Facility Automation Management Engineering (FAME) Systems
33 Hoffman Avenue, Lake Hiawatha, NJ 07034

Tuesday, 30 August 2005

To Whom It May Concern:

The review that follows this introductory letter is a critical assessment of the opinions expressed by Steve Novella, MD, which were published on the http://newhavenadvocate.com/gbase/News/content?oid=oid:122769 web page that I visited as a part of my research in this area on 18 August 2005.

In general, to clearly differentiate between my assessment comments and those of the author, the author's printed statements are quoted in a "Times New Roman" font followed by this reviewer's remarks in an indented "**Nimrod**" font.

In cases where there is an important spelling or grammatical error, that error is noted by using a parenthesized "sic; *correction*" text "(sic; *xxxxx*)" insertion inserted immediately after the error.

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

For those who have access to a color printer, this reviewer's comments are made in a blue color with text needing correction in **red**.

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

Respectfully,

Paul G. King

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

PS: A draft of this review was provided to Dr. Novella on 24 August 2005 and a few others. To date, neither Dr. Novella nor the others have provided any evidence-supported rebuttal to the points raise. This only review includes minor revisions to the original draft and, as an attachment, this reviewer's response to and Dr. Novella's e-mail concerning the draft.

"FEAR NOT
Vaccinations **dont (sic; don't)** give children autism. They save children from disease.
by M.D. Steven Novella - August 18, 2005"

"Before the polio vaccine, many victims ended up in an iron lung. One of the most memorable scenes in *The Big Lebowski*, the classic 1998 Coen Brothers movie starring Jeff Bridges as 'the Dude,' is when Walter Sobchak, played with overweight aplomb by John Goodman, shows up at the house of the young boy he believes stole the Dude's car. Little Larry is, it turns out, the son of one Arthur Digby Sellers, a serial writer from the early days of television who happens to have written one of Sobchak's favorite shows. But Sobchak can't exactly address Arthur, not to his face anyway, because Arthur resides at the far end of the living room in an iron lung.

To most people alive today, the iron lung is not even a distant memory" "it's a relic of history, from the days when polio swept across the country in periodic waves, leading parents to yank their children from poolsides and seashores and sequester them inside, leaving desolate beaches in their wake. It was the disease that crippled a president, though most Americans had no idea how much trouble it was for Franklin D. Roosevelt just to walk from one side of the room to another. Most terrifying of all, it was a disease that made its victims wait in terror for the final verdict: The virus would come and then leave, and only a week or two later would paralysis set in" "if, in fact, it was going to set in. Some survived polio with no lasting effects; others ended up in an iron lung.

Thanks to the good doctors Salk and Sabin, polio is practically gone in America, not a menace since the early 1950s."

First, Steven Novella, MD, let me thank you for choosing a clear example that, having a historical record that spans half a century, can be used to understand the true "benefits" and "problems" associated with this vaccine, in particular, and one of the "benefits" introduced by the "Thimerosal preserved" Diphtheria and Tetanus ("DT") vaccines that preceded the introduction of the polio vaccines.

The comments that follow are based on a recent review publication[1] by Neil Z. Miller[2], a recognized medical journalist and health advocate.

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[1] Neil Z. Miller, ***Medical Veritas* 1** (2004). 239–251, "The polio vaccine: a critical assessment of its arcane history, efficacy, and long-term health-related consequences.

[2] "Neil Z. Miller is a medical research journalist and natural health advocate. He is the author of numerous articles and books on vaccines, including ***Vaccines: Are They Really Safe and Effective?*** (updated and revised 2004); *Vaccines, Autism and Childhood Disorders* (2003); *Immunizations: The People Speak* (1996); and *Immunization Theory Versus Reality* (1995). He is a frequent guest on radio and TV talk shows, including Donahue and Montel Williams, where he is often seen and heard debating doctors and other health officials. Mr. Miller has a degree in psychology," and "is the director of the *Thinktwice Global Vaccine Institute* (www.thinktwice.com), ... Neil Miller is a health pioneer who presented documentation about vaccine safety and efficacy problems long before these concerns were made public. For example, several years ago he complained about toxic mercury being put into childhood vaccines and provided evidence linking vaccines and autism. ... Mr. Miller has publicly debated the pros and cons of mandatory vaccines with several pediatricians and other health practitioners, including the chief medical epidemiologist for the National Immunization Program at the Centers for Disease Control and Prevention (CDC). ..."

The incidence of reported clinical polio cases increased from "5.8 to 8.4" cases per 100,000 people in the 10-year period (1935-1944) before the DT vaccine was introduced to 16.8 to 24.8 in the 10-year period (1945-1954) after the DT vaccine was introduced (see Reference 1, Figure 1).
[Note: Compared to DSM "autism," with an estimated incidence rate of 300+ in 100,000, clinical polio, *at its peak*, was less that 1/10th the epidemic that "autism" is. If looked at from the stand point of all neurological disorders and behavioral problems, the current clinical mercury poisoning level of "1 in 6" or 16,000+ per 100,000 children is 650+ times the size of the clinical polio epidemic at its peak.]

Thus, the introduction of the "Thimerosal preserved" DT vaccine more than doubled the disease incidence rate for clinical polio.

This finding indicates that, whatever the benefits of the DT vaccine, it also apparently carried with it an increased risk for people to have a polio case that produced symptoms that rose to the clinical polio level.

In addition, in the year (September 1954 to August 1955) after the introduction of the mass vaccination with the polio vaccine, the number of reported polio cases INCREASED significantly over the previous year ending August 1954 – thus the original Salk polio vaccine INCREASED the disease incidence significantly instead of REDUCING it as a scientifically sound vaccine should (see Reference 1, Figure 2). [Note: To "address" this reality, in 1956, the government simply changed the diagnostic criteria for clinical polio in an apparent attempt to hide this reality.]

Based on this data, the original Salk "killed virus" polio vaccine was neither safe nor effective.

Moreover, during a period of less than 5 years in the mid-1990's, the use of a Sabin oral polio vaccine resulted in:

a. More than 13,600 documented serious adverse reactions,
b. More than 6,300 that were serious enough to require an emergency room visit, and
c. 540 reported deaths (see Ref. 1, Fig. 3).

[Note: Based on these experiences, including the polio infections in persons who supposedly were vaccinated but came into contact with the vaccinated children or their feces and then contracted polio, the U.S. switched back to the Salk vaccine.]

Based on this data, the Sabin oral "live virus" polio vaccine was/is even less "safe" than the Salk "inactivated" polio vaccine.

As shown in Reference 1's Figure 4, the polio death rate was DECREASING before the polio vaccine was introduced.

***In order to "guarantee" that the polio incidence rate would decrease*, the definition of polio was changed in 1956 (after mass vaccination with the Salk poliovirus vaccine was started) to EXCLUDE "Aseptic Meningitis" and "coxsackie virus" cases that had been previously counted as polio cases from the definition of a polio case (see Ref. 1 page 242, starting at the bottom of column 1).**

Worse, because of contamination of many lots of both types of polio vaccines with a monkey virus, SV-40, which:

a. **Is present in the monkey kidneys in which the polio vaccine was/is cultured,**
b. **Survives the Salk formaldehyde "inactivation" process,**
c. **Has been shown to "cause" cancer in humans, and**
d. **Has infected between 30 and 100 million of those vaccinated with it between 1953 and 1964 (including this reviewer),**

those infected with the SV-40 virus have a higher risk of getting cancer – just what one would NOT want from a vaccine.

Though there are many other issues that Reference 1 raises, the most interesting is that the current polio outbreaks are mutated forms of the viruses in the current polio vaccines.

Thus, the polio vaccine's behavior creates new virulent strains of the polio virus that require new vaccines that, in turn, beget even more mutated virulent polio strains – just what the makers of polio want – a never ending need for the polio vaccine.

If you want to read the whole sorry state of affairs about the polio vaccine and consider its ramifications with respect to other similar vaccines, this reviewer encourages you to read the entire article and the 100+ published references appertaining to these issues.

Based on all of the preceding, the polio vaccine is an accident waiting to happen in the U.S. – when a mutated virulent strain of polio, for which there is virtually no partial immunity from vaccination for the prior polio-virus strains, is unleashed on the public.

However, since nearly everyone is vaccinated, this reviewer suspects that the medical establishment, *unwilling to admit that, because of its tendency to mutate, the polio virus is an inherently "bad" vaccine candidate*, will probably call the outbreak some other disease – perhaps a "new" virus – should such an incident occur. [Note: The sum of the diagnoses clinical "polio" cases and the cases for those viruses split from it in 1956 is roughly a constant in the U.S. today. And the number of clinical polio cases hovers at a "close to zero" level.]

At least Dr. Novella your, "polio is practically gone in America**," indicates that you admit that the polio virus is still alive and well in America.**

"Smallpox, too, has vanished, meaning that nobody is scarred anymore in the manner of Sadie Burke, the smallpox victim from Robert Penn Warren's great 1946 novel *All the President's Men*."

Given your "polio is practically gone in America**" statement, your use of the word "**too**" in this sentence is inappropriate.**

Factually, *though still hanging around in small amounts in virus repositories and being used in the development of biological weapons and biological-weapon countermeasures*, only smallpox "has vanished."

Moreover, *though the effective weaponization of the smallpox virus might require deploying the mutated form with its vector organism, the "bed bug,"* that technology is becoming increasing available and, with the move to the use of cold-water washing that some "bed bugs" survive, is becoming an ever more viable option in America.

Finally, highly contagious and virulent strains of the related monkey pox virus, for which only older Americans (who have cross immunity from their smallpox vaccinations) have some immunity, might be the next pox virus that "breaks out" in America.

"Were it not for vaccinations, thousands, even millions, of people would still be crippled and scarred by these diseases every year; thanks to vaccines, very few are."

First of all, in developed countries there were never "millions" of people crippled by the polio virus.

Nor were "millions" scarred by the smallpox virus in recent history (1900 onwards).

Further, when we include all of those probably harmed by being infected with the SV-40 virus and the other monkey virus or their mutated forms that may have infected us, there are MILLIONS on the planet that have been damaged by contaminants in the polio vaccines that they were given (the simian [monkey] viruses, including, but not limited, to the monkey "B" virus, foamy agent virus, haemadsorption viruses, the LCM virus, arboviruses, simian cytomegalovirus (SCMV), SV-40, "SIV," and simian variants of the human echo virus, coxsackie, herpes [HHV-6, HHV-7, and HHV-8], and adenoviruses from the kidney cells used to grow the polio virus; the BSE and Bovine immunodeficiency virus [BIV] from the calf serum also used to grow the polio virus; and the respiratory syncytial virus [RSV] from the chimpanzees also used in the production of polio vaccines).

What a win for the vaccine makers, they managed to vaccinate millions with a vaccine that created many more illnesses than it "prevented" even though, *based on the evidence*,

- **the polio vaccine initially increased the polio incidence rate and**
- **much of the polio vaccine's purported success can be traced to a change in the definition of the viruses that are classified as "polio causing" in 1956 just after mass vaccination was started.**

Thus, the polio vaccine seems to be one of the most harmful "preventive drug products" foisted upon the American public under the guise that it "protects" them from getting polio.

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

All that this reviewer can agree with is that vaccines have contributed to the reduction of some "serious infectious diseases**."**

Since there are no studies that have compared the overall health of our vaccinated population with a comparable unvaccinated population, it is not possible to independently judge the "successes" of the vaccine program with respect to the health of the American public.

However, informal limited comparisons between groups, like the Amish, who do not vaccinate, and their vaccinating neighbors seem to indicate that the non-vaccinating group is healthier overall than the vaccinated group with respect to today's "neurodevelopmental disorders and behavioral problems,**" which are frequently seen in the vaccinating group, but are virtually absent in the non-vaccinating group.**

"Public support for the vaccination program remains strong, especially in the United States, where vaccination rates are currently at an all-time high of 93 percent."

Since:

- **The federal government and the vaccine companies spend millions each year to promote vaccination,**
- **The states have coercive laws that "promote" vaccination,**
- **The child healthcare professionals are paid to promote full childhood vaccination,**
- **The true risks, if any, in each vaccine, are concealed from the general public, and**
- **Absent valid information on all of the true risks associated with each vaccine, no one can truly give his or her informed consent,**

the true public "support for the vaccination program**" is as difficult to measure as the true popularity of any other dictatorial program.**

Thus, your "93 percent**" vaccination rate for the vaccination program is about as informative as the 98+ percent of the vote that "elected" dictators, like Castro, receive when they "run" for election."**

"Yet despite their 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 to be the risks."

Since, the "polio vaccine" you present as your "basis" vaccine:

- **Has a proven history of safety problems, some of which this review touches on,**
- **Lacks a long history of safety, and**
- **Has dubious effectiveness,**

it would seem that these "vaccine" critics have raised valid issues.

Issues which the "establishment" has swept under the rug and, in turn, sought to discredit these critics by impugning their understanding (your "some parents**") and/or scientific standing (your "**tiny fringe of doctors**").**

"Some fears of vaccines have a basis in truth. The polio vaccine can, on extremely rare occasion, cause polio."

