

Monday, 31 March 2008

To All:

The text following this page is an updated review of the excerpted text from an article in the November 1, 2007 issue of the ***Skeptical Inquirer*** that was written by Steven Novella, MD.

The excerpted text of the article, titled, “**Vaccines and Autism: Myths and Misconceptions,**” was located and then downloaded on 21 November 2007 from:

<http://www.encyclopedia.com/doc/1G1-170731919.html>

The formal review, which is titled “**A Review of the Doublespeak in: ‘Vaccines and Autism: Myths and Misconceptions,**” begins on the next page.

## Introductory Remarks

First, *to simplify this review*, the statements in the article by the writer, Steven Novella, MD, will be quoted in a “Times New Roman” font.

Second, remarks by this reviewer, Paul G. King, PhD, will be presented in indented text following each of the writer’s quoted remarks.

In addition, this reviewer’s remarks will be in a **dark blue** “News Gothic MT” font except when he quotes: **a)** from or refers to any federal statute or regulation, the text will be in a “Lydian” font and **b)** from other sources, the quotations will be in an “Arial” font.

When this reviewer quotes from statements made in the writer’s column, this reviewer will use an *italicized “Times New Roman”* font.

Finally, should anyone find any significant factual error for which they have published substantiating documents, please submit that information to this reviewer so that this reviewer can improve his understanding of factual reality and appropriately revise his views and the final review.

With these things in mind, this review of “**Vaccines and Autism: Myths and Misconceptions,**” begins on the next page.

Respectfully,

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## An Updated Review of the Doublespeak in: “Vaccines and Autism: Myths and Misconceptions”

Before beginning this updated review, this reviewer must thank Dr. Novella for the inputs that triggered this update.

“The anti-vaccination movement: despite the growing scientific consensus that vaccines are safe and that neither vaccines nor mercury cause autism, a stubborn vocal minority claims otherwise, threatening the effectiveness of this public health program. (VACCINES & AUTISM: Myths and Misconceptions)(Clinical report)

From: *Skeptical Inquirer* | Date: 11/1/2007 | Author: Novella, Steven”

This reviewer notes the writer begins with: “*The anti-vaccination movement:*” a beginning that assigns an incorrect label (the writer’s “*anti-vaccination*”) to a supposedly large dynamic group (the writer’s “*movement*”).

Yet, the writer’s next statement comes closer to the truth when, *in the context of the Establishment*, he casts the group as “*a stubborn vocal minority*” – those who are pro-vaccine safety and, therefore, opposed to the use of Thimerosal on vaccines.

However, *as any unbiased review of all the recent peer-reviewed toxicological, case, and reviewable epidemiological studies published since 2000 shows*, the writer’s “*despite the growing scientific consensus that vaccines are safe and that neither vaccines nor mercury cause autism, ...*” is Orwellian newspeak that presents the opposite of the truth as truth.

With respect to the writer’s:

“*..., a stubborn vocal minority claims otherwise, threatening the effectiveness of this public health program,*”

how can the claims of any minority, *vocal or otherwise*, threaten the effectiveness of the vaccination program?

Finally, this reviewer observes that the article speaks of the views of “*scientific consensus*” rather than of scientific evidence *apparently* because even the writer knows that the growing body of scientific fact has established and supports the factual reality that vaccines and mercury can and do, *in many instances*, cause the neurodevelopmental harm that generates the set of symptoms used to diagnose autism.

“Michelle Cedillo has autism, which her parents believe is the result of her childhood vaccines.”

While the writer’s statement may be what “*her parents believe,*” the article fails to state that the parents also think that their daughter’s severe autism was potentiated by the preservative levels (100 ppm) of Thimerosal (49.6-weight-percent [wt.-%] mercury) in her early childhood vaccines and triggered by the live-virus MMR vaccine given to her.

Thus, the Cedillo case is a “Thimerosal-MMR” test case in the “Autism Omnibus.”

“In June 2007 they had the opportunity, along with eight other families, to make their case to the Autism Omnibus--a U.S. Court of Federal Claims that was presided over by three “special masters” appointed for the purpose.

Here, the article is mistaken because only the Cedillos had an opportunity to “*make their case*” in June of 2007

Since June 2007, the cases of the other two “Thimerosal-MMR” cases from the “*eight other families*” have been heard and one of the Thimerosal cases, ***Poling v. Sec. Health and Human Services (HHS)*** [case #: 02-1466V] has been conceded in the family’s favor.

Factually, the Secretary of HHS conceded the “vaccine [Thimerosal]-autism” claim and denied the “vaccine-seizures” claim in the ***Poling*** case, one of the 3 originally scheduled “Thimerosal causes autism” Autism Omnibus test cases, on November 9, 2007.

In this “Thimerosal-autism” case, 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).

Moreover, this concession clearly reveals the dishonesty of the continual media spin coming from public health officials and others who maintain there is no proof that Thimerosal, or any other part of any vaccine, has ever caused autism or, according to some, no proof that Thimerosal in vaccines has harmed anyone in any way.

Finally, this decision is historic since it the first of 354-plus “Decided,” “Autism” cases that has been found to be compensable in the federal administrative vaccine dispute resolution system; the prior “354,” “Decided,” “Autism” cases were dismissed.<sup>1</sup>

“These nine cases are the first test cases that 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.”

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 those vaccine-injury cases where the petitioners can establish that their neurodevelopmentally damaged child has received vaccines that contain Thimerosal (49.55 weight-% mercury) and was mercury poisoned (by a valid urine porphyrin-profile-analysis [UPPA] test, chelation challenge, or other means), ***Poling*** has clearly shown that the federal government has implicitly conceded that injecting Thimerosal-preserved vaccines into children can mercury poison some to the point that their brain’s function is damaged and they develop a neurodevelopmental disorder that manifests as an ASD rather than have the full case presented in the vaccine court.

“Vaccines are one of the most successful programs in modern health care, reducing, and in some cases even eliminating, serious infectious diseases.

This reviewer understands that the vaccination programs for vaccines developed in the late 1800s and the early 1900s for highly infectious and/or deadly diseases (e.g.,

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<sup>1</sup> [http://www.hrsa.gov/vaccinecompensation/statistics\\_report.htm](http://www.hrsa.gov/vaccinecompensation/statistics_report.htm) **Table II** “Adjudications,” last updated 4 Feb. 2008; last visited 27 Feb. 2008.

the vaccines for smallpox, rabies, diphtheria, tetanus, polio, measles, and rubella) 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, were this reviewer to be bitten by a possibly rabid animal, he would immediately begin the vaccination series for rabies.

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 of months (even though some severe adverse outcomes do not begin to emerge until several 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 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).

"Public support for the vaccination program remains strong, especially in the United States where vaccination rates are currently at an all-time high of >95 percent (CDC 2004)."

First, this reviewer does not dispute the writer's "*vaccination rates are currently at an all-time high of >95 percent (CDC 2004).*"

However, this reviewer understands that one cannot accurately assess the "*(p)ublic 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 wish to do so.

"Yet, 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."

Here, this reviewer only notes that the writer is stating his and the vaccine apologists' biased view of the truth that: "*vaccines have always had their critics.*"

Moreover, 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 outweigh the theoretical benefits from widespread vaccination with those vaccines (e.g.:

- The hepatitis B vaccines [which, *as given*, 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],
- Influenza vaccines [which are not effective],
- The chickenpox vaccine [which appears to cause more harm long-term than it prevents disease and currently appears to have a reported efficacy that is less than 75%],
- Rotavirus vaccines, *including the withdrawn one*, [which give 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] and
- The HPV vaccines [which 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]).

In addition, this reviewer opposes any vaccine formulation that contains any level of Thimerosal (49.55 wt.-% mercury), 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)]).

Thus, this reviewer is a critic 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 underascertainment-corrected costs of the harm these vaccines cause are included in the cost calculations.

However, this reviewer is neither anti-vaccine nor a part of the writer's perceived "*anti-vaccination movement*."

"In recent years, the anti-vaccination movement, largely based on poor science and fear-mongering, has become more vocal and even hostile (Hughes 2007)."

Here, the writer is again using prejudicial terms (e.g., "*anti-vaccination movement*") that have been fabricated to paint the legitimate criticism of some vaccines in a less than favorable light.

Moreover, the phrases that he is using here in this article (and that his fellow vaccine apologists use [e.g., the cited article: "(Hughes 2007)"]: "*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.

"[ILLUSTRATIONS OMITTED]"

Of course, vaccines are not without risk (no medical intervention is), although the benefits far outweigh those risks."

Here, the writer starts with a general truth, "*Of course, vaccines are not without risk (no medical intervention is)*," but then links it to a *purposely* vague generalization that the article cannot, and does not even attempt to, factually substantiate, "*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 Lyme-disease vaccine, the vaccines containing whole-cell pertussis lysates [the DTwP vaccines] when the purified acellular pertussis vaccines were found to be much safer [the DTaP and Dtap vaccines], to name some) clearly indicate that, *for these vaccines*, the benefits did not even outweigh the risks – much less, as *the article claims*, "*far outweigh those risks*".

