenat Diagn* 2005;25:968-969.
93. Geier DA, Geier MR. Early downward trends in neurodevelopmental disorders following removal of Thimerosal-containing vaccines. *J Am Phys Surg* 2006;11:8-13.
94. Geier MR, Geier DA, Small T. Interview with Dr. Mark Geier and David Geier: Decreasing trends in autism and neurodevelopmental disorders following decreasing use of Thimerosal-containing vaccines. *Medical Veritas* 2006;3:935-948.
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97. 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;66:182-188.
98. Abrams DJ, Geier MR. A comparison of patient satisfaction with telehealth and on-site consultations: a pilot study for prenatal genetic counseling. *J Genet Couns* 2006;15:199-205.
99. Geier DA, King PG, Geier MR. Influenza vaccine: review of effectiveness of the US immunization program and policy considerations. *J Am Phys Surg* 2006;11:69-74.
100. Geier DA, Geier MR. A prospective assessment of porphyrins in autistic disorders: a potential marker for heavy metal exposure. *Neurotox Res* 2006;10:57-63.
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103. Geier MR, Geier DA. The role of androgens and the methionine cycle-transsulfuration pathway in understanding and treating autism: a new paradigm. *Autoimmunity Reviews, Abstracts of 5<sup>th</sup> International Congress on Autoimmunity, Sorrento, Italy, November 29 – December 3, 2006*, pg 71.
104. Geier DA, Geier MR. A meta-analysis epidemiological assessment of neurodevelopmental disorders following vaccines administered from 1994 through 2000 in the United States. *Neuro Endocrinol Lett* 2006;27:401-413.
105. Geier DA, Geier MR. A clinical trial of combined anti-androgen and anti-heavy metal therapy in autistic disorders. *Neuro Endocrinol Lett* 2006;27:833-838.
106. Geier MR. Evolving views on the causes of autistic spectrum disorders. *Lancet Neurol* 2006;6:212. Geier DA, Sykes LK, Geier MR. A review of Thimerosal (Merthiolate) and its ethylmercury breakdown product: specific historical considerations regarding safety and effectiveness. *J Toxicol Environ Health B Crit Rev* 2007;10:575-96.
107. Geier DA, Geier MR. A case-series of children with apparent mercury toxic encephalopathies manifesting with clinical symptoms of regressive autistic disorders. *J Toxicol Environ Health A* 2007;70:837-51.
108. Geier DA, Geier MR. A prospective study of Thimerosal-containing Rho(D)-immune globulin administration as a risk factor for autistic disorders. *J Matern Fetal Neonatal Med* 2007;20:385-90.
109. Geier DA, Geier MR. A prospective study of mercury toxicity biomarkers in autistic spectrum disorders. *J Toxicol Environ Health A* 2007;70:1723-30.
110. Geier DA, Geier MR. A prospective assessment of androgen levels in patients with autistic spectrum disorders: biochemical underpinnings and suggested therapies. *Neuro Endocrinol Lett* 2007;28:565-73.

**Publication Awards**

1. Recipient of the 2003 “Stanley W. Jackson Prize” which recognizes the best article published in the last three years in the *Journal of the History of Medicine and Allied Sciences* (Published by Duke University) for my paper, “The True History of Pertussis Vaccination: A Sordid Legacy?”
2. Among the Top 10 Most Frequently Downloaded Articles for 2004 [1,988 Downloads] in the *Medical Science Monitor* for my paper, “A Comparative Evaluation of the Effects of MMR Vaccination and Mercury Doses from Thimerosal-Containing Childhood Vaccines on the Population Prevalence of Autism.