Based on the actual data, the polio virus vaccines, and the mutated polio viruses arising from these vaccines, are the principal cause of all of today's polio cases.

Furthermore, giving either polio virus vaccine to people gives almost everyone who receives it a case of polio that, in the case of the "live" vaccine used in much of the developing world, is as lethal overall, if not more lethal, than the original wild polio virus strains that existed before the first vaccine.

Accurately, the "killed/inactivated" polio vaccine seldom causes polio cases that require medical intervention – perhaps that is what you meant when said, "The polio vaccine can, on extremely rare occasion, cause polio**."**

"Millions have been spared this scourge, but that's small consolation to the parents of a sick child."

This reviewer can find no data to support your contention that, with respect to the polio virus, "(m)illions have been spared this scourge**," because almost all of the world's 3 to 5 billion people have had or will have "polio" when they get vaccinated or, in some cases, at some time after being vaccinated, from being exposed to mutated vaccine-related polio viruses, but only a small percentage, on the order of 1 in a 100,000 (30 to 50 thousand) each year will develop into a clinical "polio" case.**

In medicine, the word "scourge" should be reserved for diseases that have combined severe permanent incapacitating injury and mortality rates above 15 percent of those infected.

Thus, smallpox was a "scourge" in the middle ages where modern hygiene, vaccination, good nutrition, and supportive therapies were not generally available, but not a "scourge" in the twentieth and twenty-first centuries in "developed" countries, where hygiene, good nutrition, vaccination, and supportive treatments were available.

In today's world, diseases like malaria, cholera, dysentery, and HIV/AIDS are worldwide scourges and viruses like Ebola, Marburg's, and Hanta are localized scourges, but the polio virus is neither – for most Americans, polio is a "nuisance" disease.

"Today, the flu vaccine can make people achy" "making one sick to prevent sickness."

While your statement is 'true," it fails to address the reality that the Thimerosal (49.55% mercury), used as a preservative in most of the doses of injected vaccine, at levels up to 125 micrograms per milliliter has not been proven to be safe to be used as a preservative [as required by 21 CFR 610.15(a)] where the standard for safe is clearly spelled out, "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."

Thus, in addition to making people "achy," **the up to 62.5 micrograms of Thimerosal (up to 31 micrograms of mercury) injected in a 0.5-milliliter dose of the vaccine poisons all who are injected with a Thimerosal-preserved vaccine to varying degrees.**

This is the case because*, even if the EPA's safe daily ingestion intake level* (0.1 microgram per kg of body mass per day) *were valid for injected Thimerosal*, the recipient would need to weigh more than 310 kilograms (684 pounds) before such a dose might be safe or, for children who are given a 0.25-mL dose, 155 kilograms (342 pounds).

However, considering the:

- **Recent findings of Burbacher et al (2005),**
- **Reports published by researchers who revisited the EPA's basis for the EPA's original value for the "safe" level for ingested methyl mercury compounds in fish,**
- **Fact that, for an unnecessary poison (unnecessary because there are other preservatives and sterilants that have and can be used in the manufacture of drug products, including vaccines) present in vaccines, the typical safety factors range from 1,000 to greater than 100,000 (for example, the safety factor for the residual "CYANIDE" in Prevnar™[3] exceeds 100,000), and**
- **20-plus-year half-life for the "bound inorganic mercury" (produced by the body's metabolism of Thimerosal) that accumulates in the brain**

the projected "safe" maximum daily injection level for Thimerosal mercury is on the order of "0.1 to 1 nanogram (ng) of mercury per kilogram of body weight per day."

On that basis, the maximum level of Thimerosal that is safe to be injected into a 6-month old baby (presuming a minimum weight of 2 kg [4.4 pounds] to cover "preemies") is 0.4 to 4 ng of mercury or, for a 0.25 milliliter injection, 1.6 to 16 ng of mercury per milliliter of vaccine (3.2 to 32 ng of Thimerosal per milliliter of vaccine [3.2 to 32 ppb Thimerosal].

"But the media and the internet continue spreading fears about vaccines that are both unreasonable and unproven."

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[3] Prevnar™ is a trademark name for Wyeth's "pneumococcal conjugate" vaccine.

This reviewer finds that your statement here is <u>not</u> supported by factual reality.

Factually, some in the media and the Internet are raising valid concerns about the toxicity of the Thimerosal that is present in some vaccines. [Note: In 2004, the U.S. Fifth Circuit Court of Appeals ruled that Thimerosal is not a vaccine just as "a piston is not an engine."]

If the federal court understands that Thimerosal (49.55% mercury) is not a vaccine, then, why can't you recognize the difference?

Please, Dr. Novella, tell my why.

Furthermore, based on:

- **A review of the published toxicology and biological literature on mercury poisoning, Thimerosal (49.55% mercury) and related antiseptic mercury compounds, and the ethyl mercury compounds used as seed fungicides as well as**
- **Reports from the unpublished toxicology experiments conducted by Eli Lily in 1971 (which were reported to have found cellular toxicity at levels 1/100th the "preservative" level of Thimerosal in vaccines [or 0.0001 %; 1 ppm]),**

the concerns being raised by the media and on the Internet are valid.

"In the past, false fears about vaccine safety have resulted in plummeting compliance rates, in Nigeria and Great Britain, followed, predictably, by disease outbreaks. The United States, by contrast, has proven very resilient to such fears. The reasons for this are unclear, but some believe it may be due to the fact that vaccinations here are compulsory for school attendance."

Here, this reviewer, for the most part, agrees with what you state in this passage.

However, your last statement should have concluded:

"… some believe it may be due to the fact that" **most people have been led to think that** "vaccinations here are compulsory for school attendance" **even in those states that have medical, religious, and philosophical exemptions.**

"In recent years, concern has focused on a possible link between childhood vaccines and the dreaded neurological disorder autism."

Properly, in recent years, the "establishment" and you have repeatedly tried, and are trying, to portray the concern as "a possible link between childhood vaccines and the dreaded neurological disorder autism**."**

Factually, the real concern is the toxicologically and biologically established link between:

- **The repeated injection 0.25- to 1- milliliter aliquots of 0.01%, and lower-level, Thimerosal-containing (mercury-containing) medicines into pregnant women, newborns, babies, toddlers, preschoolers,**

kids in grades "K" through "5," pre-adolescents, adolescents, young adults, adults, and the elderly, and

- **The clinical levels of mercury poisoning exhibited by some of those who have been so 'treated" – where the percentage having clinical "mercury poisoning" symptoms is "currently" estimated to exceed 15 % of the population between birth and 18 years of age – if the CDC's 2004 estimates are to be believed.**

In "simple" terms, repeatedly injecting toxic doses of a highly toxic bio-accumulative poison, Thimerosal (49.55% mercury), into humans:

- **Poisons all to some degree and**
- **At some point in their lives, poisons some of the people so injected to the point that they begin to exhibit one or more of the symptoms that are characteristic of the slow mercury poisoning of humans by sub-acute doses of an organic mercury compound (Thimerosal).**

Thimerosal (49.55% mercury) is an organic mercury compound that is easily metabolized by the human body into an intermediate metabolite that can cross all of the protective "barriers" in the human body.

Ethylmeurihydroxide, *the initial mercury-containing metabolite*, present inside each organ can be metabolized into the bio-bound "inorganic mercury" that slowly poisons the human organs in which it resides.

The "establishment" doctors can't or won't accept the preceding realities and the extensive body of scientifically sound toxicological and biological information that establishes the validity of these realities.

Valid experimental studies have clearly established that injecting the American population with toxic doses of Thimerosal (49.55% mercury), a severe poison, results in the mercury poisoning of some people so injected to the point that those people begin to exhibit symptoms – symptoms that are recognized as the known symptoms for mercury poisoning.

Unfortunately, just as the medical profession:

- **Somehow failed to "recognize" the mercury poisoning caused by the addition of Calomel [mercury(I) chloride] to baby's teething powders in the late 1800's and early 1900's as mercury poisoning and, instead,**
- **Called that mercury-laced-teething-powder mercury poisoning "Pink Disease" and/or "Acrodynia" – even though the toxicologists of the day recognized these babies were being mercury poisoned by the mercurous chloride (Calomel) in their teething powders,**
- **Ignored the fact that the clinical characteristics, listed in Table A on the next page, were the "same" as those for mercury poisoning.**

the medical profession has similarly hidden the current Thimerosal (49.55% mercury) mercury poisoning behind a plethora of "disorders,"

"syndromes" and "diseases" having no proven "cause" or "defined therapy (or treatment regimen)":

- **"Neurodevelopmental disorders" [e.g., autism, Asperger's disorder, ADHD, ADD, childhood disintegrative disorder, Rhett syndrome];**
- **"Behavioral disorders" [e.g., Childhood Bipolar Disorder, Dysthymic Disorder, Obsessive-Compulsive Disorder (OCD)];**
- **"Endocrine disorders" [e.g., Cushing syndrome, Graves' disease, Hashimoto thyroiditis, and precocious puberty];**
- **"Metabolic disorders" [e.g., lipid disorders, childhood Type II diabetes];**
- **"Digestive disorders" [e.g., irritable bowel syndrome];**
- **"Dermal disorders" [e.g., scleraderma]; and ·**
- **"Mental disorders in the aging" [e.g., Alzheimer's],**

which only came to be "prevalent" after Thimerosal dosing was increased in the late 1980's.

Table A. Clinical Characteristics of Acrodynia [A/K/A Pink Disease]

System	Characteristic
Central nervous	Irritability Extreme photophobia (patient burrows head or covers eyes to block out light)
Cardiovascular	Hypertension Tachycardia
Gastrointestinal	Stomatitis with anorexia Colitis with diarrhea or constipation Salivation
Renal	Proteinuria Nephrotic syndrome progressing to renal failure in extreme cases
Dermal	Erythema of the palms, soles, and face Edema and desquamation of the skin of hands and feet Pruritus
Muscular/Skeletal	Hypotonia
Various	Gingivitis Diaphoresis Paresthesia Generalized pain

Hopefully, you and open-minded readers, now:

- ❖ **See the parallels between the mercury poisoning of babies by the Calomel-laced teething powders rubbed on their gums and the**

mercury poisoning of us all by the Thimerosal-containing vaccines you and other healthcare providers have injected into us, and

- **Realize the enormity of the harm caused by the uninterrupted medical mercury poisoning that has been inflicted on the American people for more than a hundred years (first by Calomel in teething powders and then by the Thimerosal and other mercury compounds in our medicines).**

In any case, this genocidal mercury poisoning will continue to be inflicted upon us all UNTIL we:

- **BAN the use of all mercury compounds in all aspects of medicine and dentistry and**
- **RECALL all in-date mercury-containing medicines unless the mercury from the compound(s) in the medicine is proven to be safe:**
  - **by long-term (lifetime equivalent) toxicological studies,**
  - **in human-parallel animal models,**
  - **under worst-case dosing conditions using recognized designs, and**
  - **with a safety factor of not less than 1000, because there is no necessity for the use of a mercury compound in the manufacture of any medicine.**

"The stakes are high on both sides of this issue. If vaccines are unsafe, then millions of children are being placed at risk. The resulting injuries could have a catastrophic cost, not only in the lives they harm **but (sic; but also)** in healthcare and special services costs to an already overburdened society. Victims and their families would require and deserve compensation. Further, since the United States exports vaccines to much of the world, there are potential implications for our foreign relations."

Therefore, the current toxicological and biological studies clearly:

- **Show Thimerosal-preserved medicines, including vaccines, are unsafe**
- **Indicate, *in general*, medicines that contain more than 10 ppb[4] of a readily metabolizable organic mercury compound whose intermediate metabolites cross the various organ and cellular barriers and, once inside the organ or cells, can be metabolized to "bio-bound inorganic mercury" compounds that are toxic to normal human biochemical processes may also be unsafe – and**

[4] As previously mentioned, it has been reported that a 1971 toxicity study conducted by Eli Lilly and Company found significant short-term toxicity when the Thimerosal level in a vaccine was 1/100th the preservative level (or 1 ppm).
Using that reported "1 ppm" toxicity level and a safety factor of 100, the appropriate general factor for an unnecessary poisonous component, like Thimerosal, in a medicine that is administered infrequently (the case for vaccines), the upper limit on the Thimerosal (49.55% mercury) in vaccines should be 10 ppb (10 nanograms per milliliter or gram). [**Note:** As the dosing frequency increases, the safety factor should be increased so that, for a medicine used for a chronic life-time condition and injected daily, the appropriate safety factor might be 10,000 or even 100,000.]

- **Suggest medicines containing more than 0.1 ppm (100 ppb) mercury are also unsafe.**

Thus, the reality is, as you have projected:

- **"(M)**illions of children" **have been** "placed at risk**,**" **hundreds of thousands have been severely harmed, and hundreds have died from being mercury poisoned.**
- "The resulting injuries" "have a catastrophic cost, not only in the lives they harm but" **also** "in healthcare and special services costs to an already overburdened society."
- "Victims and their families" "require and deserve compensation."