"Because vaccines are somewhat compulsory in the United States--although opting out is increasingly easy--a National Vaccine Injury Compensation Program was established to streamline the process for compensation for those who are injured due to vaccines (USDOJ 2007)."

Regardless of the information provided by the reference cited, the reader should be aware that it 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,
- ❑ 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 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 NVIC 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 Autism Omnibus 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.

“It is this program to which the Cedillo and 4,800 other families are applying for compensation.”

Here, this reviewer agrees with the writer but notes that, *contrary to the contextual tone of this statement*, this is a federal program where federal law forced the Cedillos “*and 4,800 other families*” to apply.

“In the last decade, the anti-vaccine movement, which includes those who blame the MMR (mumps-measles-rubella) vaccine for autism, has largely merged with those who warn that mercury toxicity is the cause of many of the ills that plague mankind.”

First, this reviewer again notes that there is no “*anti-vaccine movement*.”

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-vaccine movement*.”

Replacing this none-existent “*movement*” with the writer’s earlier, more accurate descriptor, “*stubborn vocal minority*,” the article should have stated:

*“In the last decade, the’ stubborn vocal minority, ‘which includes those who blame the MMR (mumps-measles-rubella) vaccine for autism, has largely merged with those who warn that mercury toxicity is the cause of many of the ills that plague mankind.”*

Since this revised statement fairly expresses the general perceptions of most vaccine apologists, this reviewer would have accepted this modified statement as a valid expression of the writer’s views.

“The two groups have come together over the issue of thimerosal, a mercury-based preservative in some vaccines.”

While this reviewer agrees that, *in the U.S.*, the “*two groups have come together*” this reviewer finds that the union of these two groups mainly encompasses the reality that the use of Thimerosal as a preservative in vaccine formulations and in other drugs without the legally mandated proof of safety to the applicable standard minimum of “*sufficiently nontoxic ...*,” *a clear current good manufacturing practice (CGMP) requirement for preservatives*, renders all such vaccines and other drugs adulterated under 21 U.S.C. Sec. 351(a)(2)(B), illegal to be introduced or delivered into commerce under 21 U.S.C. Sec. 331. Prohibited acts, and renders the vaccine makers and the products subject who introduce or deliver such into commerce to the legal sanctions set forth in 21 U.S.C. Sec. 333. Penalties.

“They believe that it was the use of thimerosal in childhood vaccines that led to the apparent autism epidemic beginning in the 1990s.”

First, this reviewer finds that the writer has misstated the evidence-based knowledge of this group as “*beliefs*.”

As a vocal member of this group, this review knows that this article has misstated the knowledge of this group.

Factually, this group understands that the use of Thimerosal (in vaccines, serums and

some other drugs) and phenyl mercuric salts or other mercury compound in some serums and other drugs are collectively a major causal factor in childhood behavioral and developmental disorders, *including 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 type-II diabetes) or rare (an ASD, where reported incidence rate estimates were on the order of 1 – 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 – 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 1980s – though, given the writer’s “*beginning in the 1990s*,” the healthcare establishment may have missed these epidemic increases until the 1990s.

“Autism is a complex neurological disorder that typically manifests in the first few years of life and primarily involves a deficiency of typical social skills and behavior.”

*Though the article is being too simplistic here*, this reviewer agrees that “autism” is a complex disorder that is defined by a set of abnormal behaviors and social-skill deficits that are mistakenly thought to be solely neurological impairments.

“In the 1990's, the number of autism diagnoses significantly increased, from between one and three to about fifteen cases per ten thousand, although the true incidence is probably between thirty and sixty per ten thousand (Rutter 2005).”

This reviewer only agrees that this article’s statement here reflects the information reported by Rutter in 2005.

“During this same period, the number of vaccines given in the routine childhood schedule also increased.”

Here, the article 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.

“This led some to assume, or at least speculate, causation from correlation--perhaps the vaccines or something in them created this ‘epidemic’ of autism.”

Here, the article is being both simplistic and ignoring:

- 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, and
- The correspondence between the symptoms of sub-acute mercury poisoning and the symptoms exhibited by children in the autism spectrum

– issues addressed, *in detail*, in this reviewer’s evaluation<sup>2</sup> of the writer’s 2005 article, “FEAR NOT Vaccinations don’t give children autism. They save children from disease.”

“We can now say, from multiple independent lines of evidence, that vaccines do not cause autism.”

Here, the writer is *knowingly* misrepresenting factual reality.

Rather than rehash the realities that establish the writer is mistaken in his beliefs, this reviewer simply asks the writer, as well as the readers of this review, to visit the CoMeD website, <http://www.mercury-freedrugs.org/>, and read the recent articles posted there which have rebutted this writer’s views with an ever-growing body of peer-reviewed published fact that contradicts the writer here.

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 the *Autism Omnibus*, even the federal government has apparently conceded that Thimerosal in vaccines may be the causal factor for an autism-spectrum-disorder diagnosis (see **Appendix A**, page: A3, item **17**, “Respondent’s Report, filed by SECRETARY OF HEALTH AND HUMAN SERVICES. (Renzi, Linda) (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),” that seeks to schedule a “status conference” to “discuss further proceedings to address damages”).

Given the preceding events as well as the test-cases petitioners’ attorneys’ having to request the Autism Omnibus 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 factor” 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 the Autism Omnibus – namely that “Thimerosal in vaccines was an 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.<sup>3</sup>

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, and 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,*

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<sup>2</sup> [http://www.mercury-freedrugs.org/docs/Thimerosal\\_Causes\\_Mercury\\_Poisoning.pdf/](http://www.mercury-freedrugs.org/docs/Thimerosal_Causes_Mercury_Poisoning.pdf/) last visited on 29 Nov. 2007.

<sup>3</sup> 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): 170-172 (a Brief Communication).

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.<sup>4</sup>

“For one thing, the autism "epidemic" probably does not represent a true increase in the disorder, but rather an artifact of expanding the diagnosis (now referred to as autism spectrum disorder, ASD) and increased surveillance (Taylor 2006).”

Here, this reviewer simply again asks the reader to reread this reviewer’s previous comment and the appropriate peer-reviewed (by thousands of readers and many scientists) articles: **a)** published in the CoMeD website, and **b)** freely available to all who are studying in this area.

“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, like those from bread and dairy that are normally broken down by the gut, to enter the bloodstream where they can access and damage the developing brain.

....

It gets worse. 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.”

First, this reviewer notes that Dr. Wakefield seems to be a competent and recognized doctor and researcher (**see Appendix D**) whose accomplishments seem to support the general validity of the findings in his published studies.

Thus, this reviewer sees no need to review the writer’s statements concerning the “MMR and Thimerosal as a joint causal factor in autism” or the “MMR as a causal factor in autism,” two of the three categories being addressed in the Autism Omnibus test cases, this reviewer finds it 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

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<sup>4</sup> 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): 971-977.  
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):407-416.  
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): 516-522.

published, and stood by, their study's findings (e.g., "he stood to personally gain from the outcome").

Interestingly, in this discussion of ethics and motives of those involved in the MMR controversy "in Great Britain," the writer does not mention, *much less address*, the reported potential British conflicts of interest among: **a**) a presiding court jurist, **b**) a management official for a British-based vaccine maker, and a **Lancet** management official, which have recently surfaced.

Further, from a scientifically sound interpretation<sup>5</sup> of the Danish epidemiological data for the introduction of the MMR vaccine and its delayed acceptance by the Danes<sup>6</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 that were diagnosed as having an ASD.

As shown in footnote 5's "**Figure 4. Prevalence of Autism in Denmark Among Individuals Aged < 15 years by Year, 1987 – 2002,**" the prevalence of Danish autism cases went from about 0.34<sub>2</sub> per 1,000 children under 15 in the period 1993 – 1994 to about 1.4<sub>6</sub> per 1,000 such children in 2000 – 2002, a "4-fold" increase.<sup>7</sup>

However, based on the two recent published<sup>8</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>9</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>10</sup>).

“[ILLUSTRATION OMITTED]

Further, during the Cedillo case testimony, 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

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<sup>5</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): 70-75.

<sup>6</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 DTP vaccine series.

<sup>7</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.

<sup>8</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>9</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/O9Feb2007PressRelease.html](http://www.safeminds.org/pressroom/press_releases/O9Feb2007PressRelease.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>10</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.

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).”