**Appendix B. Curriculum Vitae of David A. Geier, BA**

<b>Full Name:</b>	David Allen Geier	1995-1998	High School Diploma with Highest Honors, The Bullis School, Potomac, MD
<b>Education</b>		<b>Science Employment</b>	
2003-2006	Graduate Student in Biochemistry, The George Washington University, Washington, DC	1998	Summer Employee at The National Institutes of Health in The Laboratory of Biochemical Genetics (June-September)
2002-2003	Graduate Student, National Institutes of Health Graduate School Program, Bethesda, MD	1999-Present	President of MedCon, Inc. Medical-Legal Consulting & Biochemical-Epidemiological Research
1998-2002	B.A. Biology, Minor History, with Honors from The University of Maryland, Baltimore County (UMBC), Catonsville, MD, an Honors College	2006-Present	Vice-President of the Institute of Chronic Illnesses, Inc. A 501(c)(3) Foundation dedicated to study-

- ing chronic diseases
- 2007-Present Vice-President of CoMeD, Inc.  
A non-profit group dedicated to advocating for those adversely impacted by environmental and medicinal toxins, and to studying environmental and medicinal toxins
- Other Employment**
- 1999-2001 Staff Writer of The University of Maryland, Baltimore County Retriever Weekly Newspaper
- Additional Training**
- 1999-2001 Journalism Internship at The Retriever Weekly Newspaper of The University of Maryland, Baltimore County
- 2002-Present CDC/ATSDR Training and Continuing Education Courses; Credits Earned:
- “Vaccine Safety Post Marketing Surveillance: The Vaccine Adverse Event Reporting System” (1.25 Category-I CME Credits; 5 November 2002)
- 2002 Health-Stream/Education-Design Continuing Education Courses; Credits Earned:
- “Anaphylaxis: Diagnosis & Management” (1.0 Category-I CME Credits; 8 January 2003)
- 2002-2003 The Foundation for Advanced Education in the Sciences, Inc.; Graduate Credits Earned:
- “Basic Principles of Immunology and Hypersensitivity” (Fall 2002, 2 Credits, Dr. John Finerty; 32 Category-I CME Credits)
  - “Introduction to Epidemiology” (Fall 2002, 3 Credits, Dr. Paul Sorlie; 40 Category-I CME Credits)
  - “Statistical Methods in Epidemiology” (Spring 2003, 3 Credits, Dr. H.M. James Hung; 40 Category-I CME Credits)
  - “Emerging Infections: A Global Threat to Human Health” (Spring 2003, 2 Credits, Dr. John Hall)
- 2003 (Mar) University of Miami Institutional Review Board Online Courses; Credits Earned:
- “Human Subject Research Training Course” (Completed All Modules and Final Examination)
- 2004 (Apr) Kaiser Permanente North-West, Research Subjects Protection Office Online Courses; Credits Earned:
- “Training in Bioethics and Human Subjects Research” (Completed All Modules and Final Examination)
- Scientific Research Experience**
- 1998 (Summer) I. T. R. A. Summer Fellow Appointment at The National Institutes of Mental Health (under Laboratory Chief Dr. Carl Merrill of The Laboratory of Biochemical Genetics); Project: Protein Gel and Phage Research
- 1999 (Summer) Researcher at Molecular Medical Medicine, Inc.; Project: Epidemiologic Analysis of Prenatal-Genetic Screens
- 1999-Present) Researcher at Medcon, Inc.; Projects:
- Epidemiologic analysis of The Vaccine Adverse Events Reporting System (VAERS) & Vaccine Safety Datalink (VSD) to Determine the Correlation Between Vaccines and Adverse Events
  - Molecular Biochemical Evaluation of the Content of Commercial Biologicals for Endotoxin, Mercury Concentrations, sterility, etc.
- Professional Societies**
- American Association for the Advancement of the Sciences
- Grants and Awards**
- 1998 Recipient of “The National Student-Athlete Day Award” from The National Consortium for Athletics and Academics and The National Collegiate Athletic Association
- 1998 Recipient of “The Advanced Placement Scholar Award” from The National Advance Placement Board
- 1998-2002 Recipient of The University of Maryland, Baltimore County “President’s Scholars Full Academic Scholarship”
- 1999 Recipient of “The Outstanding Academic Performance Award” from the Golden Key National Honor Society
- 2003 Recipient of “Stanley W. Jackson Prize” which recognizes the best article published in the last three years in the *Journal of the History of Medicine and Allied Sciences* (Published by Duke University) for my paper, “The True History of Pertussis Vaccination: A Sordid Legacy?”
- Honors**
- 1999 Selected to the National Dean’s List for College Students
- 1999 Selected to the Honors College at the University of Maryland, Baltimore County
- 2001 Selected to the Golden Key International Collegiate Honor Society
- 2001 Selected an All-American Scholar by the United States Achievement Academy
- 2001 Spring Semester Academic Honors at UMBC
- 2002 Selected to the 2000 Outstanding Scholars of the 21<sup>st</sup> Century
- 2002 Selected to Marquis Who’s Who in the World, 19<sup>th</sup> Edition
- 2004 Among the Top 10 Most Frequently Downloaded Articles for 2004 [1,988 Downloads] in the *Medical Science Monitor* for my paper, “A Comparative Evaluation