However, your "Further, since the United States vaccine makers export vaccines to much of the world, there are potential implications for our foreign relations**" is misplaced, it is the vaccine makers, <u>not</u> the United States, who bear the liability for the harm caused by the vaccines they manufacture.**

As the U.S. Supreme Court has repeatedly ruled, the drug product manufacturer is liable for the harm that their products cause – not the government of the United States, (or the firm who only shipped the product to the customer, <u>provided</u> the shipping temperature and humidity controls were meant).

Furthermore, it is the drug manufacturers (who have directly and indirectly profited from the harm knowingly caused by those responsible individuals and firms who made these poisonous products since 1968) who should be held accountable for all of the costs of this century plus of the knowing mercury poisoning of the most vulnerable of people, our babies and children and the half century plus of the mercury poisoning of us all.

"On the other side, unwarranted fear about vaccine safety could reduce public confidence and threaten the vaccine program. A decrease in vaccine compliance would result in an increase in serious and potentially fatal infectious illnesses. Baseless class action suits against vaccine manufacturers could unfairly bankrupt companies or keep pharmaceutical companies out of the risky vaccine business, leading to potential shortages and a greater increase in preventable infections."

Since the mercury poisoning from the Thimerosal (49.55% mercury has been established by scientifically sound and appropriate toxicological and biological studies, you have no need to be overly concerned about the following:

- "On the other side, unwarranted fear about vaccine safety could reduce public confidence and threaten the vaccine program."
- "A decrease in vaccine compliance would result in an increase in serious and potentially fatal infectious illnesses."

- ❖ "Baseless class action suits against vaccine manufacturers could unfairly bankrupt companies or keep pharmaceutical companies out of the risky vaccine business, leading to potential shortages and a greater increase in preventable infections."

because decisive action by the federal government under the criminal RICO statutes coupled with transparent and open government-supervised corrective drug reformulation to remove Thimerosal (49.55% mercury) and other mercury compounds from all those manufacturing processes that use such, *including those vaccines processes that still use Thimerosal (49.55% mercury)*, could:

- ✓ **"Resolve" the problem of the continuing "mercury poisoning" of the public by medicines that contain toxic levels of some mercury compound**
- ✓ **Restore public confidence in the medicines they are given,**
- ✓ **Provide the funds needed to pay for the harm done, and**
- ✓ **"Shield" the drug manufacturers from "**class action suits**" that could "**bankrupt companies or keep pharmaceutical companies out of the risky vaccine business."

Until:

- ❖ **All of the harm done has been paid for,**
- ❖ **The directly or indirectly added severely poisonous organic mercury compounds removed from all medicines,**
- ❖ **All those who were directly or indirectly harmed compensated for their injuries,**
- ❖ **All those who were clinically mercury poisoned have recovered to as near-to-normal health as curative medicinal and educational therapies can provide,**
- ❖ **Those management personnel responsible for allowing the mercury poisoning to continue after 1968: a) have their assets seized and b) are appropriately tried for their crimes and**
- ❖ **The government recovers for the extra costs it incurred in treating and/or educating those who have been mercury poisoned,**

the federal government would:

- **Continue to operate these seized drug companies and, for public companies, pay the seized firms' shareholders the same dividend percentage of sales per share as was paid before the government's takeover,**
- **Add 40% of the remaining profits made to the government's coffers,**
- **Use 40% of the remaining profits to reduce the prices that the consumer pays for those companies' drugs, and**

- **Place the remaining 20% into a "contingency" fund to cover unexpected capital and cash-flow expenses.**

When:

- ✓ **The healthcare and injury costs have been recovered,**
- ✓ **The mercury compounds used completely removed from all manufacturing processes or, if not removed, the mercury-compounds in the medicine or preparation administered have been proven to be safe, and**
- ✓ **Those firms' policies and procedures have been irreversibly altered so that no similar lapses can occur in the future,**

the federal government could then return control of those public firms seized under RICO to their shareholders of record and the control of the private firms to their owners, if any, who were not convicted of any RICO or other federal misdemeanor or felony charge. [Note: For private firms whose owners have all been convicted of a federal misdemeanor or felony, the federal government should sell that firm to highest U.S. bidder and use the proceeds to pay down the federal debt.]

"We can't afford to be wrong on this issue."

This reviewer agrees with you here.

"We cannot simply err on the side of caution, because caution resides equally on both sides."

Here, this reviewer must disagree with you.

Given: a) the overwhelming proof of knowing mercury poisoning and b) the knowing failure of the firms to prove that their mercury-compound-containing medicines, including vaccines, are safe before marketing them, we must err of the side of the people who have been harmed.

This is clearly the case because the public has been knowingly mercury poisoned by the mercury-based preservatives and sterilants used in the manufacture of medicines by "responsible" management officials and firms who ignored the clear requirements that their medicines must be proven safe [as set forth in 21 U.S.C. 351(a)(2)(B)] before they are marketed.

For those government officials who also have been and/or are involved in aiding and abetting this mercury poisoning, they should also be handled using the criminal RICO statutes to seize their assets and prosecute them to the full extent permitted by law.

Finally, where appropriate, the most responsible persons should be prosecuted for murder in the second degree in those instances where those persons severely poisoned by the mercury in the medicines administered to them died as a direct result of being administered medicines containing poisonous amounts of any mercury compound added to or allowed to be present in any medicine.

"We need to know if our vaccines are safe and we need to have confidence in the institutions that monitor and regulate the vaccine program."

On this "we**" agree.**

However, today, lacking truly long-term safety studies, and proof of the intrinsic safety of all of the components or "impurities" (chemical and biological) present in each vaccine formulation and lot, we do not know that "our vaccines are safe**."**

Today, the evidence is equally clear that "the institutions that monitor and regulate the vaccine program**" are more concerned about helping the firms they are supposed to monitor and regulate than in monitoring and regulating the vaccines and other drugs in a manner that fully complies with all the applicable laws and statutes.**

Until these institutions stop protecting the manufacturers and blatantly misleading the public with statements that are clearly at odds with one or more of the following:

- **At least four (4) U.S.-licensed vaccines, other than the influenza vaccine, are still Thimerosal preserved,**
- **Several other marketed vaccines have a reduced level of Thimerosal but are not truly "Thimerosal free,"**
- **Monoclonal antibody drug products that contain undisclosed levels of Thimerosal are _____, _____ and _____.**
- **There are older lots of Thimerosal-preserved vaccines that are still in circulation even though, in the U.S., only lots that contain a "reduced Thimerosal" and/or are truly "mercury-free" are CURRENTLY being shipped into U.S. market,**
- **The 1999 "Lister Hill" and 2000 "Simpsonwood" meetings with government, industry, and academic participants illegally excluded the public and the media.**
- **Important information discussed at both meetings, "Lister Hill" and "Simpsonwood," was illegally withheld from the public.**
- **The researchers conducting epidemiological evaluations on the VSD Datalink database,**
  - **Violated the fundamental rules governing epidemiological studies**
  - **Improperly manipulated the dataset parameters and**
  - **Added lower-quality data from another source**

  with the intent to reduce the statistically significant odds ratio values found initially for the relationships between the total Thimerosal dose and the risk for a wide range of developmental disorders, including "DSM autism" until, for "DSM autism," the computed odds ratio was significantly less than 2 at the 95-percent

confidence level (the legal threshold for evidence of a causal linkage),

- **_____ deliberately deleted/"lost" the original datasets so that the studies reported or published by Verstraeten et al could not be replicated**
- **The findings of the 2001 and 2004 IOM committee reports are not valid because they were essentially predetermined by the pre-review instructions provided by the CDC.**

"Fortunately, we have a tool that can reliably answer such important questions: It is called science."

This reviewer knows that science is many things, and science, in general, does provide tools that can reliably answer the important issues that you have raised.

Specifically, some of its experimental branches, toxicology, biochemistry, and histology can answer, and have already partially answered, questions about the toxicity of Thimerosal, the specific biochemical pathways that it and its metabolites poisons, the biochemical mechanisms by which the poisoning of a given system is effected, and the visible and microscopic morphological changes in the tissues that make up the mercury poisoned system or systems being studied.

However, epidemiology[5]**, "**the branch of medicine dealing with the incidence and prevalence of disease in large populations and with the detection of the source and cause of epidemics of infectious diseases [1870—1875]**," which is a branch of biometry [1825—1835] the science that addresses the statistical properties of biological ensembles (biological statistics), can only be used to establish the possibility/probability of a link between a "putative" cause and some "observable" effect – epidemiology cannot validly be used to prove the link nor, *more importantly*, to prove that there is no link.**

With these realities in mind, let us proceed with this review

"**1: Do vaccines cause autism or other developmental disorders?**"

If a person's basis premise is not scientifically sound, then, the first thing that must be done is to establish a scientifically sound basis premise.

Since:

- **Logically, the question is: "Does <*subject*> cause <*object*>?"**
- **The <*subject*> of the question that you should be asking is:**

[5] ***Webster's New Universal Unabridged Dictionary***, Barnes & Noble Publishing (2003), page 652, at the bottom of column 3.

"Thimerosal (49.55% mercury)" [which is not a vaccine, as most scientists know and the U.S. Fifth Circuit Court of Appeals confirmed in a decision[6] published on 22 May 2005], and

- **The <*object*> of the question that you should be asking is: "Mercury intoxication" or, in simple terms, "mercury poisoning,"**

as toxicologists who have studied Thimerosal and other organic mercury compounds know.

This is the case because "autism or other developmental disorders" **are "disorders" that do not have an exact definition but are described by the symptoms exhibited by the patient –SYMPTOMS that just "happen" to be the same as those seen in documented cases of chronic sub-acute mercury poisoning in mammals including humans exposed to organic mercury compounds.**

Therefore, the proper question that needs to be answered is:

"1: Does injecting vaccine formulations that contain the highly toxic (severe poison) Thimerosal (49.55% mercury) cause mercury intoxication (poisoning) in some of those injected with these Thimerosal-containing vaccines?"

When the question is cast in its scientifically proper form, absent any data, most would think that the answer to the root question,

"Does injecting "mercury" cause "mercury poisoning?"

is a "no brainer."

However, since the toxicity of most poisons is "dose" dependant, the secondary question becomes,

"What is the minimum injected dose of Thimerosal (49.55% mercury) that can cause some of those injected to, *at some time after dosing*, begin to exhibit any of the recognized symptoms of clinical mercury poisoning?"

With the preceding in mind, let us continue examining your statements

"Autistics typically develop normally for the first year or two of life, and then start to lose cognitive ground."

Your statement is a generalization that lacks clarity and speaks of persons, "autistics" who have a "disorder" ("autism") that is neither well defined nor has been found to have some tangible cause.

Moreover, since there are two forms of "autism," profound (from birth) and regressive (autism that starts and progresses at some time after birth, a more accurate statement would be:

"Children who come to be diagnosed with the regressive form of DSM autism develop normally for some period of time and then start to

[6] Mabel Annette Hughes McDonal, et al. v. Abbott Laboratories, et al., No. 02-60773, 5th Cir.

lose cognitive ground at some point later in their lives. In general, this cognitive regression usually begins after the first year or two of life, but may occur at later times during the development of the child, up to and including the time at which a child is preparing to attend college."

Based on the empirical evidence contributed by the observations of thousands of parents, this regression begins shortly after one of the vaccination episodes that their child has experienced.

In general, that "triggering" vaccination event includes vaccination with one or more Thimerosal-containing vaccines.

In cases where the regression is very close to the inoculation date, the prevailing experience is that the child was either being treated with some other drug that may inhibit the body's ability to safely "handle" heavy metals or, for some reason, is receiving multiple vaccines containing Thimerosal (49.55% mercury).

In the few cases for children entering college, the regression has been observed:

- **By both the parent and the affected "child,"**
- **To begin shortly after the child is inoculated with a dose of a Thimerosal-preserved vaccine, Menomune® (Aventis, Inc.), drawn from a multi-dose vial.**

"They often retreat into their own world, stop talking or making eye contact, and do not interact with others. The disorder is devastating to parents; having an autistic child has a profound effect on the entire family. Although most researchers believe the evidence for a genetic cause is very strong, the exact cause or causes of autism are not clearly known."

The tables in Appendix A clearly delineate the parallels between the characteristics of DSM "autism" and those of mercury poisoning, which clearly show that "autism" is a form of mercury poisoning.

"Historically, the incidence of autism has been reported to be around 3-4 cases per 10,000 people. Starting in the early 1990's, however, the number of autism diagnoses began to climb steadily, to about 13 per 10,000. When you consider not only autism but also all related disorders (collectively called pervasive developmental disorders, or PDD), there has been a ten-fold increase, by most estimates, in the number of diagnoses being made, not only here **but (sic; but also)** in other Western nations. Some believe that we are in the midst of an autism epidemic."

In general, this reviewer agrees with your statements.

Except that, *based on the latest data*, the increase in incidence of "regressive autism" has increased more than ten-fold from the late 1980's to the late 1990's and, for the PDDs, the increase has also been more than ten-fold.