While this reviewer does not challenge the testimony of the U.S.-government-selected and -paid experts who testified in the “*Cedillo case*,” this reviewer notes that other researchers have apparently independently confirmed Wakefield’s original findings and extended them.<sup>11</sup>

However, this reviewer suggests that, *rather than arguing about the absence or presence of a causal link between the MMR vaccine and autism*, the American public would be bet

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- <sup>11</sup>
- a. Horvath K, Papadimitriou JC, Rabsztyrn A, Drachenberg C, Tildon JT. Gastrointestinal abnormalities in children with autism. *J. Pediatrics*, 1999 November; **135**(5): 559-563.
  - 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): 2285-2295
  - c. Furlano RI, Anthony A, Day R, Brown A, McGavery 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): 366-372
  - d. Ashwood P, Murch SH, Anthony A, Pellicer AA, Torrente F, Thomson M, Walker-Smith JA, Wakefield AJ. Intestinal Lymphocyte Populations in Children with Regressive Autism: Evidence for Extensive Mucosal Immunopathology. *J. Clin. Immunol.* 2003 November; **23**(6): 504-517
  - 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): 664-673.
  - 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): 979-981.
  - 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): 827-836.
  - 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): 723-729.
  - 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): 359-364.
  - 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**: 855-861.
  - 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; **3**: 796-802.

ter served by the development of a safer measles vaccine – one that, *based on VAERS reports of the harm and deaths attributed to the MMR vaccine*, harms a smaller percentage of those inoculated with it and causes the death of no child (unlike the current Merck MMR-II® vaccine).

“[ILLUSTRATION OMITTED]

All of this, plus other allegations still coming out, has caused Britain's General Medical Council to call Wakefield before its ‘Fitness to Practise’ panel for review of his alleged professional misconduct (GMC 2007).”

While this reviewer does not dispute the reality of what is happening, he cannot but note that:

- Wakefield seems to be being “scapegoated” since the MMR uptake rates were falling before the *Lancet* article was published,
- Regardless of the allegations, Dr. Wakefield should be presumed innocent until the time these allegations are proven to be the case
- Subsequent studies have confirmed Dr. Wakefield’s findings and elucidated more about the immunological factors affected by the measles virus in some children with an ASD diagnosis,
- Much of the work done in an attempt to discredit Wakefield’s original studies seems to be, *at best*, suspect and/or to be intentionally designed to minimize the risk that these post-Wakefield studies will find a significant effect, and
- The MMR-II continues to be a significant causal factor in many severe adverse vaccination events, including death.

“Believers in the MMR-autism hypothesis dismiss the findings of 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. Wakefield is unrepentant and maintains his innocence (Gorski 2007).”

Here, this reviewer simply advises the reader to ignore this writer’s shameless demagoguery.

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.

Thus, this reviewer finds that 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.

With respect to this writer's, "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," this reviewer again counsels the reader to focus on the apparent validity of Wakefield's published findings and to ignore this attack on Wakefield's alleged actions and motives until and unless they are substantiated.

Regarding the writer's, "Wakefield is unrepentant and maintains his innocence (Gorski 2007)," this reviewer simply notes that, in our system of government, Wakefield should be presumed innocent.

Thus, *lacking the requisite specific medical case evidence to refute Andrew Wakefield's findings*, this writer has again chosen to attack 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.

"With the MMR-autism hypothesis scientifically dead, attention soon shifted to thimerosal, a mercury-based preservative found in some childhood vaccines (although not the MMR vaccine)."

Here, the article is attempting to rewrite history because:

1. Factually, the "MMR-autism hypothesis" is not scientifically dead, and
2. The "Thimerosal-autism" hypothesis predates the "MMR-autism hypothesis" by decades because medical researchers and toxicologists have warned about Thimerosal's ability to cause serious neurological harm (via sub-acute mercury poisoning) since the 1930s.<sup>12</sup>

Moreover, while the current lots of Merck MMR-II may not contain Thimerosal,<sup>13</sup> this reviewer notes that: **a)** there is no prohibition for giving Thimerosal-containing vaccines at the same time as the current MMR vaccine, **b)** the federal government has continued to license and recommend the use of several U.S.-licensed Thimerosal-containing vaccines and **c)** pediatricians still administer these Thimerosal-containing vaccines as we approach 2008, 9 years after they and the vaccine industry promised to remove Thimerosal from vaccines as soon as possible.<sup>14</sup>

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<sup>12</sup> See: [http://www.mercury-free-drugs.org/docs/070824\\_CoMeDCitizenPetitionPart2.pdf](http://www.mercury-free-drugs.org/docs/070824_CoMeDCitizenPetitionPart2.pdf).

<sup>13</sup> There is evidence that, lots of MMR-II shipped prior to 2002 did contain a low level of mercury, reported as < 0.03 microgram per milliliter: [http://poisonevercure.150m.com/vaccines/package\\_inserts/package\\_inserts.htm](http://poisonevercure.150m.com/vaccines/package_inserts/package_inserts.htm) last updated in March of 2003.

<sup>14</sup> Notice to Readers: Thimerosal in Vaccines: A Joint Statement of the American Academy of Pediatrics and the Public Health Service. *MMWR* July 09, 1999 July 9; **48**(26): 563-565:

"Nevertheless, 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. ...

PHS and AAP are working collaboratively to assure that the replacement of thimerosal-containing vaccines takes place as expeditiously as possible while at the same time ensuring that our high vaccination coverage levels and their associated low disease levels throughout our entire childhood population are maintained.

The key actions being taken are

1. A formal request to manufacturers for a clear commitment and a plan to eliminate or reduce as expeditiously as possible the mercury content of their vaccines.
2. A review of pertinent data in a public workshop.
3. Expedited FDA review of manufacturers' supplements to their product license applications to eliminate or reduce the mercury content of a vaccine.
4. Provide information to clinicians and public health professionals to enable them to communicate effectively with parents and consumer groups.
5. Monitoring immunization practices, future immunization coverage, and vaccine-preventable disease levels.
6. Studies to better understand the risks and benefits of this safety assessment."

Ironically, except for continual misrepresentations regarding the removal of Thimerosal from vaccines, those who made the promise to remove Thimerosal from vaccines seem to have *intentionally* forgotten to honor this promise.

“There is little doubt, and no controversy, that mercury, the major component of thimerosal, is a powerful neurotoxin, or poison to the brain.”

Here, the article employs the tactics of understatement and misdirection.

Actually, Thimerosal, itself, is highly toxic and a proven human teratogen, mutagen, carcinogen and immune-system poison at levels below 0.01 part-per-million – levels that are more than 10,000 times lower than the 100-ppm level in most Thimerosal-preserved influenza vaccines.

Moreover, Thimerosal’s bioaccumulative metabolites<sup>15</sup> are tissue-bound “inorganic” mercury species, which have an estimated half-life of about two (2) decades in the human brain.<sup>16</sup>

From the published work of Burbacher et al. in developing baby monkeys,<sup>17</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.

“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.”

First, this reviewer notes that the article is mistaken.

Actually, 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.

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 [biocomplexed Hg<sup>2+</sup>]) have been proven to be highly toxic in short-term ( $\leq 2$  days) studies using various human tissues and cells at mercury levels in the range from  $< 0.0001$  ppm to about 0.01 ppm, and
- Recent peer-reviewed published research studies<sup>18</sup> have clear established that

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<sup>15</sup> Metabolites are the things (compounds and complexed ions) into which the body converts Thimerosal.

<sup>16</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

<sup>17</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): 1015-1021.

<sup>18</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 symptoms of regressive autistic disorders. *J Toxicol Environ Health A* 2007; **70**: 837-851.

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 Autism Omnibus, 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,

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 an autism spectrum disorder.

Moreover, a November 2007 paper<sup>19</sup> (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 epidemiology study<sup>20</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 calculational error and a less-than-appropriate choice of t-tail statistical test.

[**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 **19**, where the original researchers provided the data) as well as
- The underlying MMR and autism cases data from Denmark (**see** footnote **5**, where the data was obtained from governmental officials and not the original authors)

points to a fundamental problem with the epidemiological studies touted by this writer

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<sup>19</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): 1309-1311.

<sup>20</sup> Ip P, Wong V, Ho M, Lee J, Wong W. Mercury exposure in children with autism spectrum disorder. *J Child Neurol* 2004; **19**: 431-434.

and other vaccine apologists as evidence of “no link” between Thimerosal or MMR and neurodevelopmental disorders, including autism.

Attempts by independent researchers to obtain the underlying data sets from the original authors, *except Ip et al.*, of the epidemiological studies that support the claims of “no link” have been rebuffed so that no independent analysis can confirm the validity, or lack thereof, of the findings reported by these other studies.

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,

this reviewer would suggest that these studies 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.

“Proponents of the mercury hypothesis argue that the ethyl-mercury found in thimerosal was given in doses exceeding Environmental Protection Agency limits.”

Since 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 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), this reviewer simply notes that the article has *inadvertently* painted government officials as “[p]roponents of the mercury hypothesis.”

“This load of mercury should be considered with prenatal vaccine loads possibly given to mothers, and to other environmental sources of mercury, such as seafood.”