tion of the Effects of MMR Vaccination and Mercury Doses from Thimerosal-Containing Childhood Vaccines on the Population Prevalence of Autism”

### Significant Talks and Presentations

- 2002 (May 21) Co-Addressed the Food and Drug Administration’s Vaccines and Related Biological Products Advisory Committee (Rockville, Maryland) about “Lyme Vaccine Safety”
- 2002 (Jul 19) Co-Addressed the National Academies of Science’s Christine Mirzayan Science and Technology Policy Internship Seminar (Washington, DC), “Prenatal Genetic Testing and Disabilities: A Medical Miracle or Eugenics in Disguise?”
- 2002 (Dec 10) Co-Submitted Materials to the United States House of Representatives Committee on Government Reform (Washington, DC) hearing on “Vaccines and the Autism Epidemic: Reviewing the Federal Government’s Track Record and Charting a Course for the Future,” about “Vaccines & Neurodevelopmental Delays: An Assessment of the Vaccine Adverse Event Reporting System (VAERS) Database & Other Studies”
- 2004 (Feb 9) Co-Addressed the National Academies of Science’s Institute of Medicine Committee on Immunization Safety (Washington, DC), “Neurodevelopmental Disorders Following Thimerosal-Containing Childhood Vaccines”
- 2004 (Aug 23) Co-Addressed the National Academies of Science’s Institute of Medicine Committee on Review of the National Immunization Program’s (NIP’s) Research Procedures and Data Sharing Program (Washington, DC), “Researcher’s Experience with the VSD Data Sharing Program”

### Original Peer-Reviewed Scientific/Medical Publications

- Geier DA, Geier MR. Rubella vaccine and arthritic adverse reactions: An analysis of the Vaccine Adverse Events Reporting System (VAERS) database from 1991 through 1998. *Clin Exp Rheumatol* 2001;19:724-6.
- Geier MR, Geier DA. Hepatitis B vaccination safety. *Ann Pharmacother* 2002;36:370-4.
- Geier DA, Geier MR. An analysis of the occurrence of convulsions and death after childhood vaccination. *Toxicology Mechanisms & Methods* 2002;12:71-8.
- Geier DA, Geier MR. Anthrax vaccination and joint related adverse reactions in light of biological warfare scenarios. *Clin Exp Rheumatol* 2002;20:217-20.
- Geier DA, Geier MR. Clinical implications of endotoxin concentrations in vaccines. *Ann Pharmacother* 2002;36:776-80.
- Geier DA, Geier MR. Hepatitis B vaccination and adult associated gastrointestinal reactions: A follow-up analysis. *Hepatogastroenterology* 2002;49:1571-5.
- Geier DA, Geier MR. An analysis of the reactivity of vaccines administered in the state of Texas from 1991 through 1999. *Tex Med* 2002;98:50-4.
- Geier MR, Geier DA. The state of polio vaccination in the world today:

The case for continuing routine vaccination. *Toxicology Mechanisms & Methods* 2002;12:221-8.