Given the more ten-fold plus increases in the incidence of this entire spectrum of "neurodevelopmental disorders," it is clear that there has been an epidemic increase in the incidence rate of the diagnosis of these "disorders."

"An 'epidemic' suggests an environmental cause for autism, rather than a purely genetic cause; in other words, if we're in the midst of an epidemic, **than (sic; then)** something we eat or inhale or come in contact with, whether a food or a germ or a toxin in the environment, is to blame."

Though this reviewer agrees with you that the epidemic rise observed must be tied to "an environmental cause**," this reviewer is surprised that the good doctor failed to include "**something we**" are injected with in your list of exposure modes for this environmental cause – indicating that you have already dismissed the injected mercury from some of the vaccines as a possible environmental cause.**

"So some people have begun to question the genetic hypothesis for autism and started searching for a toxin or other environmental trigger."

While this reviewer agrees with the substance of your statement, this reviewer notes that, among your "some people**," are world-recognized research scientists, including doctors, toxicologists, biochemists and analytical chemists, who have no autistic child – not just the "**many parents of autistic children**" of which you seem to speak.**

"In this camp are many parents of autistic children, who understandably have the sense that something has 'happened' to their child. As Amy Carson, founder of Moms Against Mercury, writes on her group's web site: 'My son was born a healthy child. As time went on and the more he was vaccinated, the more he started to change.'"

Based on the recent independent assessment of the "birthday" videos of children before they start to regress and the videos of those children after the children start to regress (which confirmed that parents are able to pinpoint the onset of the change in their children), it is clear that these parents do more than "sense that something has 'happened' to their child**."**

Factually, these "parents of autistic children**":**

- **Correctly observe, and, in many cases, document the onset of the regression; and,**
- **Based on the subsequence diagnosis of their children as having mercury poisoning, have correctly linked their child's mercury poisoning, originally misdiagnosed as "autism," to the mercury-containing [Thimerosal (49.55% mercury)-containing] vaccines with which their child was inoculated (and to which their child had a strong adverse reaction when, or shortly after, these Thimerosal-containing vaccines were administered to their child).**

"Carson and others turned their attention to vaccines. Over the same period of time that autism rates were soaring, the childhood vaccine schedule was also increasing, with more and more vaccines being added to the routine program."

> **Again, you cast the increase in terms of "**more and more vaccines**" as if the environmental problem is the number of vaccines, ignoring the reality that the critical increase was in the number of Thimerosal-preserved vaccines administered, *as the 1991 Merck memo clearly establishes*, and not the increase in number of vaccines per se.**

"And many vaccines happen to be given around the same time that the symptoms of autism first become apparent."

> **While your statement is accurate, the reality is that cumulative dosing of these one- to two-year-old children with Thimerosal-containing vaccines exceeded 37.5 micrograms of mercury at one year and 62.5 micrograms at two years from the Thimerosal shortly before "**the symptoms of autism first become apparent**." [Note: Given the current understanding of the toxicity of Thimerosal and the "inorganic mercury" metabolites produced from its injection into people, Dr. Novella's continuing failure to express the issue in terms of "mercury" and "mercury poisoning" instead of the misleading "vaccines" and "autism" appears to indicate that he does <u>not</u> understand the basic science, toxicology, that should be used to address environmentally caused disease.]**

"Two particular items came under fire: the first was the mumps, measles and rubella vaccine (MMR), and the second was thimerosal, a mercury-based preservative used in some vaccines at the time (and since removed from all vaccines given to American children, but much more on this later)."

> **While you are correct in that the two items that "**came under fire**" were the MMR vaccine and Thimerosal, your parenthetical remark, "**(and since removed from all vaccines given to American children, …)**," is factually incorrect, as anyone who reviews "Table 3" the FDA's current Thimerosal page (see: <u>http://www.fda.gov/cber/vaccine/thimerosal.htm</u>) and the previous Table 3 in the early-July 2005 version of that page can easily verify.**
>
> **Until medical professionals who comment on theses issues can:**
>
> - **Truthfully state the actual status of Thimerosal-containing vaccines in the FDA's current "Table 3" list, and**
> - **Admit that in-date lots of the previous Thimerosal-preserved vaccines, which have been superseded by "reduced Thimerosal" or "truly Thimerosal free" vaccines, may be available in some doctors' offices until some time in 2007,**
>
> **this reviewer (and others) will, as they should, have difficulty in accepting, at face value, the veracity of any of that person's remarks.**

"In 1998, the researcher Andrew Wakefield and some colleagues published a study in the *Lancet,* a prestigious English medical journal, that claimed to show a connection between the MMR

vaccine and autism. 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. This then allows for certain toxins and chemicals, including those from bread and dairy, that normally **broken (sic; are broken)** down by the gut to enter the bloodstream, where they can get access to and damage the developing brain."

All that this reviewer can add is:

- ✓ **Dr. Wakefield's theory has <u>not</u> been disproved,**
- ✓ **The key point in his theory is the agent and/or predisposition that generates the "**susceptible**" children of which Dr. Wakefield speaks,**
- ✓ **The mercury poisoning caused by Calomel in teething powders for babies and Thimerosal in vaccines has been documented to attack the gut and to damage its protective immunity systems along with the damage it causes to the other biological systems in the human body – predisposing those damaged to the additional harm that may be inflicted by the MMR vaccine on their already mercury-poisoned systems.**

"Although the study was small, and the evidence was considered preliminary, this article sparked a firestorm. The vaccine-autism movement was soon in full swing."

This reviewer notes that you fail to report that some follow-up studies have confirmed the damage caused in those who are "susceptible**" to MMR damage.**

In addition, *besides altering the diet to remove gluten and milk products*, some physicians report marked improvement in about 1/8th of their "mercury poisoned patients" when their parents give their poisoned children Cod-liver oil instead of beta-carotene as the source of the necessary Vitamin A and the drug, bethanechol hydrochloride, to help promote peristalsis in the gut.

"The case against thimerosal has been well documented in *Evidence of Harm,* a new book by journalist David Kirby (although Kirby makes it clear that he's not taking sides in the debate, just reporting about it)."

Here, you appear to "speak with a forked tongue," because you:

- **Fails to note that Mr. Kirby has also thoroughly documented the case <u>for</u> Thimerosal as he understood it from a journalist's viewpoint at the time he finished the final draft about a year ago, but**
- **States that "**Kirby makes it clear that he's not taking sides in the debate, just reporting about it**."**

Had you wished to be fair and accurate, you would have stated:

"The cases for and against Thimerosal as the cause for the harm observed have been well documented in *Evidence of Harm*, a new book by journalist David Kirby …"

"The alleged link between thimerosal and autism has also been publicized, with approval, by the environmental lawyer Robert F. Kennedy Jr., in the online magazine *Salon* and elsewhere."

This reviewer is at a loss to understand the message that you attempted to communicate in this convoluted and obtuse sentence.

A sentence that, among other things, fails to note that several world-renowned knowledgeable scientists and doctors have been publicizing, *in your basis lexicon*, the "link between thimerosal and autism**" in the scientific community for decades and conducting scientifically sound experimental studies, which collectively support, *in the scientific basis lexicon*, the proven validity of the link between Thimerosal (49.55% mercury) and the mercury poisoning being observed for decades. [Note: This reviewer suggests that you should carefully review and study the fundamental scientific precepts contained in "Ockham's Razor." If you do so with an open mind, you should realize that the creation of the set of scientifically deficient "disorders," "syndromes," and "diseases" that "have no provable cause," violates both aspects of Ockham's Razor and renders these ill-defined "conditions" scientifically suspect. From the viewpoint of Ockham's Razor, these conditions are simply attempts to obscure the fundamental reality "mercury poisoning" by hiding it under a pile of obfuscatory names. However, like the rose, mercury poisoning remains mercury poisoning no matter what the obscuring name you, or anyone else, give to any "variety of it.]**

"The radio talk show host Don Imus has used his radio show to rage against what he believes to be a horrific crime against humanity."

IF the mercury poisoning of fetuses in their mothers' womb, newborns, babies, toddlers, preschoolers, etc. by injecting Americans of all ages with toxic doses (which have never been proven safe as required by law [21 CFR 610.15(a)]) of a bio-accumulative severe poison, Thimerosal (49.55% mercury), hidden in vaccines represented as the safest medicines that are made, is not a horrific crime against humanity,
THEN what is?

Since you feel it was important to tell us what Don Imus believes, please Dr. Novella, tell us what you believe this multi-generation mercury poisoning of the American people is?

If this not a horrific crime against humanity, then what is it?

Simply another "opportunity" for you and the healthcare industries to improve revenues?

"And many parent activist groups have formed to advocate specifically for the mercury-causes-autism hypothesis, or to lobby against thimerosal."

While unfortunately buying into the establishment's false propositions that the issue is:

- **"Vaccines cause autism" or**
- **"Mercury causes autism"**

instead of the scientifically sound proposition:

- ❖ **"Repeatedly, injecting small, but poisonous amounts of Thimerosal (49.55% mercury) into the American public causes all Americans to be mercury poisoned to some degree with some being poisoned to the point that they 'exhibit' one or more of the recognized clinical symptoms associated with mercury poisoning,"**

or, simplistically,

- ❖ **"Repeatedly injecting Thimerosal (49.55% mercury) into most Americans is slowly:**
  - ➢ **Clinically mercury poisoning more than 15% of us to some degree, and**
  - ➢ **Severely mercury poisoning, including those babies who the Thimerosal poisoning kills, about 1% of us,**

the science-based groups have coalesced to demand that all mercury compounds must be removed from all medicines and medical preparations and uses UNLESS scientifically sound and appropriate long-term chronic toxicology studies PROVE THEM SAFE at the maximum dosing frequency allowed for the medicine at 100 times the maximum level present in the formulation.

Further, those science-based groups have recommended final *population safety factors of not less than*:

- **10 for those medical products and preparations, including vaccines, that are administered very infrequently,**
- **100 for those that are administered infrequently,**
- **1000 for those that are given at a frequency no higher than monthly,**
- **10,000 for those administered at a frequency no higher than semi-weekly, and**
- **100,000 for those given more frequently than twice a week.**

"They have refined their argument to make the following claims:"

This reviewer finds that your understanding of the claims made by these groups is, at best date, an unsubstantiated concerns, which, in the comments that follow, this reviewer will attempt to bring you up to date.

"During the 1990s, the vaccine schedule was increased to include many vaccines that use thimerosal as a preservative to prevent the growth of bacterial contaminants."

Factually, our stated position, *using your words as much as possible*, is: "During the 1990s, the vaccine schedule was increased to include many vaccines**":**

- **In which the vaccine manufacturers illegally used Thimerosal** "as a preservative**" knowingly[7] in violation of 21 CFR 610.15(a), and**
- **Because Thimerosal**
  - **is known to induce sensitization and immediate life-threatening allergic reactions in a percentage of those inoculated with dilute preparations of it and**
  - **there are other safer FDA-approved preservative chemicals that do not act as powerful immune response triggering agents,**

these Thimerosal-preserved vaccines were also illegally allowed by the U.S. FDA to retain their license in violation of the clear statutory mandates set in 42 U.S.C. 300aa-27(a)(2).

"Thimerosal contains ethylmercury, a known neurotoxin."

Factually, Thimerosal does not "contain" ethyl mercury.

Thimerosal ("sodium ethylmercurithiosalicylate," 49.55% mercury) is a bio-accumulative "severe poison" that poisons all animal systems and a "sensitizing agent" that can be absorbed through the skin.

When dilute (0.01% or lower) aqueous preparations [concentrations used in vaccines and other drugs] are prepared, some of the Thimerosal is converted into ethylmercurihydroxide and, *when injected into the human body*, the rest of the Thimerosal is rapidly converted into the mercury-containing metabolite, ethylmercurihydroxide,"

The ethylmercurihydroxide formed rapidly distributes through out the body and, because of its affinity for non-aqueous environments and its "ability" to readily cross all self-protective human barriers (e.g., blood-brain and placenta-fetus), is preferentially absorbed into "fat"-rich areas, like the brain.

In the brain and the other areas where it tends to concentrate, various metabolic systems convert some of the ethylmercurihydroxide into, as yet unidentified, "inorganic mercury" species that are the end-product metabolism products.

These "inorganic mercury" species are the long-term mercury poisoning agents, which less-than-reversibly poison a variety of critical metabolic pathways and systems.

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[7] Perhaps the recent discovery that Eli Lilly found, but apparently did not formally report to the FDA, significant "Thimerosal" toxicity at levels of Thimerosal 1/100th the "preservative" level explains why the vaccine makers knowingly failed to conduct, or at least, did not report, the required toxicity studies. In any case, Eli Lilly abruptly exited the vaccines business in 1975, perhaps to avoid the direct liability for the mercury poisoning of the American public by their Thimerosal-preserved vaccines and other biological products.