While this reviewer agrees that the post-natal “*load of mercury should be considered with prenatal vaccine loads*” and other mercury-containing drugs taken by the child’s mother, this reviewer again notes that the consideration should be the specific dose transferred from the mother to the fetus (which has been estimated, based on animal studies, to be about 80% of the dose given to the mother<sup>21</sup> and depends on the weight of the developing child 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 antiseptics solutions, creams, and gels until 2002].)

This reviewer shares the writer’s concern about exposure “*to other environmental sources of mercury, such as seafood.*”

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<sup>21</sup> The monitoring of mercury levels in maternal human hair during pregnancy has confirmed that the fetus absorbs mercury from the mother.

However, *except for a heavy fish eater*, this reviewer understands that fish consumption is not a major contributor because, *if it were a major factor*, then autism 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 postpartum babies 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).

Again, 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>22</sup> were withdrawn from the U.S. market in the early 1940s.<sup>23</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 widely used.

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 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.

Finally, this reviewer questions how coincidental it was 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

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<sup>22</sup> These teething powders contained up to 25% Calomel (chemically, mercurous chloride,  $\text{Hg}_2\text{Cl}_2$ ; 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>23</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.

effectiveness as an antiseptic.

In this reviewer's understanding of science, such marketing coincidences (Thimerosal in/Calomel out) are just 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 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.

"Furthermore, underweight or premature infants received a higher dose by weight than larger children."

Here, the writer is simply stating a fact: for a given dose of Thimerosal, the specific dose (the writer's "*higher dose by weight*") increases as the weight of the infant decreases.

"Some children, they argue, may have a specific inability to metabolize mercury, and perhaps these are the children who become autistic."

Here this reviewer finds the writer is being 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 drugs (e.g., acetoaminophen and many antibiotics) – children who often have some evidence of illness, like irritability, or have some other diagnosed infection (for example, an ear infection) when the Thimerosal-containing vaccines and other drugs were administered

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 problems (e.g., ADD),
- A food allergy (e.g., peanut allergy), and/or
- A food intolerance (e.g., gluten intolerance).

"Fear over thimerosal and autism was given a huge boost by journalist David Kirby with his book **Evidence of Harm** (Kirby 2005)."

As most vaccine apologists do, the writer has chosen to use the word "*Fear*" when the word "Concern" is clearly the appropriate non-prejudicial choice.

Otherwise, this reviewer agrees that journalist David Kirby's 2005 book, **Evidence of Harm**, did raise public awareness and concern about the link between Thimerosal in vaccines and autism.

"Kirby tells the cliched tale of courageous families searching for help for their sick children and facing a blind medical establishment and a federal government rife with corruption from corporate dollars. Kirby echoes the core claim that as the childhood vaccine schedule increased in the 1990s, leading to an increased cumulative dose of thimerosal, autism diagnoses skyrocketed."

Except to replace this writer's "clichéd *tale*" with "story" and his "*skyrocketed*" with "increased rapidly," this reviewer finds that the writer's review of Kirby's book is fairly accurate.

"In the end, **Evidence of Harm** is an example of terrible reporting that grossly misrepresents the science and the relevant institutions."

Here, the writer begins his attack on Kirby's book by making unsubstantiated slanders (e.g., "... *an example of terrible reporting ...*" and "...*grossly misrepresents ...*") against it.

"As bad as Kirby's position was in 2005, in the last two years the evidence has been piling up that thimerosal does not cause autism."

Here, the article simply states the opposite of the truth as if it were true.

As the preceding references clearly indicate, the unbiased evidence has been accumulating that Thimerosal-containing vaccines do cause the sub-acute mercury poisoning, which manifests as a neuroencephalopathy and produces the 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 has already conceded one of the three "Thimerosal in vaccines causes autism" test cases originally scheduled to be heard in the Autism Omnibus (see *Hannah Poling v. Sec. HHS* [02-1466V], case entries "**17**" and "**18**").

Since the government's reasons for conceding this vaccine injury case (see **Appendix E**) cite mitochondrial dysfunction, a condition for which Thimerosal is a proven causative factor (see 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 Polling received were causal factors.

"Rather than adjusting his claims to the evidence, Kirby has held fast to his claims, which has made him a hero alongside Wakefield of the mercury-autism-connection crowd as he has squandered his credibility."

This reviewer finds that the preceding statement is beneath contempt and suggests that the reader should ignore it.

"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). I have already mentioned that the current consensus holds that there is no real autism epidemic, just an artifact of how the diagnosis is made. If there's no epidemic, there's 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 concluded that the evidence does not support the conclusion that thimerosal causes autism (IOM 2004)."

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, this reviewer hopes that the reader will ignore the preceding and read and study the case-control studies 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 groups of children with a diagnosis in the autism spectrum have confirmed the role of mercury poisoning in these disorders.

“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. 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).”

Here, the article must be speaking of some alternate universe.

This is the case because, since the 2002 CDC recommendation<sup>24</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 children at birth (the initial hepatitis B shot) 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*, and
- The FDA, *by continuing to approve Sanofi-Aventis’ Thimerosal-preserved Fluzone formulation for use in children as young as 6 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>25</sup>

Since:

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<sup>24</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 ...”

<sup>25</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): 565-567.

- 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.

“In fact, autism expert Eric Fombonne testified in the Autism Omnibus hearings that Michelle Cedillo displayed early signs of autism clearly visibly on family video taken prior to her receiving the MMR vaccine (USCFC 2007).”

This reviewer again notes that Fombonne testified only that “*Michelle Cedillo displayed early signs of autism,*” and not that she could be diagnosed with autism, “*prior to her receiving the MMR vaccine (USCFC 2007).*”

“Meanwhile, evidence is accumulating that autism is largely a genetic disorder (Szatmari 2007). This by itself does not rule out an environmental factor, but it is telling that genetic research in autism has proven so fruitful.”

Again, this reviewer notes that the truth is the opposite of what the article represents it to be here.

Even the largest studies have failed to find any definitive genetic pattern that is always associated with autism.<sup>26</sup>

Moreover, this writer ignores the genetic reality that Thimerosal is a proven teratogen and mutagen that, *for decades*, has been known to induce genetic harm.<sup>27</sup>

Given the preceding realities, it may be that many of the genetic anomalies appearing today may be the result of generations of the *apparently knowing* mercury poisoning of babies – first by Calomel (in the late 1880s to the early 1940s in the U.S. and 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 acetate) in other drugs.

“Mercury alarmists, in the face of this negative evidence, have been looking for rationalizations.”

Since this reviewer and the others with which he works are research scientists and not “*Mercury alarmists,*” we know:

- The scientifically sound studies support the “Thimerosal in vaccines causes autism” hypothesis and
- The “*negative evidence*” of which the article speaks is derived from provably less-

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<sup>26</sup> For an in-depth text addressing the genetic realities associated with autism, this reviewer suggests that one study Richard Lathe’s 2006 book, **Autism, Brain, and Environment** (published by Jessica Kingsley Publishers; ISBN 1 84310 4385).

<sup>27</sup> a. Goncharuk GA. Experimental investigation of the effect of organomercury pesticides on generative functions and on progeny. *Hyg Sanit.* 1971; **36**: 40-43. [Note: Paper shows second-generation effects even though the first-generation progeny were not given any organic mercury-containing compounds – clearly showing teratogenic effects to the first-generation progeny’s reproductive systems.]  
b. Verschaeve L, Kirsch-Volders M, Susanne C, et al. Genetic damage induced by occupationally low mercury exposure. *Environ Res* 1976; **12**: 306-16.

than-sound, improperly manipulated and/or intentionally misdesigned studies.

Given the preceding realities, this reviewer and those with whom he works have no need to be “looking for rationalizations.”

Finally, this reviewer notes that the current Novella article being reviewed is, *at best*, a weak attempt to rationalize the healthcare 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 verbal map of the world, and **h)** create dissonance between reality and what the writer said or did not say.

“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).”

Again, this article presents settled factual reality as an argument and quotes a study that 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] in with the group of mothers who did receive Thimerosal-preserved Rho(D) injections as was done in the Miles 2007 paper that the writer cites to support this statement).

As with any research that lacks a sound foundation, this study has been thoroughly discredited by independent scientists.<sup>28,29</sup>

“[ILLUSTRATION OMITTED]

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.”

This paragraph is again a classic example of doublespeak where the writer asserts:

- “*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 a cherry pie make*,
- “*Multiple independent lines of evidence all point in the same direction:*” when all of the evidence the writer cites is 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 (49.55% mercury by weight) in vaccines include the set of symptoms used to diagnosis autism in children in the autism spectrum.
- “*Furthermore, true autism rates are probably static and not rising,*” when, *as all of the re*

<sup>28</sup> [http://www.safeminds.org/pressroom/pres\\_releases/Review\\_Miles\\_Takashashi\\_6-20-07.pdf](http://www.safeminds.org/pressroom/pres_releases/Review_Miles_Takashashi_6-20-07.pdf)

<sup>29</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): 385-380.

searchers in this area know, there are no “true autism rates” (i.e., autism rates that are: **a**) not biased by missing some children, **b**) by birth cohort (the year of birth), and **c**) derived from patient interviews and diagnostic work-ups – not from surveys or records’ reviews).