- Geier DA, Geier MR. The VAERS and CDC Reportable Disease databases are new tools for those in vaccine-related forensic medicine. A case in point: Adult hepatitis B vaccine. *The Forensic Examiner* 2002;11(7-8):21-9.
- Geier DA, Geier MR. Lyme vaccination safety. *Journal of Spirochetal and Tick-borne Diseases* 2002;9:16-22.
- Geier DA, Geier MR. Serious neurological conditions following pertussis immunization: An analysis of endotoxin levels, the Vaccine Adverse Events Reporting System (VAERS) database and literature review. *Pediatr Rehabil* 2002;5:177-82.
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- Geier MR, Geier DA. Neurodevelopmental disorders following Thimerosal-containing vaccines: a brief communication. *Exp Biol Med* 2003;228:660-4.
- Geier MR, Geier DA. Thimerosal in childhood vaccines, neurodevelopment disorders, and heart disease in the United States. *J Am Phys Surg* 2003;8(1):6-11.
- Geier MR, Geier DA, Zahalsky AC. Influenza vaccination and Guillain Barre Syndrome. *Clin Immunol* 2003;107:116-21.
- Geier MR, Geier DA, Zahalsky AC. A review of hepatitis B vaccination. *Expert Opin Drug Safety* 2003;2:113-22.
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- Geier MR, Geier DA. Gastrointestinal adverse reactions following anthrax vaccination: An analysis of the Vaccine Adverse Events Reporting System (VAERS) database. *Hepatogastroenterology* 2004;51:762-7.
- Geier DA, Geier MR. A comparative evaluation of the effects of MMR vaccination and mercury doses from Thimerosal-containing childhood vaccines on the population prevalence of autism. *Med Sci Monit* 2004;10(3):PI33-9.
- Geier DA, Geier MR. A review of the Vaccine Adverse Event Reporting System database. *Exp Opin Pharmacother* 2004;5:691-8.
- Geier DA, Geier MR. A case-series of adverse events, positive-rechallenge of symptoms and, events in identical twins following hepatitis B vaccination: An analysis of the Vaccine Adverse Event Reporting System (VAERS) database and literature review. *Clin Exp Rheumatol* 2004;22:749-55.
- Geier DA, Geier MR. Neurodevelopmental disorders following Thimerosal-containing childhood immunizations: A follow-up analysis. *Int J Toxicol* 2004;23:369-76.
- Geier DA, Geier MR. A two-phased epidemiological study of the safety of Thimerosal-containing vaccines: A follow-up analysis. *Med Sci Monit* 2005;11(4):CR160-170.
- Geier DA, Geier MR. A case-control study of serious autoimmune adverse events following hepatitis B immunization. *Autoimmunity* 2005;38:295-301.
- Geier DA, Geier MR. Early downward trends in neurodevelopmental disorders following removal of Thimerosal-containing vaccines. *J Am Phys Surg* 2006;11:8-13.
- 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;69:1481-1495.

31. 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;12:CR231-CR239.
32. 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;66:182-188.
33. Geier DA, Geier MR. A prospective assessment of porphyrins in autistic disorders: a potential marker for heavy metal exposure. *Neurotox Res* 2006;10:57-64.
34. Geier DA, King PG, Geier MR. Influenza vaccine: a review of the effectiveness of the US immunization program and policy considerations. *J Am Phys Surg* 2006;11:69-74.
35. Geier DA, Geier MR. A meta-analysis epidemiological assessment of neurodevelopmental disorders following vaccines administered from 1994 through 2000 in the United States. *Neuro Endocrinol Lett* 2006;27:401-13.
36. Geier DA, Geier MR. A clinical trial of combined anti-androgen and anti-heavy metal therapy in autistic disorders. *Neuro Endocrinol Lett* 2006;27:833-8.
37. Geier DA, Geier MR. A case-series of children with apparent mercury toxic encephalopathies manifesting with clinical symptoms of regressive autistic disorders. *J Toxicol Environ Health A* 2007;70:837-51.
38. Geier DA, Geier MR. A prospective study of Thimerosal-containing Rho(D)-immune globulin administration as a risk factor for autistic disorders. *J Matern Fetal Neonatal Med* 2007;20:385-90.
39. Geier DA, Geier MR. A prospective study of mercury toxicity biomarkers in autistic spectrum disorders. *J Toxicol Environ Health A* 2007;70:1723-30.
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### Medical Hypotheses

1. Geier MR, Geier DA. The potential importance of steroids in the treatment of autistic spectrum disorders and other disorders involving mercury toxicity. *Med Hypotheses* 2005;64:946-55.