The baby-monkey studies conducted by Burbacher et al (2005) clearly established that, with respect to the residual mercury species ("inorganic mercury") that were found to be trapped in the monkey's brains, injected ethylmercurihydroxide led to more than twice as much poisonous mercury's (the "inorganic mercury" species') being trapped in the brain of the monkeys injected with low doses of Thimerosal than the level of poisonous mercury (the "inorganic mercury" species) trapped in the brains of another matched group of baby monkeys fed comparable levels of methylmecurihydroxide.

Hopefully, you and other readers now understand something of the currently known chemistry for the metabolism of Thimerosal in mammals, including primates and humans.

"When the total doses of ethylmercury for all vaccines in the schedule are added together, in some cases they exceed by many times the Environmental Protection Agency (EPA) or Food and Drug Administration (FDA) safety limits for mercury."

Yet again, your understanding seems to be incomplete.

In 1991, not 1999, when a senior Merck scientist added up the mercury, *not the ethylmercurihydroxide* ("ethylmercury**"), from the nominal label claim for the Thimerosal in the Thimerosal-preserved vaccines in the then-recommended vaccination schedule for a fully-vaccinated on-schedule two-year-old child, he reported to Merck management that that child could receive "**87-times**" the EPA-recommended intake level.**

In his memo to Merck's management, he also indicated that the U.S. FDA had no concern about the Thimerosal in vaccines, indicating that he had also shared his concerns with the FDA managers who were then in charge of biological product issues.

Thus, the later widely reported "light bulb" incident, while an interesting anecdote, is not the point in time where the vaccine makers and the FDA knew that the level of Thimerosal was, *based on the 1991 Merck memo and the 125% maximum overage allowed for the Thimerosal in the vaccines*, in 1991, by two years of age, some children could have received more than 100 times the intake level that the EPA though was safe for children for mercury from ingested fish, or more than 25 times the FDA's suggested limit for drugs administered to adults.

"The developing brains of infants, they argue, are probably more susceptible to the effects of mercury. All of which spells danger.**"**

Here, your rhetoric ignores the following scientific particulars:

- **Both in vitro and in vivo studies have shown that the developing brain is much "**more susceptible to the effects of mercury**" than the fully developed brain.**

- **The baby's brain only weighs about 350—400 g versus the 1,300—1,400 g for the fully developed human brain, slightly more than one-fourth the size of the adult brain.**
- **The average baby's weight at a given vaccination milestone is on the order of 1 % to, at most, 10 % of the average adult's weight.**
- **The dose of vaccine for the baby is typically 50 % of the dose given to older children and adults.**
- **The distribution ratio for the ethylmercurihydroxide is such that more than 50 % of the equilibrium dose administered is found in the brain.**

Based on the preceding, even if, *contrary to fact*, the brains of the babies were no more susceptible to the effects of mercury than the developed adult brain, the differential dose and concentration effects would result in more harm to the developing brain.

Thus, the facts speak for themselves, there is no need to argue them, and, therefore, your rhetoric, "they argue,**" is both condescending and disparaging to those who, based on your rhetoric, you look down on.**

"The specter of mercury can be compelling. As Carson, of Moms Against Mercury, writes: 'I was outraged that I was not told that the most powerful neurotoxin was going to be injected in my newborn child. It has devastated and changed our lives forever.'"

This reviewer agrees that the "specter of mercury**," mercury poisoning, is compelling and the fact that this mercury poisoning has knowingly been, and is knowingly being, inflicted upon the American people by an establishment that seems more interested in preserving the myth of "vaccine safety" than in addressing the catastrophic harm that their knowing actions and inactions have inflicted and are inflicting on all Americans.**

"She and others believe there is a compelling overlap between autism and the signs and symptoms of known mercury toxicity: speech delay, sensory hypersensitivity, and motor symptoms."

Dr. Novella, please carefully read Appendix A.

In it you should see two things:

- **The symptoms of those labeled with DSM "autism" extend far beyond your limited neurological view, and**
- **In most all cases, the symptoms described in every area are essentially the same as the symptoms for mercury poisoning.**

Given this reality and the similar reality for the previous wide-spread mercury poisoning by a medicine, mercury(I)-chloride-laced teething powders for babies, which the medical establishment also insisted on labeling "Acrodynia" and "Pink Disease" rather than calling it what it clearly was, mercury poisoning, the label "autism" is clearly one of the

many labels that the medical profession is knowingly using to conceal the underlying mercury poisoning caused by the repeated injection of sub-acute toxic doses of Thimerosal contained in some the vaccines offered to all Americans under the guise of protecting the health of the public.

"They point to toxicological studies that suggest autistic children may have been exposed to more mercury than their non-autistic peers (although scientists feel the validity and implications of these studies are still unclear)."

Contrary to your views, the comparative toxicology studies only indicate that your "autistic children**" have accumulated more of the mercury to which they have been exposed through injected Thimerosal than their "equally" exposed "**non-autistic peers**."**

In addition, those "autistic**" children who, *for a given "nominal" level of injected Thimerosal*, are tested for, and then diagnosed with, clinical mercury poisoning, the levels of mercury in their baby hair and current hair samples are usually, below, or at the low end of, the normal range of the mercury levels in comparable hair samples from their apparently non-clinically-mercury-poisoned peers.**

"They also claim that autistic children may also be especially susceptible to mercury, or may have impaired mechanisms for clearing mercury from their system."

Factually, variability in the number of "thio" groups in a biological compound that is key to the removal of "inorganic mercury" from the brain has been shown to correlate with the detoxification capability of that biological compound.

Thus, the variability in the "mechanisms for clearing mercury from their system**" has clearly been established.**

Given the preceding realities, "They**" do not, per se, "**claim autistic children may also be especially susceptible to mercury, or may have impaired mechanisms for clearing mercury from their system**."**

"Some even link thimerosal and MMR, arguing that mercury impairs the immune system, allowing the live measles virus to cause a damaging infection."

Since, numerous toxicology studies dating back to the 1940's have clearly established that mercury poisons the immune system, we have no need to "argue" this point.

Hopefully, you and others will read some of the more recent of these studies and reach the same conclusion.

"Promoters of the vaccine-autism hypothesis also claim that the Centers for Disease Control (CDC), which is responsible for monitoring vaccine safety, and the FDA, responsible for approving vaccines as safe and effective, are engaged in coverup."

You are factually incorrect here.

Since the true "(p)romoters of the vaccine-autism hypothesis,**" include key "**Centers for Disease Control**" and Prevention (your "**CDC**") and FDA personnel, the promoters of this defective "**vaccine-autism**" hypothesis obviously do not accuse themselves of being "**engaged in coverup.**"**

Based on documents (including those published and those obtained through the Freedom of Information Act and discovery in legal cases) those researchers engaged in determining "who knew what," "when they knew it," and "what, if anything, was done to address what was known," have been able to establish that:

1. **The industry, FDA, and "CDC" have inflated the safety of, and hidden the risks associated with, the vaccines in the current U.S. immunization schedule,**
2. **The industry has knowingly failed to comply with the law (21 CFR 610.15(a) for more than 30 years requiring PROOF of the safety of the use of Thimerosal (49.55%) as a preservative BEFORE it is used in any vaccine formulation – yet, *as FDA officials have repeatedly testified*, the required toxicology studies have, as of October 5, 2004, not been submitted to the FDA nor has the National Institutes of Health (NIH), the "CDC," or the FDA conducted any such studies.**
3. **In addition to knowingly not proving the safety of Thimerosal for use as a preservative as required by law the vaccine makers have knowingly marketed products that are, by statute, adulterated.**
4. **Though the FDA knows that Thimerosal-preserved vaccines are, by statute, adulterated drugs, the FDA has taken no action to remove these from the market or fine the manufacturers for distributing these unsafe and adulterated Thimerosal-preserved drug products.**
5. **The "CDC," NIH, FDA, health officials and key representatives of the vaccine maker have met twice in conferences that ILLEGALLY excluded the general public and the media (the 1999 "Lister Hill" conference and, the more widely referenced, 2000 "Simpsonwood" conference) that discussed key safety issues related to the epidemic rise in mercury-related harm from the increased dosing with Thimerosal-preserved vaccines.**
6. **These closed meetings encouraged the participants to withhold the information discussed, and the concerns raised, from the public as well as touched on ways to "manage" the public's concerns and direct them away from the Thimerosal issue.**
7. **The "discovered" transcript of the first closed-door meeting of the 2001 IOM committee nominally reviewing vaccine safety issues (but couching their review in terms of "vaccines and _____" issues) clearly indicates that, among other things, the "CDC"**

instructed that IOM to not find any link between "vaccines" and the "autism" before that CDC-hired IOM committee reviewed any of the evidence.

8. **Following their charge, the 2001 IOM committee found no proof of the CDC's hypothesized "**vaccine-autism link**" and recommended additional research.**
9. **Reacting to the scathing report published by Congress (Burton's "*Mercury In Medicine*" report, in 2004, the CDC rehired the IOM committee and, *based on the actions of that reconstituted IOM committee and other testimony*, directed that IOM committee to only consider evidence that did not support the CDC's "**vaccine-autism link**" hypothesis and to recommend that there be no more research in this area even though unpublished research that was in the process of being published clearly showed that more research should be conducted.**
10. **Returning to the FDA's role, the FDA HAS deliberately and, since 1986, knowingly IGNORED the statutory REQUIREMENT set forth in 42 U.S.C. 300aa-27(a)(2), which, if heeded, would have forced the FDA to revoke the license of any vaccine that contains any level of Thimerosal that, by itself, causes any reducible adverse reactions BECAUSE:**
    a. ***By statute*, the FDA is supposed to do all that it has the authority to do "**to reduce the risks of adverse reactions to vaccines**,"**
    b. **Thimerosal is not a NECESSARY component and**
    c. **There are several other FDA-licensed sterilants and preservatives, which can be used in a vaccine to satisfy Thimerosal's use as a process sterilant or product preservative that are known to intrinsically "**reduce the risks of adverse reactions to vaccines**" as the cited statute directs,**

    and

    AGAIN COOPERATED with the vaccine makers to leave an unsafe, unnecessary, and allergy-inducing, severe poison, Thimerosal, to continue to be used in vaccines and other drugs for about two decades in this case.

Based on all of the evidence discovered, it is more than evident that government health agencies and officials, the pharmaceutical industry executives and officials, and paid consultants have colluded with each other to hide not only the risks from, but also the harm caused by, the Thimerosal in our vaccines and other drugs.

Thus, those scientists and parents who know that injecting toxic levels of Thimerosal (49.55%) hidden in vaccines and other drugs causes mercury poisoning make no claims, but rather rely on the proofs of collusion to cover-up the harm that injecting Thimerosal-containing preparations into humans has caused, is causing, and will continue to cause, until this UNNECESSARY severe poison is removed from all medicine and the use

of all mercury compounds is banned from medicine UNLESS there is absolute toxicological proof that the level of that mercury compound is sufficiently low as to be incapable of causing clinical harm under the most frequent dosing regimen to the most susceptible human beings in our population.

"Robert Kennedy Jr. writes, 'The story of how government health agencies colluded with Big Pharma to hide the risks of thimerosal from the public is a chilling case study of institutional arrogance, power and greed.'"

As the previous review of the facts has established, Mr. Kennedy was simply reporting the facts, as they are clearly understood.

"There are numerous complex issues involved in this controversy. I will address each one in turn."

This reviewer can only agree with you that there "are numerous … issues involved.**"**

"2: Is there a real autism epidemic?

There is no doubt that between 1990 and 2001 there was a dramatic increase in the number of diagnoses of autism and related disorders, about 10 times by most estimates."

This reviewer agrees with you here.

"The scientific community accepts this fact, which has been demonstrated in numerous epidemiological studies."

Again, this reviewer agrees with you.

"Many autism activists believe this increase represents a genuine, and disturbing, epidemic."

Here, this reviewer again agrees with your statement, but notes that those scientists, especially those toxicologists who are studying in this area, also know that this increase "represents a genuine, and disturbing, epidemic**."**

"However, the scientific community is fairly united behind a different interpretation."

This reviewer, speaking on behalf of those segments of the scientific community, who have:

- **recognized that the true reality is "injecting mercury compounds causes mercury poisoning" and**
- **reviewed the only long-term study applicable to the exposure experience of the American public, the California DDS' confirmed "DSM autism" tracking database (which tracks those most damaged**

by the mercury poisoning inflicted on about 1/7th of the children living in America),

understands:

- **This epidemic is real and <u>strongly</u> tracks the increase in mercury exposure from "injected Thimerosal mercury" which has caused the increase in the incidence of mercury poisoning observed**
- **The establishment** "scientific community," **who buys and sells the false** "autism" **label for this disease, is your** "scientific community" "united behind a different interpretation."

"Dr. Fred Volkmar, a child psychiatrist at Yale and world-renowned autism expert, points to two other important forces. First, the range of symptoms that are considered to be 'autistic' has greatly expanded."

If the studies that have looked at this issue in the California "autism" population – not the wider "autistic" population, you will see that statistically, *because California requires all DSM/CDER "autism" cases to be confirmed by a recognized specialist*, the change in the definition of "autism" has not significantly affected the increase in the incidence rates reported.