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).

Accurately, there are no true autism rates — only crude disjoint retrospective estimates of the autism incidence rates derived from surveys and/or the review of records.

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 using 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.

“The only researchers who are publishing data that contradicts this consensus are the father-and-son team of Mark and David Geier.”

Here, the article is simply mistaken.

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 and assigned FDA Docket # 2007P-0331, clearly show.<sup>30</sup>

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<sup>30</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>31</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 healthcare 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** : 130-145. 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): 2092-2095.
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): 109-117. 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): 1258-1261. 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): 935-941. 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. Epub 2006 Sep 24.
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): 536-539.
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): 474-482. 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): 685-692.
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): 657-666.
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.

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<sup>31</sup> <http://www.ncbi.nlm.nih.gov/sites/entrez>

16. Koch M, Trapp R. Ethyl mercury poisoning during a protein A immunoadsorption treatment. *Am J Kidney Dis.* 2006 Feb; **47**(2): e31-e34. Review.
17. Cohly HH, Panja A. Immunological findings in autism. *Int Rev Neurobiol.* 2005; **71**: 317-341. 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): 971-977.
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): 1015-1021.
20. Havarinasab S, Hultman P. Organic mercury compounds and autoimmunity. *Autoimmun Rev.* 2005 Jun; **4**(5): 270-275. 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): 254-257.
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): 407-416.
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): 132-140. 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): 109-121.
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.

“They have looked at the same data and concluded that thimerosal does correlate with autism.”

Here, the writer begins with a clever lie, “*They have looked at the same data*” when the Geiers actually examined different data sets or, in a few cases, similar data sets – not the same data – and ends with a fact, the Geiers’ studies found that the level of Thimerosal exposure from vaccines, *in the writer’s words*, “*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 December; **10**(8): 575-596.
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): 837-851.
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): 385-390.
4. 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): 837-851.

5. 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 August; **27**(4): 401-413.
6. Geier DA, Geier MR. An evaluation of the effects of thimerosal on neurodevelopmental disorders reported following DTP and Hib vaccines in comparison to DTPH vaccine in the United States. **J Toxicol Environ Health A.** 2006 Aug; **69**(15): 1481-1495.
7. Geier DA, Geier MR. A two-phased population epidemiological study of the safety of thimerosal-containing vaccines: a follow-up analysis. **Med Sci Monit.** 2005 April; **11**(4): CR160-CR170. Epub 2005 Mar 24.

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.

“However, the hammer of peer-review has come down on their methods and declared them fatally flawed, thus rendering their conclusions invalid or uninterpretable (Parker 2004).”

First this reviewer notes that “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 used by the Geiers in evaluation 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>32</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 rigorous peer-reviewed journals, it is clear that the unbiased "*hammer of peer-review*" had forged the articles into documents that the journals had no problem publishing.

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 the article's "... *has come down on their methods and declared them fatally flawed, thus rendering their conclusions invalid or uninterpretable*" is simply an attack on the outcomes because they are at odds with the healthcare establishment's unsubstantiated views

"Also, like Wakefield, their reputations are far from clean. They 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)."

First, the writer attempts to tie the reputation of the Geiers to that of Dr. Wakefield and to impugn the Geiers' reputations by stating "*their reputations are far from clean,*" where the "*far from clean*" is a doublespeak euphemism for "dirty."

The writer's next statement, "*They have made something of a career out of testifying for lawyers and families claiming that vaccines caused their child's autism*" is a brazen fabrication because:

- Too few legal cases have been brought to any court, vaccine or other, for any expert to make something of a career out of testifying,"
- 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 only Dr. Geier testifies in vaccine injury cases and the writer's source "*(Goldacre 2007)*" is an editorial piece in a U.K. newspaper where the cited on-line source is a dead link, the reader should simply ignore the article's unsupported allegation because, *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 addition, Dr. Geier is a distinguished medical practitioner, geneticist, epidemiologist and researcher with impeccable credentials (**see Appendix B**).

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

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

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<sup>32</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.

Here again, the writer distorts the truth.

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>33</sup> this reviewer understands the reason that 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 testify as an expert in other than the conceded Poling case.

“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.”

Here, the article begins by impugning the ethics of the Geiers with an unsupported claim that the “*Geiers are now undertaking an ethically suspect study.*”

### **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 who have an autism 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 “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 writer’s phrasing, “*in conjunction with powerful hormonal thera*

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<sup>33</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**: P133 –P139

py 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 abnormal these conditions, as they should be.

“Chelation therapy removes mercury, and so it is dependent upon the mercury hypothesis, which is all but disproved.”

Here, the writer begins with an approximation of the truth.

However, since the writer is addressing the chelation therapy offered to mercury-poisoned patients by the Geiers, his initial thought, “*Chelation therapy removes mercury,*” he should have opened with something like:

“The chelation therapy used by the Geiers typically employs DMSA (meso-2,3-dimercaptosuccinic acid) in oral capsules and/or anal suppositories to remove mercury from their mercury-poisoned patients.”

Thus, contrary to the writer’s assertion, 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 mercury.

Finally, the article’s “... *mercury hypothesis, which is all but disproved,*” fundamentally appears to be: knowing Orwellian newspeak in which the opposite of the truth is again presented as the truth.

“Moreover, there is no clinical evidence for the efficacy of chelation therapy.”

Since Dr. Novella is a medical doctor with access to the peer-reviewed published literature, this reviewer must conclude that this statement is *knowingly* misleading.

This is the case because “*the efficacy of chelation therapy*” has long been recognized.<sup>34</sup>

“The treatment is far from benign and is even associated with occasional deaths (Brown 2006).”

Again, the writer is simply misrepresenting reality because 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.

The reference that this writer cites, “(Brown 2006)” [“Brown, M.J., T. Willis, B. Omalu, and R. Leiker. 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 che

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<sup>34</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. (Pergamon Press, Oxford, 1982).

lating agent – the death was caused by medical negligence and not chelation.

“With the scientific evidence so solidly against the mercury hypothesis of autism, proponents maintain their belief largely through the generous application of conspiracy thinking.”

Here, *as the clinical and case evidence cited by this reviewer shows*, this article begins with a misrepresentation, “*With the scientific evidence so solidly against the mercury hypothesis of autism.*”

Compounding this distortion, the article’s writer 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, *like this writer*, 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, “Any preservative used shall be sufficiently nontoxic so that the amount present in the recommended dose of the product will not be toxic to the recipient, ...,” (21 C.F.R. Sec. 610.15(a)) before, by law, a biological product (or, by inference, any preserved drug) containing a preservative level (taken to be between 0.001% and 0.01%) of Thimerosal can be approved for use.

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, as far as this reviewer has been able to ascertain, the evidence appears to establish, *at a minimum*, collusion among the parties.

“The conspiracy claim has been made the loudest by Robert F. Kennedy Jr. in two conspiracy-mongering articles: **Deadly Immunity** published on Salon.com in 2005 (Kennedy 2005), and more recently **Attack on Mothers** (Kennedy 2007). In these articles, RFK Jr. completely misrepresents and selectively quotes the scientific evidence, dismisses inconvenient evidence as fraudulent, accuses the government, doctors, and the pharmaceutical industry of conspiring to neurologically damage America's children, and accuses scientists who are skeptical of the mercury claims of attacking the mothers of children with autism.”

Here, this reviewer notes that Robert F. Kennedy Jr. is more than capable of defending the remarks that he has made and, therefore, this reviewer leaves it to Mr.

Kennedy to answer the statements the article being reviewed made here.

“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.”

Here, the article seems to be from some alternative universe because none of the article’s assertions here are factually accurate.

Factually, in July of 1999,<sup>35</sup> the federal government issued a press release (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 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.”

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 17 January 2008) will show, and the permissible age ranges for the use of each vaccine will confirm.

Fifth, with respect to the writer’s claim, “*by 2002 no new childhood vaccines with thimerosal were being sold in the U.S.,*” this reviewer notes that 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>36</sup> at a time when all doses of the influenza vaccine approved for “healthy children aged 6–23 months.”

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

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<sup>35</sup> *Morbidity Mortality Weekly Report* 1999 July 09; **48**(26): 563-565. [Note: The original press release issued on July 7, 1999] This announcement can be found by appropriately searching <http://www.cdc.gov/mmwr/>.

<sup>36</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. [Specifically, with underlining added for emphasis: “The 2002 recommendations include five principal changes or updates, as follows: ..., influenza vaccination of healthy children aged 6–23 months is encouraged when feasible. ...”]

their second and third trimesters of their pregnancies during the influenza season, thereby knowingly 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>37</sup> clearly found that Thimerosal-preserved influenza vaccines administered 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, microcephaly, and pyloric stenosis).

Thus, no part of the article's statement is factually accurate.

“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.”

If, as this article 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 on medicine, 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.