### Research Letters, Abstracts, and Letter to the Editors/Commentary Publications

1. Geier MR, Geier DA. Arthritic reactions following hepatitis B vaccination: An analysis of the Vaccine Adverse Events Reporting System (VAERS) data from 1990 through 1997. *Clin Exp Rheumatol* 2000;18:789-90.
2. Geier MR, Geier DA. Hepatitis B vaccine and gastroenterological adverse reactions. *Hepatogastroenterology* 2001;48(37).
3. Geier MR, Geier DA. Immunological reactions and hepatitis B vaccine. *Ann Intern Med* 2001;134:1155.
4. Geier DA, Geier MR. Hepatitis B vaccination and arthritic adverse reactions: A follow-up analysis of the Vaccine Adverse Events Reporting System (VAERS) Database. *Clin Exp Rheumatol* 2002;20:119.
5. Geier DA, Geier MR. Smallpox and Anthrax in the United States. *Emerging Drugs & Devices* 2002;7(8):27-31.
6. Geier MR, Geier DA. Vaccine causation of selected adverse reactions: Epidemiology of the Vaccine Adverse Event Reporting System (VAERS). *Thimerosal & Vaccines* 2002;1(1):32-42.
7. Geier DA, Geier MR. Cutaneous immunological reactions to hepatitis B virus vaccine. *Ann Intern Med* 2002;136:780-1.
8. Geier DA, Geier MR. Reply: Hepatitis B vaccine safety. *Ann Pharmacother* 2002;36:1649-50.
9. Geier MR, Geier DA. Reply: Clinical implications of endotoxin concentrations in vaccines. *Ann Pharmacother* 2002;36:1650-1.
10. Geier DA, Geier MR. Chronic adverse reactions associated with hepatitis

B vaccination. *Ann Pharmacother* 2002;36:1970-1.

11. Geier DA, Geier MR. Response to comments by J. R. Mann. *Exp Biol Med* 2003;228:933-4.
12. Geier MR, Geier DA. Response to critics on the adverse effects of Thimerosal in childhood vaccines. *J Am Phys Surg* 2003;8:68-70.
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15. Geier MR, Geier DA. Study misses link between Thimerosal and neurodevelopmental disorders. *Pediatrics* 2004; Published P<sup>3</sup>R Letter to the Editor.
16. Geier MR, Geier DA. Parents' worries about Thimerosal in vaccines are well founded. *Pediatrics* 2004; Published P<sup>3</sup>R Letter to the Editor.
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21. Geier MR, Geier DA. The role of androgens and the methionine cycle-transsulfuration pathway in understanding and treating autism: a new paradigm. *Autoimmunity Reviews, Abstracts of 5<sup>th</sup> International Congress on Autoimmunity, Sorrento, Italy, November 29 – December 3, 2006*, pg 71.

### Conference/Meeting Proceedings - Scientific Publications

1. Geier DA, Geier MR. Lyme vaccination and arthritic conditions in the US adult population: An analysis of the Vaccine Adverse Events Reporting System (VAERS) database from December 1998 through October 2000. *15<sup>th</sup> International Scientific Conference on Lyme Disease and Other Tick-Borne Disorders Handbook*, 6-7 April 2002.
2. Geier MR, Geier DA. Epidemiology of the Vaccine Adverse Event Reporting System (VAERS): Proof of causation in various cases. *Mealey's Publications LexisNexis Vaccine Conference Handbook*, 18-19 March 2002.
3. Geier MR, Geier DA. An epidemiological assessment of the association between Thimerosal concentrations in vaccines and neurodevelopmental disorders in children. *Mealey's Publications LexisNexis Thimerosal in Vaccines Conference Handbook*, 3 December 2002.
4. Geier DA, Geier MR. Vaccines & neurodevelopmental delays: An assessment of the Vaccine Adverse Event Reporting System (VAERS) database & other studies. *The United States House of Representatives Committee on Government Reform hearing on "Vaccines and the Autism Epidemic: Reviewing the Federal Government's Track Record and Charting a Course for the Future," Congressional Record*, 10 December 2002.
5. Geier DA, Geier MR. Neurodevelopmental disorders following Thimerosal-containing childhood vaccines. *Fall DAN! 2004 Conference Handbook*, Los Angeles, CA, 1-3 October 2004, pgs 95-107.