Further, if you look at the underlying disease, *mercury poisoning*, the data clearly indicate that, *as it should*, the California confirmed-"autism" case incidence *rate for mercury poisoning tracks the increase in the total* Thimerosal-related *mercury dose* that the fully inoculated child is supposed to receive.

"Doctors and parents now speak of an 'autism spectrum disorder'" "you can be a little autistic, more autistic, less autistic."

While your statement is true, it contributes nothing of substance to you premise.

"Autism is not a specific disease; you can't do a blood test or a CAT scan to see if it exists. It is, rather, a disorder: It is defined solely by the constellation of signs and symptoms that it displays."

Beyond not adding substance to your premise, your statement supports the position that "Autism" **is simply a convenient artificial label used to obscure the underlying disease, *mercury poisoning*, that the establishment of which you are a part is doing all in its power to conceal.**

In contrast to your "Autism" **label, there are tests that can confirm the underlying disease, *mercury poisoning*.**

"This means that the number of autistics can be greatly expanded or contracted by changing the criteria for diagnosis. During the 1990s, many milder forms of the disorder were being recognized and diagnosed, as was a broader list of possible manifestations, and in fact new

diagnoses, such as Asperger's syndrome, began to be considered autistic. So a wider net was being cast. Here's an example to show what I mean: If you had a loose category called "intelligent," and it was understood to mean people who could do calculus well, then only 1 percent of Americans might be "intelligent." But if you changed the definition to include everyone who can carry on a decent conversation about politics, or everyone who can do algebra, then you'd diagnose a lot more people as "intelligent." That makes a disorder very different from a disease like cancer: You either have cancer or you don't, but autism isn't quite so clear-cut."

Thus, your "wider net**" analogy has been disproved for the only case where there is a solid body of decades-spanning data for confirmed DSM/CDER "autism," the California DDS' included-confirmed-"autism"-case tracking database.**

Moreover, the widening of the range of symptoms that label a child as falling within the "autistic**" spectrum has little to do with whether or not there is a real *mercury poisoning* epidemic, because the California data clearly support that California has an "**autism**" epidemic and DSM/CDER "**autism**" has been proven to be no disease, *as your rhetoric agrees*, but rather is a label used by the establishment to cover up the underlying disease, *mercury poisoning*, caused by their knowing failure to protect the public from being poisoned by the organic mercury (Thimerosal) hidden in some of the purportedly "safest drugs" – vaccines.**

"In addition to changes in diagnoses, systems for surveillance were also being increased" "more nets, with tighter weaves, were being cast."

Here, this reviewer is at a loss.

What surveillance systems are you talking about?

Outside of California, the only comprehensive systems seem to be educational reporting systems, which are NOT medical surveillance systems!

Thus, your rhetoric, "more nets, with tighter weaves, were being cast**," is, *as far as this reviewer can ascertain*, not supported by the facts.**

"Because of the availability of special services and early-intervention programs to help autistic children, there was a huge effort to perform routine screenings of all children by qualified professionals, which led to a great increase in the number of children seen by doctors looking for autism."

Unless and until you can provide the published scientific studies that support your statement here, this reviewer must discount your words as being more fantasy than fact.

In this reviewer's limited recent experience with the systems in place in Texas and New Jersey, there is no real "effort to perform routine screenings of all

children" **and the persons, who are involved in these "screening" programs there, are often less than the "**qualified professionals**" of which you speak.**

Moreover, since the supported costs for these "special services and early-intervention programs**" far exceed the funds available, most have no, or limited, "**special services and early-intervention programs**" notwithstanding the applicable provisions in the underfunded "no child shall be left behind" legislation.**

"Finally, health-care programs have provided an incentive to give children a diagnosis that is covered by insurance, and autism fits the bill."

Since most healthcare insurance policies provide no coverage for any DSM diagnoses, including "autism," which have no recognized cause or standard treatment regimen, this reviewer must conclude that either you are misinformed on this issue or that you are informed and your statement is knowing Orwellian doublespeak.

Factually, a confirmed diagnosis of the underlying disease, *mercury poisoning* (mercury intoxication), or the general condition, "heavy metal intoxication," is more likely to be reimbursable than any of the DSM "disorder" or "syndrome" diagnoses used to cover up that *mercury poisoning*.

"That doesn't mean that parents are eager to have their children diagnosed as autistic, of course, but that some doctors might, to help the parents get services, be looking for a diagnosis for a child with developmental problems and might settle on a diagnosis of autism."

Again, Dr. Novella, what are you smoking?

If a qualified doctor truly wanted to help a parent get the "services" that possibly mercury poisoned children need, he or she would, *after adding up their total mercury exposure from vaccines as of the date the children are being seen and finding a total of more than 1 microgram of mercury*:

- **Test those children with an appropriate battery of hair and, after a screening chelation challenge, blood and urine analyses for evidence of mercury poisoning, and**
- **Depending upon the heavy metal results and results' pattern found, give that child a primary diagnosis of either "mercury intoxication" or "heavy metal intoxication" followed by, *based on the other symptoms of mercury poisoning exhibited*, secondary diagnoses for the reimbursable medical conditions that those children are exhibiting.**

Only when a child with regressive development has been proved <u>not</u> to be poisoned by mercury, lead, bismuth, arsenic, manganese, or some combination of these, would a qualified concerned doctor look to the DSM for guidance.

"This issue, diagnosis, is absolutely critical to the question of vaccines and autism."

Again, your statement does Orwell proud.

However, the California data, and the scientifically sound "diagnosis**" review studies of that data, clearly refute your "**diagnosis**" contention.**

"If the increase is an artifact of expanded diagnosis and increased surveillance, then there is no epidemic."

Since the well-documented California (where about 1/7th of the children in America reside) confirmed-"autism"-incidence-rate increase is <u>not</u> an artifact, there most definitely is an epidemic – one whose principal cause is the parallel increase in the total dose of Thimerosal (49.55% mercury) administered to children in their vaccines.

"This fact alone would kill the vaccine-autism hypothesis, which is based largely on the correlation of increasing vaccines and increasing autism."

First you make a statement that asserts an unsupported hypothesis and, in the next "breath," convert that hypothesis into a "fact**" which you use to "**kill**" another bogus "**hypothesis**" that you created.**

Dr. Novella, you are indeed a magician.

However, your magic seems to be false magic and your hypotheses are not grounded in any sound science of which this reviewer is aware.

"Defenders of a link have rejected this very important argument."

Since this reviewer is one of the defenders of the true link – the link between the amount of mercury injected and the incidence of mercury poisoning effected and this reviewer has carefully addressed and discredited your "very important argument**," your assertion here is a false one.**

Sound science that refutes your "argument**" has rejected your "**this very important argument**" – not this reviewer.**

"Kennedy, for example, has wondered, if earlier cases of autism were simply going undiagnosed, where are all the autistics who are now in their twenties? But this observation is a bit too simple."

Dr. Novella, since you have no basis to refute Kennedy's valid observational question and have no good answer, you attack the question by calling it "a bit too simple**."**

"First, many of the previously undiagnosed cases were toward the milder end of the spectrum."

> ***If the previous cases were undiagnosed*, how can you <u>know</u> that these undiagnosed cases "**were toward the milder end of the spectrum**"?**
>
> **Are you, Dr. Novella, in addition to being a magician, also clairvoyant?**

"Also and more important autism is known, in many cases, to improve with age."

> **Knowing of no scientifically sound published study where <u>untreated</u> DSM "autism" cases have been shown "**to improve with age**," and having come into contact with cases where the untreated children's symptoms worsen with age, this reviewer must also reject your statement as the wishful "it is known" language that those lacking proof of an assertion use to cover its insubstantial basis.**

"Finally, there is no reason to believe that adults with autism undiagnosed as children should somehow be apparent to casual observation."

> **Apparently, you have not seen pictures or videos of, or had much contact with, untreated children or adults who have been severely mercury poisoned.**
>
> **If you had, you would know that is <u>not</u> possible not to notice these children or adults the moment you meet them.**
>
> **Having had the privilege, this reviewer knows that your assertion is as baseless as your dismissive and wishful "**many of the previously undiagnosed cases were toward the milder end of the spectrum**."**

"In other words, we still have good reason to believe that increased surveillance and more liberal diagnosis accounts for much, potentially all, of the spike in diagnoses."

> **Dr. Novella, science deals with the world of proof, religion deals with the world of belief.**
>
> **Since you have claimed to be speaking in the world of science, what you believe (or anyone else believes) must be ignored in this realm.**
>
> **Thus, your, "**we still have good reason to believe that increased surveillance and more liberal diagnosis accounts for much, potentially all, of the spike in diagnoses**," should, and will, be ignored by those who are scientists.**

"Those who believe in the vaccine-autism link have a number of studies they point to. None, however, is very convincing."

> **As with most apologists, you begin by stating your view of others' views, expressed in terms of your language and not theirs, and then dismissing them with, "**None, however, is very convincing**," before discussing even one of the studies.**

Based on your approach here, this reviewer must caution those reading your remarks to be on guard for other such attempts to prejudice the discussion.

"For example, a study recently published (but not peer-reviewed) by the MIND institute and authored by Dr. Robert Byrd concluded that the rising rate of autism diagnosis in California was not due to an influx of cases into the state, a change in diagnosis criteria, or a mislabeling of autism as mental retardation."

As one of the several scientists who have carefully reviewed, "Report to the Legislature on the Principal Findings from, The Epidemiology of Autism in California, October 17, 2002**" by Dr. Robert Byrd et al published inline by the M.I.N.D. institute, this reviewer presumes that this is the report to which you are referring.**

Since this report has been available for almost three years and has been widely reviewed by those on both sides of this issue, this report has, contrary to your view, been peer reviewed.

Moreover, its findings have repeatedly been found to be valid.

"This study is widely used to dismiss the 'increased surveillance' explanation."

On this we agree.

"But this study did not look at the effects of increased awareness, and therefore reporting, of autism or programs to increase surveillance."

Since California has been <u>fully</u> aware of the need to find, diagnose and report DSM "autism" for more than two decades, there obviously is, and was, no need to "look at the effects of increased awareness**" since such could not be present in a fully aware setting, is there?**

Thus, your feigned concern is "red herring" designed simply to mislead the reader rather than raise a substantive issue of concern.

Thus, the California increase <u>cannot</u> be explained away on the basis of increased awareness, can it?

Thus, that report:

- ✓ **Fully assessed and considered those factors that, *other than a true increase in the incidence rate*, might have artificially increased the apparent incidence rates,**
- ✓ **Found that none of these other factors had had a significant impact, and Reported, "**Without evidence for an artificial increase in autism cases, we conclude that some, if not all, of the observed increase represents a true increase in cases of autism in California, and the number of cases presenting to the Regional center system is not an overestimation of the number of children with autism in California,**"**

the California report's conclusion is valid.

"Experts also seriously doubt the credibility of this analysis, citing specifically that it is not peer-reviewed."

Since the only specific credibility issue of this report that your unnamed "(e)xperts**" cite is "**that it is not peer-reviewed**" and that issue has been discredited by this reviewer, it would seem that the analysis of the critical issues addressed in that October 17, 2002 report by Dr. Robert Byrd et al is both credible and scientifically sound.**

"A much better study suggests that actual autism rates are not increasing; the study therefore supports the "increased surveillance" hypothesis."

As with all such endeavors, studies that involve foreign populations, in this case an English population, that do not have comparable vaccination schedules and/or do not use the same Thimerosal-containing vaccines as the vaccination schedules and vaccines in the U.S. cannot validly be used to support, or discredit, the findings in like studies conducted in the U.S.

In spite of the scientific duplicity of attempting to compare the findings from non-comparable population studies, you begin by prejudging the value of the study you have chosen to cite with, "A much better study suggests that actual autism rates are not increasing; **…"**

Further, without presenting any sound evidence to support your interpretation of the study you are going to introduce, you claim, "…the study therefore supports the 'increased surveillance' hypothesis**."**

Since the epidemiological starting points for the United Kingdom studies are not comparable to the U.S. starting points, *contrary to your assertion*, no scientifically valid comparative conclusions can be drawn.

"This study essentially controls for diagnostic and surveillance differences, and therefore is very powerful evidence that there is, in fact, no autism epidemic."

This reviewer must disagree with you because there are other critical factors, like differences in cohort age, Thimerosal dosing levels, and vaccination rates that, as reported, the study seemed not to control for.

"From 1992 to 1995, Suniti Chakrabarti and Eric Fombonne studied the incidence of autism in Stafford, England. Ten years later, they repeated their exact methods of diagnosis and surveillance with a cohort of children born in 2002, at the peak of the alleged autism 'epidemic'."

First, your "From 1992 to 1995, Suniti Chakrabarti and Eric Fombonne studied the incidence of autism in Stafford, England**," seems to be incorrect.**

Though you cite no reference, this reviewer believes the published article to which you are referring is:
Suniti Chakrabarti and Eric Fombonne, "Pervasive Developmental Disorders in Preschool Children," *JAMA*, 285, pages 3093-3099 (2001).