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, this reviewer finds that 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.

“This 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.”

Since:

- Thimerosal has not been removed from all vaccines,

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<sup>37</sup> Heinonen OP, Slone D, Shapiro S. 1977. **Birth Defects And Drugs In Pregnancy.** Littleton: Publishing Sciences Group, Inc.

- 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,

all of the writer's statements here speak to some future event or to some alternative population (nation), where:

- The promise has been kept and
- 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 reviewer's assertion about the presence of Thimerosal in vaccines, this reviewer offers the following list of U.S.-licensed vaccines containing Thimerosal that are currently being distributed:

Factually, *at the end of 2007*, the 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, all who read this review will:

- Stop talking about the absence of Thimerosal in vaccines and

#### Current (March 14, 2007) FDA-Listed Vaccines That Contain Thimerosal

Vaccine	Trade Name	Manufacturer	Thimerosal Concentration <sup>1</sup>
DTaP	Tripedia	Sanofi Pasteur, Inc	≤ 0.00012%
DT	No Trade Name	Sanofi Pasteur, Inc	< 0.00012% (single dose)
		Sanofi Pasteur, Ltd	<b>0.01%</b>
Td	No Trade Name	Mass Public Health	<b>0.0033%</b>
	Decavac	Sanofi Pasteur, Inc	≤ 0.00012%
TT	No Trade Name	Sanofi Pasteur, Inc	<b>0.01%</b>
Hepatitis B	Engerix-B Pediatric/adolescent	GlaxoSmithKline Biologicals	< 0.0002 %
HepA/HepB	Twinrix	GlaxoSmithKline Biologicals	< 0.0002 %
Influenza	Fluzone	Sanofi Pasteur, Inc	<b>0.01%</b>
	Fluvirin	Novartis Vaccines and Diagnostics Ltd	<b>0.01%</b>
	Fluvirin (Preservative Free)	Novartis Vaccines and Diagnostics Ltd	< 0.0004 %
	Fluarix	GlaxoSmithKline Biologicals	< 0.0004 %
	FluLaval	ID Biomedical Corporation of Quebec	<b>0.01%</b>
	Afluria	CSL Ltd, (Approved 28 Sept. 2007) <sup>2</sup>	<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 and A/C/Y/W-135	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.

<sup>2</sup> Added by this reviewer since it was licensed after the FDA last updated Table 3 on 14 March 2008.

- 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, 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.

"In 2005, I personally interviewed David Kirby on the topic, and we both agreed that this would be a fair test of our respective positions. Also, in an e-mail to science blogger Citizen Cain, Kirby wrote, 'If the total number of 3-5 year olds in the California DDS [Department of Developmental Services] system has not declined by 2007, that would deal a severe blow to the autism-thimerosal hypothesis' (Cain 2005)."

Since the preceding is based on a false premise, the removal of Thimerosal from vaccines for the developing child (which has not been done), both of the contingent statements in this passage are non sequiturs, which should be ignored.

"Well, 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)."

As the table provided in this review shows, the truth is that Thimerosal is still in vaccines at preservative and lower levels; and these Thimerosal-containing are being indirectly (while the developing child is in utero) and directly (post partum) given to developing children, this reviewer only ask the skeptical reader 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..

To those who know the truth, this reviewer simply suggests that they ignore the non-relevant remarks made by Dr. Novella in the preceding paragraph.

"Those who argue for the link have put forth increasingly desperate notions. Kirby has argued that mercury from cremations was increasing environmental mercury toxicity and offsetting the decrease in mercury from thimerosal.":

Since 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 gets a Thimerosal-preserved flu shot, and
- Increasingly added more maximum Thimerosal exposure by:
  - Adding a 0.25-mL flu shot for infants 6 – 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 apart 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 that all children would benefit from getting 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 without banning the administration of any Thimerosal-preserved influenza vaccine to pregnant women and children,

there is no need to address these other less-direct-exposure sources here.

Moreover, Dr. Novella, you need to stop this misrepresentation and rejoin the real world where, today, Thimerosal-preserved vaccines are being *knowingly* given to U.S. children.

“The Geiers simply reinterpreted the data using bad statistics to create the illusion of a downward trend where none exists (Geier 2006).”

Since:

- Dr. Novella has not, as far as this reviewer can ascertain, asked the Geiers for the raw data, found errors in it, and/or reanalyzed the published data the Geiers used, and found a different result,
- 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 its analysis, recommended the article be published, and
- The journal obviously published this article,

this reviewer must dismiss this writer's unsupported and apparently baseless allegations.

“Robert Kennedy Jr. dodges the issue altogether by asking for more studies, despite the fact that the evidence he asks for already exists. He just doesn't like the answer. Kennedy and others also 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).”

First, the writer's declaration here simply reports unsubstantiated statements made by a Mr. Leitch, who is a resident of the U.K.

Based on this alone, this reviewer simply recommends that the readers should ignore the writer's doublespeak, gobbledygook, and distortions here.

In addition, 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, this reviewer simply notes that that is the CDC has used the same methodology to survey autism rates.

Based on the preceding reports and facts, this reviewer must conclude that the writer is being, *at best*, misleading here.

"The Autism Omnibus hearings have concluded, and while we await the decision due early next year, I am optimistic that science and reason will win the day."

Again, the writer, speaking in the first person, begins by incorrectly stating, "*The Autism Omnibus hearings have concluded,*" when all that has concluded in the Autism Omnibus are the presentations for the three test cases for the first theory of causation is "Prior or concomitant Thimerosal exposure and the MMR vaccine cause autism."

This misrepresentation is particularly egregious because one of the original three vaccine injury test cases chosen in the Autism Omnibus hearings for second theory of causation, "Thimerosal in vaccines causes autism," ***Hannah Poling v. Sec. HHS*** (vaccine-injury case no: 02-1466V) was, *as this reviewer established earlier in this review*, conceded on 9 November 2007.

"Just as shown in the 2005 Dover trial of intelligent design where the full body of scientific evidence was given a thorough airing in court and subjected to rules of evidence and the critical eyes of experienced judges, science tends to win out over nonsense. By all accounts, 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."

While this reviewer applauds the writer for his clever use of words, he is compelled to dismiss the comments here, as they have no bearing on the facts.

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).

"But the stakes are high, and not just for the 4,800 families. If the petitioners win these test cases despite the evidence, it will open the floodgates for the rest of the 4,800 petitioners."

Again, the writer's statements should be ignored, as they are obvious doublespeak.

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 – as the writer states –

*“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 – obviously obliterating the writer’s *“will open the floodgates”* analogy because no more than 50 cases a year is more of a “trickle” than a “flood.”

“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.”

First, 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 concern expressed by the writer in his first statement is, at best, misplaced.

With respect to the writer’s second statement: *“Pharmaceutical companies will be reluctant to subject themselves to the liability of selling vaccines if even the truth cannot protect them from lawsuits,”* this reviewer offers the following 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, all their assets, and
  - Then operate these vaccine makers as not-for-profit firms where the profits made 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.

On the bright side, this reviewer notes that if the federal government were to seize and operate these pharmaceutical companies, then the resulting firms would, in general, be immune to being sued by those injured or their legal representatives.

“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.”

Here, the writer again begins with a false premise – that Thimerosal is “*a necessary preservative.*”

### 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)

While the FDA regulations for some multi-dose (“*multi-shot*”) vaccines do require a preservative, 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:

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.

Therefore, the article’s, “*Anti-thimerosal hysteria therefore also threatens the health of children in poor countries,*” rhetoric lacks substance.

Furthermore, if the U.S. experience teaches us anything, 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, seems to outweigh the mitigated (by appropriate vitamin supplementation [e.g., vitamin A to ameliorate the harm from measles]) short-term harm from those children who contract these contagious childhood diseases covered by today’s vaccines.

“And of course 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.”

As this reviewer has established, 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, *like this one*, which continually misrepresent Thimerosal’s proven toxicity and/or its continuing presence in U.S. vaccines.

Thus, the writer needs to look into the mirror and see that the misleading statements and prevarications that he and others of his ilk 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 the article speaks.

“This decrease in confidence will lead, as it has before, to declining compliance and an increase in infectious disease.”

First, if there is a decline in confidence in the implied national vaccination program, then:

- Vaccine apologists who continually lie about the removal of Thimerosal from vaccines given to children from before their birth until they reach 18 years of age will only have themselves to blame, and
- **IF** there is an increase in childhood disease, **THEN**, *given today’s better medicines for treating infectious diseases*,
  1. Almost all of our children will recover and, *except for chickenpox*, 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.

“The forces of irrationality are arrayed on this issue.”

Here this reviewer agrees with this writer that the “*forces of irrationality are arrayed on this issue.*”

However, this reviewer finds that the vaccine apologists, health officials, child health-care 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 which a child born today may receive from conception to the age 18 years,

are the actual “*forces of irrationality*” of which the writer, Dr. Novella, is speaking.