### Medical/Science Consensus Papers

1. Adams JB, Baker SM, Binstock T, Bock K, Borriss M, Cave S, Deth R, Edelson SM, Freedfeld S, Geier DA, Geier MR, Goldblatt A, Green J, Haley BE, Hardy PM, James SJ, Levinson A, Lonsdale D, McCandless J, McDonnell MH, Megson M, Mumper E, Neubrandner J, O'Hara N, Peirsel P, Quig D, Redwood L, Rimland B, Schneider C, Underwood LW, Usman A, Vojdani A. Treatment options for mercury/metal toxicity in autism and related developmental disabilities: consensus position paper. *San Diego, CA: Autism Research Institute, 2005*, pp. 1-42.

### History Publications

1. Geier DA, Geier MR. The true story of pertussis vaccination: A sordid legacy? *J Hist Med Allied Sci* 2002;57:249–84.
2. Geier MR, Geier DA. Disease. *Colonization and Settlement (1608-1760)*. Editor Nash G. B., Facts on File, Inc., Encyclopedia of American History 2003;2:90–3.

### Appendix C. Curriculum Vitae of Andrew J. Wakefield, MB, BS, FRCS, FRCPath

Dr. Wakefield currently serves as Executive Director, Thoughtful House Center for Children, Austin Texas, 78746. He received his medical education at St. Mary's Hospital Medical School, London (1976-1981) and his MB BS degree from the University of London (1981). Dr. Wakefield completed primary and final fellowship at the Royal College of Surgeons (London) during 1983 and 1985, respectively. He completed a fellowship of the Royal College of Pathologists (U.K.) in 2001.

Dr. Wakefield is the recipient of the 1987 Toronto General Hospital Resident's Research Prize, the 1988 First Prize from the Basic Science, Mount Sinai Hospital Department of Medicine (Toronto), the 1992-3 SMART I Award and 1993-4 SMART II Award for Research and Technology from the Department of Trade and Industry, and the 2000 NVIC Courage in Science Award.

Dr. Wakefield has been a reviewer to the following scientific journals: *Lancet*, *American Journal of Gastroenterology*, *Gastroenterology*, *Gut*, *Digestive Diseases and Science*, *European Journal of Gastroenterology and Hepatology*, *Alimentary Pharmacology and Therapeutics*.

#### Appointments

1. House Surgeon to Mr. D. C. Britton, Royal United Hospitals, Bath, Avon, Aug 1981 - Feb 1982.
2. House Physician to Dr. J. G. Walker, Dr. R. Elkeles, Dr. C. Coulter and Professor Wickramasinghe, St. Mary's Hospital, London, W2, Feb 1982 - Aug 1982.
3. Two-year appointment to St. George's Hospital, General Surgical Senior House Officer Rotation Casualty Officer, St. George's Hospital, Tooting (Mr. A. Barker), Aug 1982 - Feb 1983.
4. The Royal Marsden Hospital, Sutton. Mr. J-C Gazet, Mr. N Breech, Dr. J. Ford, Dr. J. Glees, Feb 1983 - Aug 1983.
5. Frimley Park Hospital, Surrey. Mr. A. H. Amery, Mr. H. Hills, Mr. K. P. R. Rutter, Mr. M. J. Solan, Mr. R. C. Lallemand, Aug 1983 - Aug 1984
6. Two-year appointment to Queen Mary's University Hospital, Roehampton, Surgical Registrar Rotation:
  - a. Registrar to Mr. R. A. D. Booth, General and Colorectal surgery, Sep 1984 - May 1985
  - b. Registrar to Mr. K. P. Robinson, General and Vascular surgery, May 1985 - Jan 1986
  - c. Registrar to Mr. J. McLean-Singleton, General and Urological surgery, Jan 1986 - Apr 1986
7. Appointment to St. George's Hospital, Tooting, Surgical Registrar Rotation
  - a. Registrar to Miss E. M. Gordon, Paediatric surgery, Apr 1986 - Nov 1986
8. Appointment as Wellcome Research Fellow to the Surgical Unit, Toronto General Hospital and the Faculty of Medicine of the University of Toronto, Toronto, Ontario, Canada: Dr. Z. Cohen and Professor B. Langer, Nov 1986 - Nov 1988
9. Appointment as Wellcome Research Fellow, Royal Free School of Medicine, Nov 1988 – Sept 1990