In that paper the authors reported the results found for a 1998 to 1999 study of 15,500 children living in Stratford, England that were born in the period from 1992 to 1995.

Second, *contrary to what you report*, the study reported in 2005, Suniti Chakrabarti, and Eric Fombonne, "Pervasive Developmental Disorders in Preschool Children: Confirmation of High Prevalence," *Am J Psychiatry* 162, pages 1133-1141, June 2005 does not report findings from "a cohort of children born in 2002, at the peak of the alleged autism 'epidemic'**."**

In the 2005 paper, the authors are reporting on the 2002 "Screening for developmental problems included 10,903 children ages 4.0 to 6.0 years who were living in a Midlands town on the survey date**."**

Thus, the children were born 4 to 6 years before 2002 ("the peak of the alleged autism 'epidemic'**") or roughly in 1996 to 1998.**

Since the time periods are close and "touching," their findings, of not much change in similar populations with short "touching" time periods, are what most knowledgeable scientists would expect.

For comparison, this reviewer has tabularized their summary findings.

This reviewer's summary can be found on the next page.

"They found no difference in the rates of either pervasive developmental delay or autism between the two groups. This study essentially controls for diagnostic and surveillance differences, and therefore is very powerful evidence that there is, in fact, no autism epidemic. The true incidence is flat over this critical period of time**."**

As the real data, not your distortion and misreporting of it, clearly establish, the facts do not support your bogus claims:

- **"…** very powerful evidence that there is, in fact, no autism epidemic,**" and**
- **"**The true incidence is flat over this critical period of time**"!**

Factually, *when considered against the "accepted" British baseline rate for* "Autistics**" *of 3 to 4 cases per 10,000 in the 1980's*, the mid-1990's rate of 17 to 22 rate per 10,000 indicates that there has been an approximate 5.5-fold in crease, which, to this reviewer seems to indicate an epidemic increase in England – though this rise is roughly half that seen in the U.S. (where the maximum Thimerosal dose was significantly higher than it was in the U.K.).**

Given the short time periods, their "touching," the small size of the population segment studied, and the 95%-confidence-interval ranges, most

knowledgeable scientists would expect that the differences observed would be minimal.

Finally, neither study presented data for 4- to 6- year-old children born in "2002" – your "critical period of time**" because the earliest the comparable data for the 2000 to 2002 period will be available for publication is sometime in 2007.**

Comparative Reported Findings 1998-1999 Study and 2002 Follow Up

Study Period	1998-1999	2002
Publication Year	2001	2005
Subject's Age Range (yrs)	2.5 to 6.5	4 to 6
Approximate Birth Year	1992 to 1995	1996 to 1998
Diagnosed Condition (British Definitions)	Average Incidence Per 10,000 Children	
"PPD"	62.6 (50.8 – 76.3)	58.7 (45.2 – 74.9)
"Autistic"	16.8	22.0
"Other	45.8	36.7

"In other words, in Stafford, England, when you use the same diagnosis criteria in 1995 and again in 2005, you don't find any more autism."

Since the studies were conducted in the 1998 to 2002 time period, this reviewer is at a loss to understand how you can speak of using "the same diagnosis criteria in 1995 and again in 2005**" UNLESS you never bothered to even read the abstracts or, worse, this statement is an intentional "whole cloth" fabrication on your part.**

This reviewer would appreciate your explaining exactly how you managed to confuse reality with your fictions in all of the instances where your words do not seem to match the facts reported by the authors in their publications.

"You only find more autism if you change the definition of autism. The true incidence is flat over this critical period of time. In other words, in Stafford, England, when you use the same diagnosis criteria in 1995 and again in 2005, you don't find any more autism. You only find more autism if you change the definition of autism."

Again, your statements continue to be at odds with the facts.

Time and time again your statements are simply a reiteration of your baseless and unsupported "wishful thinking."

Moreover, given the magnitude of your misstatements, a retraction and a formal apology to the readers would be appreciated.

"To be clear, it is not possible for such studies to rule out a small signal in the noise. In fact, it is logically impossible to prove that something does not exist."

This reviewer is at a loss to understand your reasons for including these remarks here.

"Responsible scientists will always be modest in their conclusions, saying, for example, that while their study has not detected a rise in autism, there could always be a real increase in autism rates, one too small to be detected. But there is no reason to believe that this is so. There a lot of things that could, in theory, exist: alien abductions, secret plots to assassinate Gov. Jodi Rell, powerful healing benefits from eating carpenter ants. But as a rule, we should only believe in them if we have evidence" "not just unproven hypotheses."

Since the rise in "autism" that you are disputing is a proven ten-fold rise from 3 – 4 cases per 10,000 in the late 1980's to 30 –40 per 10,000 in less than a generation, this reviewer would suggest that you delete this misleading and non-relevant discourse.

If you persist in this vein, then, this reviewer warns that you risk destroying what little remaining credibility that you have in the scientific community concerned with these issues; but the choice is yours.

"3: Does the MMR vaccine cause autism?

Subsequent to the seminal article in the *Lancet,* many follow-up studies were performed to see if autism is truly correlated with the MMR vaccine. It is important to note that epidemiological studies cannot prove a cause and effect, that MMR causes autism. They can only show a correlation: When this goes up, so does this. However, if there is true causation, then epidemiological studies should show multiple correlations. For example, autism should go up as MMR vaccinations do, and it should go down when vaccinations go down; they should go up and down predictably over time, depending on when the vaccinations are given; the autism rate and severity should correspond to the size of the vaccine dose. The more these correlations hold up, the greater the case for a cause-and-effect relationship. Finally, of course, biological data should show how MMR might cause autism" "in other words, there should be actual evidence for the 'leaky gut' theory, or some other theory."

"As the follow-up studies started being published, however, it became more and more clear that there was no link between MMR and autism. For example, a study in the *British Medical Journal* found that autism rates continued to climb in areas where MMR vaccination rates were not increasing. Another article there found no association with MMR and autism or GI (gut) disorders. Other studies showed no difference in diagnosis rate of autism either before or after

MMR vaccine, or between vaccinated and unvaccinated children. Most recently, a study found there was no decrease in autism rates following removal of the MMR vaccine in Japan.

In May of 2004 the Institute of Medicine (IOM) reviewed all of the MMR-autism data available to date and concluded that there was no association and that the case is essentially closed" "a conclusion confirmed by still later studies, such as the one in Japan."

"Believers in the MMR-autism hypothesis largely dismiss these findings as biased. They also dismiss the findings of the larger and more powerful epidemiological studies. Bernard Rimland, who leads the Autism Research Institute, rejected the IOM report, writing that the evidence 'does not exclude the possibility that MMR vaccine could contribute to ASD in a small number of children.' Rimland interpreted this as support for a link. Rather, it merely reflects the logical necessity I referred to above: It is impossible to prove a risk of zero.

In May 2004, 10 of Wakefield's co-authors on his original paper withdrew their support for its conclusions. One author, Dr. Simon Murch, stated: 'There is now unequivocal evidence that MMR is not a risk factor for autism" "this statement is not spin or medical conspiracy, but reflects an unprecedented volume of medical study on a worldwide basis.' The editor of *Lancet* also announced that they withdrew their endorsement of the paper, and cited as part of the reason an undisclosed potential conflict of interest for Wakefield, namely that at the time of its publication he was conducting research for a group of parents of autistic children seeking to sue for damages from MMR vaccine producers.

Sadly, the controversy led to decreased vaccination of children in England. There was an increase in measles, mumps, and rubella, each of which can, in rare circumstances, be fatal."

This reviewer's read of your representations is that they are neither fair nor balanced.

However, beyond the general remarks that this reviewer made earlier in this review, this reviewer will leave it up to Dr. Wakefield to respond in detail to the statements you have made here.

Plainly, your mishandling of the facts in your "2: Is there a real autism epidemic?" section compels me to defer to the person most expert in the study of the link between the MMR vaccine and the form of mercury poisoning that is labeled as DSM "autism" or, more recently, "CDER status 1 autism."

From this reviewer's holistic point of view, *where the reality is "repeatedly injecting small but toxic doses of mercury (Thimerosal) cause some to be poisoned to the point that some exhibit the symptoms of mercury poisoning that have been misdiagnosed/labeled as "autism,"* the mercury poisoning inflicted enables the MMR vaccine to cause harm that, *absent the mercury poisoning*, might otherwise <u>not</u> occur.

"4: Does thimerosal cause autism?"

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

You again begin by attempting to understate and minimize reality.

Factually, Thimerosal, sodium ethylmecurithiosalicylate, is a severe poison that is toxic to a wide range of biological pathways where the key regulators contain critical sulfur linkages which tend to be bound by Thimerosal's metabolites, ethylmecurihydroxide and the "inorganic mercury" species into which the biochemical processes in the body convert the ethylmecurihydroxide.

In vitro studies involving growing neurons have established that inorganic mercury is toxic to growing neurites at solution concentrations below 20 parts per billion (20 nanograms per milliliter or gram).

To date, no toxicologically determined safe level has been established for the repeated injection of Thimerosal preparations.

The preponderance of the current data clearly indicates that the safe level for infrequent repeated injection (the vaccine case) is somewhere below 10 nanograms per dose where, for an UNNECESSARY severe poison and, for infrequent injection, a safety factor of 100 may be adequate; for more frequent dosing, the safety factor should be raised appropriately, because the half-life of the "inorganic mercury" species bound up in various organs has been reported to be as long as 27 years.

"However, toxicity is always a matter of dose."

You begin with a statement that is, at best incomplete.

More accurately, the major factors that affect toxicity are:

1. **Specific Dose (dose divided by the weight of the person receiving it),**
2. **Administration route and rate,**
3. **Metabolism**
4. **Intervention**
5. **Co-factors, and**
6. **Half-life.**

"Everything is toxic in some dose; too much Vitamin C can kill you. So the real question is whether the amount of mercury given to children in vaccines containing thimerosal is enough to cause neurological damage."

This reviewer <u>cannot</u> agree with you concerning your "real question**" because your question is, *depending upon your point of view*, either too simplistic, too narrow, or simply the wrong basis question.**

Scientifically, ethically and morally, the *first question* that must be answered about Thimerosal (or, for that matter, any "severe

bio-accumulative poison" like it) and any product that may contain some level of Thimerosal or its equally or more highly toxic metabolite, ethylmecurihydroxide is:

"Is it absolutely necessary to use Thimerosal in the manufacture of this product?"

Only when the answer to this question is "YES" can anyone be truly justified in using this "bio-accumulative severe poison," or any compound like it.

When the answer to the *first question* is "NO," then the use of Thimerosal is UNNECESSARY and Thimerosal should not be used or, *where it is being used*, the Thimerosal should be immediately removed and replaced by an alternative, less toxic compound or compound mixture.

In order to simplify the questions, from here forward, the discussion will be limited to vaccines.

Since the answer to the *first question* is "NO," but Thimerosal (49.55% mercury) has been, and is still being, used, then, *for those who are untroubled by actions that are less than scientifically sound, ethical, and/or moral*, the *second question* that must be answered is:

"Is it legal to use Thimerosal in this process or to have it end up in any medicine, treatment, procedure, or preparation?"

For the answer to that question, we need to ask and truthfully answer other questions.

The *third question* that needs to be answered is:

"Is Thimerosal being used as a preservative in a vaccine?"

If the answer is "YES," then, among other things, the legal requirements for a preservative in vaccines as set forth in 21 CFR 610.15(a) must be satisfied

That regulation states (bolding added for emphasis):

"TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES—

PART 610--GENERAL BIOLOGICAL PRODUCTS STANDARDS

Sec. 610.15 Constituent materials.

(a) Ingredients, preservatives, diluents, adjuvants. All ingredients used in a licensed product, and any diluent provided as an aid in the administration of the product, shall meet generally accepted standards of purity and quality. **Any preservative used shall be sufficiently nontoxic so that the amount present in the recommended dose of the product will not be toxic to the recipient**, and in the combination used, it shall not denature the specific substances in the product to result in a decrease below the minimum acceptable potency within the dating period when stored at the recommended temperature. …"

Thus, the "preservative" issues are:

- ✓ "sufficiently nontoxic" — **the level of non-toxicity must be sufficient, implying the need for a safety factor**
- ✓ "amount present in the recommended dose of the product will not be toxic to the recipient"— **a single-dose must not be toxic to <u>any</u> recipient.**

The only way that these issues can be unequivocally addressed is for the vaccine manufacturer to comply with this binding law.

To do this, the vaccine manufacturer must conduct scientifically sound and appropriate toxicology studies.

Since Thimerosal is a delayed action, bio-accumulative, severe poison, for administration to humans, those toxicology studies must include:

- **Valid acute, intermediate-term and long-term studies, and**
- **Studies in two animal models that have similar sensitivity to mercury poisoning as humans,**
- **One of the two animal models must be a primate species, and**
- **The mode of administration must be the same mode as that intended for the vaccine.**

As far as this reviewer can find, and as FDA officials have repeatedly testified before Congressional committees in this century, these mandatory safety studies have <u>not</u> been conducted by any of the current vaccine manufacturers, or, if these studies have been done, they have been concealed from the FDA.