“There are conspiracy theorists, well-meaning but misguided citizen groups who are becoming increasingly desperate and hostile, irresponsible journalists, and ethically compromised or incompetent scientists.”

Here again, this reviewer agrees with Dr. Novella, but this reviewer continues to point out that the persons and groups of which the writer is speaking are those continuing to defend allowing vaccines and other drugs that contain Thimerosal to be marketed without **proof of safety**.

“The science itself is complex, making it difficult for the average person to sift through all the misdirection and misinformation.”

Here, this reviewer, a simple scientist and researcher, disagrees with this writer.

Factually, when this reviewer asks 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, *as this article indicates*, is still being put out by those with an overriding interest in maintaining the status quo, including the writer of the article that is being reviewed.

“Standing against all this is simple respect for scientific integrity and the dedication to follow the evidence wherever it leads.”

As one who has an abiding respect for scientific integrity and has dedicated the past 6-plus years of his life to uncovering the truth and studying the ever-increasing evidence that Thimerosal is a major causal factor for childhood behavioral and developmental disorders, including ADHD and the autism spectrum disorders (ASDs), this reviewer accepts the validity of the sentiments expressed here.

“Right now the evidence leads to the firm conclusion that vaccines do not cause autism.”

Given the proofs of causation that this reviewer has cited and the government’s concession in *Hannah Poling v. Sec. HHS* (case #: 02-1466V), it should be obvious to the reader that the writer is again attempting to mislead the public by stating the opposite of the truth here.

What is true is that the scientifically sound mercury-poisoning “*evidence leads to the firm conclusion that*” Thimerosal-containing vaccines are a major causal factor in autism.

“Yet, if history is any guide, the myth that they do cause autism will likely endure even in the face of increasing contradictory evidence.”

Again, this writer is stating the opposite of the truth as if it were the truth.

Hopefully, the reader will:

- ❑ See through this writer’s final misleading statement and
- ❑ Understand the truth that 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.

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Steven Novella, MD, is an assistant professor of neurology at Yale University School of Medicine. He is the host of *The Skeptics' Guide to the Universe*, a weekly science podcast ([www.theskepticsguide.org](http://www.theskepticsguide.org)), author of the *NeuroLogica* blog ([www.theness.com/NeuroLogicaBlog](http://www.theness.com/NeuroLogicaBlog)), and president of the New England Skeptical Society ([www.theness.com](http://www.theness.com)).”

In addition to the information on his web site<sup>38</sup>, this reviewer is the NJ Representative for the Coalition for Mercury-free Drugs (CoMeD) [<http://www.mercury-freedrugs.org>], the current District-33 Democratic Committeeman for Township of Parsippany-Troy Hills, Morris County, NJ, a poet, Taoist philosopher and servant of Elohim.

As a scientist and student of the federal regulations and statutes governing drugs, Dr. King led CoMeD in the drafting and submission of the current in-depth “Citizen Petition,” submitted to the FDA on 24 August 2007, and posted in the FDA Public Docket in Docket #: 2007P-0331 with the title: “Ban Use of Mercury In Medicine, UNLESS Proven Toxicologically Safe to the CGMP Standard Sufficiently Nontoxic.”

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<sup>38</sup> <http://www.dr-king.com>.

## APPENDICES

<b>Appendix</b>	<b>Title</b>	<b>Pages</b>
<b>A</b>	<b>Pertinent Results from PACER All Cases Search: "Poling, Hannah" Performed on 27 November 2007</b>	<b>A1-A3</b>
<b>B</b>	<b>Curriculum Vitae of Mark R. Geier, MD, PhD, ABMG, DABFM, FACE</b>	<b>B1-B8</b>
<b>C</b>	<b>The Curriculum Vitae for David A. Geier, BA</b>	<b>C1-C7</b>
<b>D</b>	<b>The Curriculum Vitae for Andrew J. Wakefield, MB, BS, FRCS, FRCPath</b>	<b>D1-D9</b>
<b>E</b>	<b>Respondent's (Sec. HHS') Rule 4(c) Report in the Poling Case [02-1466V]</b>	<b>E1-E2</b>

# Appendix A

Pertinent Results from PACER All Cases Search: "Poling, Hannah"  
Performed on 27 November 2007

## U.S. Party/Case Index

### All Types Name Search Results

1 Total Party match for selection POLING, HANNAH for ALL COURTS  
Search Complete

Tue Nov 27 23:44:54 2007

Selections 1 through 1 (Page 1)

#### Civil Cases

Name	Court	Case No.	Filed	NOS	Closed
1 POLING, HANNAH POLING, et al v. HHS	<a href="#">cofce</a>	<a href="#">1:2002vv01466</a>	10/25/2002	469	

**1:02-vv-01466-UNJ** POLING, et al v. HHS

Unassigned, presiding

Patricia E. Campbell-Smith, referral

**Date filed:** 10/25/2002 **Date of last filing:** 11/21/2007

#### Case Summary

**Office:** COFC

**Jury Demand:**

**Nature of Suit:** 469

**Jurisdiction:** U.S. Government Defendant

**County:**

**Origin:** 1

**Filed:** 10/25/2002

**Demand:** \$0

**Cause:** 42:300 Vaccine Injury Act

**Disposition:**

**Terminated:**

**Reopened:**

**Lead Case:**

None

**Related Case:**

None

**Other Court Case:** None

**Def Custody Status:**

**Flags:** AUTISM, ECF

**US Court of Federal Claims  
United States Court of Federal Claims (COFC)  
CIVIL DOCKET FOR CASE #: 1:02-vv-01466-UNJ**

POLING, et al v. HHS  
Assigned to: Unassigned  
Referred to: Special Master Patricia E. Campbell-Smith  
Demand: \$0  
Cause: 42:300 Vaccine Injury Act

Date Filed: 10/25/2002  
Nature of Suit: 469 Injury - Other  
Jurisdiction: U.S. Government Defendant

**Petitioner**

**HANNAH POLING**  
*a minor, by her Parents and Natural  
Guardians*

represented by **Clifford John Shoemaker**  
Shoemaker and Associates  
9711 Meadowlark Road  
Vienna, VA 22182-1951  
703 281-6395  
Fax: 703 281-5807  
Email: cliff@attorneyaccess.net  
**LEAD ATTORNEY**  
**ATTORNEY TO BE NOTICED**

**Petitioner**

**TERRY POLING**  
**AND**

represented by **Clifford John Shoemaker**  
(See above for address)  
**LEAD ATTORNEY**  
**ATTORNEY TO BE NOTICED**

**Petitioner**

**JON POLING**

represented by **Clifford John Shoemaker**  
(See above for address)  
**LEAD ATTORNEY**  
**ATTORNEY TO BE NOTICED**

V.

**Respondent**

**SECRETARY OF HEALTH AND HUMAN  
SERVICES**

represented by **Gregory William Fortsch**  
U. S. Department of Justice  
Vaccine/Torts Branch, Civil Division  
P.O. Box 146  
Ben Franklin Station  
Washington, DC 20044-0146  
(202) 616-4122  
**TERMINATED: 08/13/2004**  
**LEAD ATTORNEY**  
**ATTORNEY TO BE NOTICED**

**Linda Sara Renzi**  
[same address as above]  
(202) 616-4133  
Email: linda.renzi@usdoj.gov  
**LEAD ATTORNEY**  
**ATTORNEY TO BE NOTICED**

**Lisa Ann Watts**  
[same address as above]  
(202) 616-4099  
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**LEAD ATTORNEY**  
**ATTORNEY TO BE NOTICED**