10. Senior Lecturer in Experimental Gastroenterology, Departments of Medicine & Histopathology, Oct. 1990–Sept. 1997.
11. Reader in Experimental Gastroenterology, Department of Medicine & Histopathology, Oct. 1997–Nov. 2001, Royal Free & University College Medical School, London.
  - a. Honorary Consultant in Experimental Gastroenterology to Royal Free Hampstead NHS Trust, London.
  - b. Director of Research and Chairman, Inflammatory Bowel Disease Study Group, RFHSM.
12. Senior Medical Adviser to the UK registered Charity VISCERAL, Dec 2001–Dec. 2004.
13. Executive Director, Thoughtful House Center for Children, Austin Texas, Dec. 2004–Present .

#### Honors, Scholarships and Awards

1. Wellcome Trust Travelling Fellowship, 1986-9
2. Runcorn Travelling Scholarship, Westminster Medical School Research Trust, 1986
3. AMI Travelling Scholarship, Royal College of Surgeons, England, 1986
4. Ethicon Foundation Scholarship, Ethicon; Foundation Fund, Royal College of Surgeons, England, 1986
5. Anglo-Canadian Scientific Exchange Scholarship, The Royal Society and the Natural Sciences and Engineering Research Council, Canada, 1986-1987
6. Wellcome Trust Travelling Fellowship, The Wellcome Trust, London, 1986-1989
7. Curie Foundation Travelling Scholarship, 1989
8. Three year extension of Wellcome Trust Fellowship, 1990-1993
9. Membre D'Honneur Etranger de la Societem, Royal Belge de Gastro-Enterologie, 1995
10. Fellow of the Royal Collage of Pathologists, 2001

#### Research and Development Interests

1. The Inflammatory Bowel Disease Study Group
2. The role of microvascular injury in the pathogenesis of inflammatory bowel disease.
3. The role of the gut in childhood developmental disorders

#### Publications

- [1] Mant TG, Lewis JL, Mattoo TK, Rigden SP, Volans GN, House IM, Wakefield AJ, Cole RS. Mercury poisoning after disc-battery ingestion. *Hum Toxicol.* 1987;6:179–81.
- [2] Silverman R, Cohen Z, Craig M, Wakefield A, Kim P, Langer B, Levy G. Monocyte/macrophage procoagulant activity (PCA) as a measure of immune responsiveness in Lewis and Brown Norway inbred rats: discordance with lymphocyte proliferative assays. *Transplantation* 1989; 47: 542–8.
- [3] Wakefield AJ, Gordon EM. A huge renal cyst presenting in childhood. Case report and review of the literature. *J R Soc Med.* 1989; 82: 443–5.
- [4] Wakefield AJ, Cohen Z, Kim P, Craig M, Levy G. The reversal of cyclosporine mediated suppression of alloantigen induced monocyte procoagulant activity by H<sub>2</sub> antagonists cimetidine and ranitidine in vitro. *Transplantation Proceedings* 1989; 21: 844–7.



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- [10] Wakefield AJ, Cohen Z, Levy GA. Procoagulant activity in *Gastroenterology* 1990; 31:239–42.
- [11] Sawyerr AM, Wakefield AJ, Hudson M, Dhillon AP, Pounder RE. The pharmacological implications of leucocyte-endothelial cell interactions in Crohn's disease. *Alimentary Pharmacology & Therapeutics* 1990; 1:1–14.
- [12] Wakefield AJ, Dhillon AP, Sawyerr AM, Sankey E, More L, Sim R, Pittilo RM, Rowles PM, Hudson M, Lewis AAM, Pounder RE. Granulomatous vasculitis in Crohn's disease. *Gastroenterology* 1991; 100:1279–87.
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