Date Filed	#	Docket Text
10/25/2002	1	PETITION by HANNAH POLING, TERRY POLING and JON POLING, FILING FEE \$150, RECEIPT #055184 (Respondent's report due 1/23/03). (FE) (Entered: 10/25/2002)
10/25/2002	2	NOTICE OF assignment to Special Master George L. Hastings Jr. . Copy to parties. (FE) (Entered: 10/25/2002)
10/25/2002		CASE assigned to Judge Unassigned. (FE) (Entered: 10/25/2002)
11/06/2002	3	NOTICE, re: Omnibus autism proceeding (signed by Special Master George L. Hastings Jr.). Copy to parties. (LTD) (Entered: 11/12/2002)
11/14/2002	4	NOTICE of Attorney Appearance for HHS by Gregory William Fortsch. Service: 11/14/02l. (LTD) (Entered: 11/18/2002)
01/21/2003	5	RESPONDENT'S REPORT. Service: 1/21/03. (LTD) (Entered: 01/25/2003)
06/02/2003	6	MOTION for appropriate relief by SECRETARY OF HEALTH AND HUMAN SERVICES.Service: 6/2/03. Response due by 6/19/2003 (jat, ) (Entered: 06/06/2003)
06/26/2003	7	ORDER re: the statutory 240-day time period for the special master's issuance of a decision in this case has expired. Petitioner may submit a notice continuing or withdrawing the petition and such notice shall be filed within 30 days. Signed by Special Master George L. Hastings. (jmm, ) (Entered: 06/29/2003)
12/29/2003	8	ORDER denying [6] Motion Appropriate Relief. The statutory 420-day time period for the special master's issuance of a decision has expired. This Notice serves as the notice required by 42 U.S.C. & 300aa-12(g)(1). Concerning the issue of a response by the petitioners to this Notice, that statute provides, at 42 U.S.C. & 300aa-21(b), that a petitioner "may submit to the United States Court of Federal Claims a notice in writing choosing to continue or to withdraw the petition" and that "[s]uch a notice shall be filed within 30 days of the provision of the notice required by section 300aa-12(g)." Signed by Special Master George L. Hastings. (tjk, ) (Entered: 01/15/2004)
08/13/2004	9	NOTICE of Appearance by Linda Sara Renzi for SECRETARY OF HEALTH AND HUMAN SERVICES. Service: 8/13/04.(tjk, ) (Entered: 08/18/2004)
12/02/2005	10	MOTION to Issue Subpoena , filed by HANNAH POLING, TERRY POLING, JON POLING. Service: 12/02/05 by hand. Response due by 12/16/2005. (tjk, ) (Entered: 12/07/2005)
12/02/2005	11	MOTION for leave to file electronically , filed by HANNAH POLING, TERRY POLING, JON POLING. Service: 12/02/05 by hand. Response due by 12/16/2005. (tjk, ) (Entered: 12/07/2005)
12/16/2005	12	ORDER granting [11] Motion for leave to file electronically Signed by Special Master George L. Hastings. (tjk, ) (Entered: 12/19/2005)
12/16/2005	<a href="#">13</a>	NOTICE of Designation of Electronic Case. (tjk, ) (Entered: 12/19/2005)
12/16/2005	14	ORDER granting [10] Motion to Issue Subpoena Signed by Special Master George L. Hastings. (tjk, ) (Entered: 12/20/2005)
01/26/2007	<a href="#">15</a>	ORDER REASSIGNING CASE: For the reasons set forth in my "Notice Regarding Reassignment," which was posted on this court's website on January 11, 2007, the above case is hereby reassigned to Special Master Patricia Campbell-Smith. Signed by Special Master Gary J. Golkiewicz. (dc1, ) (Entered: 01/26/2007)
08/31/2007	<a href="#">16</a>	NOTICE OF FILING on Compact Disc pursuant to Vaccine General Order #12 filed by TERRY POLING.Compact Disc due by 9/10/2007. (Attachments: # (1) Table of Contents)(Shoemaker, Clifford) (Entered: 08/31/2007)
09/13/2007		Compact Disc Received by the Clerk's Office re [16] Notice of Filing on Compact Disc. (tjk, ) (Entered: 09/17/2007)
11/09/2007	<a href="#">17</a>	<b>Respondent's Report, filed by SECRETARY OF HEALTH AND HUMAN SERVICES. (Renzi, Linda) (Entered: 11/09/2007)</b>
11/14/2007	<a href="#">18</a>	<b>SCHEDULING ORDER:</b> On or before 11/30/2007, the parties shall contact the undersigned's chambers and propose three dates and times for the next status <b>conference in this matter to discuss further proceedings to address damages.</b> Signed by Special Master Patricia E. Campbell-Smith. (cc2, ) (Entered: 11/14/2007)
11/21/2007	<a href="#">19</a>	NOTICE of Appearance by Lisa Ann Watts for SECRETARY OF HEALTH AND HUMAN SERVICES.. (Watts, Lisa) (Entered: 11/21/2007)

## Appendix B

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

**Full Name:** Mark Robin Geier

**Address:** 14 Redgate Court  
Silver Spring, MD 20905

**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

**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, Diplomat
- 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

#### **Publications:**

1. Merrill CR, Geier MR. The effect of freezing and DEAE-D in spheroplast assays. *Virology* 1970;42:780-2.
2. Merrill CR, Geier MR, Petricciani J. Bacterial virus gene expression in human cells. *Nature* 1971;233:398-400.
3. Geier MR, Merrill CR. Lambda phage transcription in human fibroblasts. *Virology* 1972;47:638-43.
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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.
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#### **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 C

### The Curriculum Vitae for David A. Geier, BA

**Full Name:** David Allen Geier

**Address:** 14 Redgate Ct.  
Silver Spring, MD 20905

#### **Education:**

- 2003-2006 Graduate Student in Biochemistry, The George Washington University, Washington, DC
- 2002-2003 Graduate Student, National Institutes of Health Graduate School Program, Bethesda, MD
- 1998-2002 B.A. Biology, Minor History, with Honors from The University of Maryland, Baltimore County (UMBC), Catonsville, MD, an Honors College
- 1995-1998 High School Diploma with Highest Honors, The Bullis School, Potomac, MD

#### **Science Employment:**

- 1998 Summer Employee at The National Institutes of Health in The Laboratory of Biochemical Genetics (June-September)
- 1999-Present President of MedCon, Inc.  
Medical-Legal Consulting & Biochemical-Epidemiological Research
- 2006-Present Vice-President of the Institute of Chronic Illnesses, Inc.  
A 501(c)(3) Foundation dedicated to studying 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 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:**

1. 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.
2. Geier MR, Geier DA. Hepatitis B vaccination safety. *Ann Pharmacother* 2002;36:370-4.
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### **Research Letters, Abstracts, & 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.
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  14. Geier MR, Geier DA. Mercury in vaccines and potential conflicts of interest. *Lancet* 2004;1217.
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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, Borris M, Cave S, Deth R, Edelson SM, Freedenfeld 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 D

### The Curriculum Vitae for 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**: 179-181.
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**: 542-548.
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**: 443-445.
4. Wakefield AJ, Cohen Z, Kim P, Craig M, Levy G. The reversal of cyclosporine mediated suppression of alloantigen induced monocyte procoagulant activity by H2 antagonists cimetidine and ranitidine in vitro. *Transplantation Proceedings* 1989; **21**: 844-847.
5. Kim P, Wakefield AJ, Cohen Z, Craig M, Levy G. The reversal of cyclosporine mediated suppression of monocyte procoagulant activity by H2 antagonists in the rat model of small intestinal transplantation. *Transplantation Proceedings* 1989; **21**: 2900-2902.
6. Wakefield AJ, Cohen Z, Craig M, Jeejeebhoy KN, Levy GA. The thrombogenicity of total parenteral nutrition solutions. I: Effect on induction of monocyte macrophage procoagulant activity. *Gastroenterology* 1989; **97**:1210-1219.

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9. Sinclair S, Wakefield AJ, Levy GA Fulminant hepatic failure. *Springer Seminars in Immunopathology*, (ed) Thomas HC 1990; 12:33-1245
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17. Wakefield AJ, Fox JD, Sawyerr AM, Taylor JE, Sweenie CH, Smith M, Emery V, Hudson M, Tedder RS, Pounder RE. Detection of herpesvirus DNA in the large intestine of patients with ulcerative colitis and Crohn's disease using the nested polymerase chain reaction. *J Med Virol.* 1992; 38:183-190.
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## Appendix E

### Respondent's (Sec. HHS') Rule 4(c) Report in the Poling Case [02-1466V]

(Redacted by removing medical information, with underlining added for emphasis)

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#### IN THE UNITED STATES COURT OF FEDERAL CLAIMS

#### OFFICE OF SPECIAL MASTERS

HANNAH POLING, a minor,	)	
by her Parents and Natural Guardians,	)	
TERRY POLING AND JON POLING,	)	
	)	
Petitioners,	)	
	)	
v.	)	No. 02-1466V
	)	Special Master Campbell-Smith
SECRETARY OF HEALTH AND HUMAN	)	
SERVICES,	)	
	)	
Respondent.	)	

#### RESPONDENT'S RULE 4(c) REPORT

In accordance with RCFC, Appendix B, Vaccine Rule 4(c), the Secretary of Health and Human Services submits the following response to the petition for compensation filed in this case.

#### FACTS

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**ANALYSIS**

Medical personnel at the Division of Vaccine Injury Compensation, Department of Health and Human Services (DVIC) have reviewed the facts of this case, as presented by the petition, medical records, and affidavits. After a thorough review, DVIC has concluded that compensation is appropriate in this case.

In sum, DVIC has concluded that the facts of this case meet the statutory criteria for demonstrating that the vaccinations Hannah received on July 19, 2000, significantly aggravated an underlying mitochondrial disorder, which predisposed her to deficits in cellular energy metabolism, and manifested as a regressive encephalopathy with features of autism spectrum disorder. Therefore, respondent recommends that compensation be awarded to petitioners in accordance with 42 U.S.C. § 300aa-11(c)(1)(C)(ii).

DVIC has concluded that Hannah's complex partial seizure disorder, with an onset of almost six years after her July 19, 2000 vaccinations, is not related to a vaccine-injury.

Respectfully submitted,  
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