As recently as an October 5, 2004 House subcommittee hearing, the FDA official testifying admitted that the FDA had no knowledge of any such studies and that the FDA had "grandfathered" the use of Thimerosal – essentially ignoring this clear legal requirement.

Moreover, it has been recently reported that Eli Lilly and Company, *who abruptly exited the vaccines business in "1975,"* had, in 1971, conducted a preliminary (apparently, *in vitro*) study and found toxicity for Thimerosal at 1/100th the preservative level — perhaps one factor in its decision to exit the vaccines business because they "knew" that, at preservative levels, Thimerosal could <u>not</u> meet this legal safety requirement set forth in 21 CFR 610.15(a) which, in 1968, was added to the laws (regulations) governing biological products, including vaccines.

Though this reviewer has been able to independently confirm the report, this reviewer has, as yet, been unable to obtain a copy of the documents to review and must, therefore, defer judgment as to the full impact of the unpublished Eli Lilly study on the "safe" level for Thimerosal.

In any case, a vaccine manufacturer's failure to comply with any applicable law renders that drug "deemed to be adulterated" under 21 U.S.C. 351(a)(2)(B) (bolding added for emphasis):

"**TITLE 21--FOOD AND DRUGS**

CHAPTER 9--FEDERAL FOOD, DRUG, AND COSMETIC ACT

SUBCHAPTER V--DRUGS AND DEVICES

Part A--Drugs and Devices

"Sec. 351. Adulterated drugs and devices

A drug or device **shall be deemed to be adulterated**--

(a) Poisonous, insanitary, etc., ingredients; adequate controls in manufacture

(1) If…; or

(2) (A) if …; or

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

Since the requisite studies have <u>not</u> been submitted to the FDA, then, at present, all lots of Thimerosal-preserved vaccines must be deemed to be adulterated — regardless of the action or inaction of the FDA.

Among other acts, the Federal Food, Drug, and Cosmetic Act prohibits:

- "The introduction or delivery for introduction into interstate commerce of any … drug… that is adulterated …" **[21 U.S.C. 331(a)], and**
- "The manufacture within any Territory of any food, drug, device, or cosmetic that is adulterated …" **[21 U.S.C 331(g)].**

Thus vaccine manufacturers who have failed to prove that Thimerosal is safe are violating federal law by engaging in prohibited acts.

In addition, 21 U.S.C. Sec. 333 establishes penalties for persons engaged in vaccine manufacture as follows:

"TITLE 21--FOOD AND DRUGS

CHAPTER 9--FEDERAL FOOD, DRUG, AND COSMETIC ACT

SUBCHAPTER III--PROHIBITED ACTS AND PENALTIES

Sec. 333. Penalties

(a) Violation of section 331 of this title; second violation; intent to defraud or mislead

(1) Any person who violates a provision of section 331 of this title shall be imprisoned for not more than one year or fined not more than $1,000, or both.

(2) Notwithstanding the provisions of paragraph (1) of this section,\1\ if any person commits such a violation after a conviction of him under this section has become final, or commits such a violation with the intent to defraud or

mislead, such person shall be imprisoned for not more than three years or fined not more than $10,000, or both.

\1\ So in original. Words 'of this section' probably should not appear."

---"

Since each violative lot manufactured or introduced into commerce is a separate violation and the vaccine manufacturers have been violating the applicable law for more than 30 years, the firms are currently facing fines in the millions and possible short-term debarment; and the accountable individuals, when convicted, are facing imprisonment for periods of not less than "three years" and, after conviction, probable permanent debarment.

In summary, the reality is that all of the current Thimerosal-preserved vaccines are adulterated products that cannot legally be distributed – much less legally administered to the public.

Thus, the answer to the "Is it legal?" question for vaccines that use Thimerosal as a preservative is "NO"!

When the answer to *question three* is "NO," the "UNNECESSARY" use or presence of Thimerosal is <u>not</u> for a preservative reason, this reviewer finds that, under "Is it legal?," *question four* should be:

"Are there other compounds, *for the non-preservative use intended*, that, at the levels required for the allowed use, produce less severe or fewer adverse reactions than Thimerosal?

This question arises because 42 U.S.C. 300aa-27(a) states (with bolding added for emphasis:

"TITLE 42 - THE PUBLIC HEALTH AND WELFARE

CHAPTER 6A - PUBLIC HEALTH SERVICE

SUBCHAPTER XIX - VACCINES

Part 2 - National Vaccine Injury Compensation Program

subpart c - assuring a safer childhood vaccination program in united states

Sec. 300aa-27. Mandate for safer childhood vaccines

(a) General rule

In the administration of this part and other pertinent laws under the jurisdiction of the Secretary, **the Secretary shall –**

(1) promote the development of childhood vaccines that result in fewer and less serious adverse reactions than those vaccines on the market on December 22, 1987, and promote the refinement of such vaccines, and

(2) make or assure improvements in, and otherwise use the authorities of the Secretary with respect to, the licensing, manufacturing, processing, testing, labeling, warning, use instructions, distribution, storage, administration, field surveillance, adverse reaction reporting, and recall of reactogenic lots or

> batches, of vaccines, and research on vaccines, in order to reduce the risks of adverse reactions to vaccines."

Thus, this statute, *enacted in 1986*, places a clear duty on the FDA with respect to licensing only vaccines that have reduced "risks of adverse reactions" for any vaccine that may be administered to any child from birth to age 18 and to pregnant women carrying the developing child.

Thus, the only vaccines that would be exempt from this statutory mandate would be those vaccines that cannot, under any circumstances, be administered to children or to pregnant women, including women who do not know they are pregnant.

That the FDA has no latitude in complying with this statutory mandate was clearly established in a unanimous 1988 Supreme Court case, Kevan BERKOVITZ, et al., v. USA [108 S.Ct. 1954, 100 L.Ed.2d 531, 56 USL W 4549 (Cite as: 486 U.S. 531, 108 S.Ct. 1954)], where the Court held that an federal administrator has no discretion in complying with any statute, regulation, or policy that specifically prescribes a course of action for a federal employee to follow.

Since, as you and other readers should know, there are other compounds that can be used in place of Thimerosal as a biocide, *the only other approvable use for Thimerosal*, which, *because they are not the severe allergen that Thimerosal is*, do not themselves elicit the immediate severe adverse reactions (including anaphylaxis and death) at the levels found in vaccines that Thimerosal elicits.

On this basis, the FDA has no legal basis for licensing any vaccine containing Thimerosal at any level where, in some sensitive children or pregnant women, injection of a vaccine containing that Thimerosal carries a risk of triggering severe adverse reactions.

Thus, unless the manufacturer has and submits scientifically sound and appropriate toxicological data that clearly established that, with an appropriate safety factor, the level of Thimerosal, in and of itself, in that vaccine formulation cannot cause an excess of severe adverse reaction over the corresponding effective level of the other less-acutely-allergy-inducing biocides that could be used, the FDA has no authority to continue the license of that vaccine unless there is no other licensed vaccine that does not contain Thimerosal for that disease.

***As far as this reviewer can determine*, the vaccines using alternative biocides, at their typical levels in comparable vaccines, cause fewer and less severe biocide-linked adverse reactions than their corresponding "trace Thimerosal" counterparts (at least for Thimerosal-containing vaccines with Thimerosal levels higher than 0.1 milligram per dose).**

On this basis, it seems to this reviewer that, lacking proof of "fewer and/or less severe" adverse reactions for "trace Thimerosal" vaccines

over their "no Thimerosal" counterparts, most of today's "trace Thimerosal" vaccines are not legal.

Further, absent the requisite acute comparative toxicology studies that show that today's "trace Thimerosal" have no higher rate of adverse reactions or no more severe adverse reactions than a comparable formulation using some alternative biocide, it is not legal today for a vaccine to contain Thimerosal as a "processing-related impurity," its classification when it is not present at a preservative level.

Therefore, we are faced with the following realities:

- **For all of the "Thimerosal preserved" vaccines, the vaccine manufacturers have been, are, and are prepared to continue, knowingly violating the law (and our government has decided to forget about protecting the public health as the law requires and to knowingly let the vaccine manufacturers "get away with" violating 21 CFR 610.15(a)), and,**
- **For "trace Thimerosal" vaccines, the FDA has been, is, and is prepared to continue, forgetting about the statutory mandate to protect the health of our children and knowingly violating a clear statutory mandate, and, ignoring the Supreme Court, the Department of Justice continues to ignore the FDA's knowing failure to follow a clearly prescribed course of action.**

Dr. Novella, do you see anything wrong with this picture?

Hopefully, you do at least recognize that knowingly breaking the law is a crime.

Factually, this reviewer has established that, ethically, morally, and legally, there seems to be no justification today for the use of Thimerosal in vaccines.

Having determined that there does not seem to be any legal basis for the ongoing use of Thimerosal in vaccines, let us return to the review of your statements.

"So the real question is whether the amount of mercury given to children in vaccines containing thimerosal is enough to cause neurological damage. On this question, there is much controversy."

Contrary to your assertions, based on the preponderance of the credible toxicological evidence, there is no scientific toxicological doubt that "the amount of mercury given to children in vaccines containing thimerosal is enough to cause neurological damage**."**

The only "controversy" this reviewer finds is the controversy generated by government, pharmaceutical industry, "conflicted" academics (such as you appear to be) and certain healthcare professionals who either have

not studied or have studied, but refuse to accept, the findings of the body of scientifically sound toxicological evidence on the issue of the insidious delayed poisoning of a variety of biological pathways in primates and the data from "accidental" (e.g., the Iraqi incidents) and deliberate (e.g., the Japanese "Minimata" incidents) human poisoning incidents.

"Proponents of the mercury hypothesis argue that the ethylmercury found in thimerosal was given in pulse doses (all at once) exceeding EPA limits."

Not understanding the chemistry involved and continually trying to distort the positions of those who know that repeatedly injecting Thimerosal (49.55%) poisons all that are injected to some degree into what you now label the "mercury hypothesis**," you persist in making unqualified statements that distort reality to suit your views.**

Accurately, the scientific proponents for mercury-free drugs assert:

- **Before and/or shortly after the injection (by definition a "bolus" dosing) of a Thimerosal-containing preparation (vaccine), the Thimerosal (49.55% mercury) in the preparation has already been "partially" converted into, and/or is rapidly "quantitatively" converted, into the initial mercury-containing metabolite, ethylmecurihydroxide.**
- **Because the resultant ethylmecurihydroxide is a small molecule that has a higher affinity for "fat" than "water," the ethylmecurihydroxide crosses all barriers (e.g., blood-brain, placental, gut) and preferentially accumulates in "fatty" tissues, like the brain and fatty layers, like those that coat our nerves. [Note: Experimental studies in mammals and studies of humans poisoned in exposure incidents have confirmed these findings.]**

Based on:

- **The published baby monkey study by Burbacher et al (which found, *for "equal" "preservative level" doses of injected Thimerosal and ingested methylmecurihydroxide*, the level of the final metabolic product "inorganic mercury" [the actual long-term neural poison] in the group of monkeys injected with Thimerosal was, on average, more than twice that found in the matched group of monkeys fed methylmecurihydroxide),**
- **The recent environmental studies that: a) revisited the studies that the EPA used in the 1970's to establish its estimated toxic minimum daily dose (1 microgram/kg/day, and b) found that that the EPA's toxic level estimate of 1 microgram of mercury per kilogram of body mass per day (their estimate without a safety factor) was two to ten times too high (indicating that, *even in mercury-toxicity-resistant population the EPA used to estimate the basis toxicity*, the basis toxicity for ingested "methyl mercury" in fish is somewhere between 0.5 microgram of mercury and 0.1 microgram of mercury/kilogram (kg) of body mass/day or, with a 10-fold safety**

factor, the EPA's recommended daily intake should be revised to be between 0.01 microgram and 0.05 micrograms of mercury per kg/day,

- **IF the EPA basis could be accurately corrected, THEN a safety factor of "100" for Thimerosal should be sufficient because Thimerosal is <u>not</u> a NECESSARY component, and**
- **However, though this reviewer knows that the EPA basis is 2 to 10 times too high but, as the review authors, <u>cannot</u> judge what the correct divisor should be, this reviewer has elected not to attempt to correct the EPA toxicity basis value but rather to use a safety factor of "500" to address the recent findings,**

the safe level for injected Thimerosal should be less than 0.001 micrograms of Thimerosal mercury per kg per day.

Using a minimum baby weight of 2 kg for the newborns who <u>should</u> be receiving their "0 day" Hepatitis B vaccination, the estimated safe level in that would be < 0.002 micrograms (µg) of mercury from Thimerosal.

Considering a 2-kg newborn receiving the Hepatitis B vaccine that still contains Thimerosal, GlaxoSmithKline's Engerix® B (that is represented to contains <0.5 µg Hg/0.5mL dose), that vaccine exceeds this reviewer's estimated safe level by 250 times.

Even if we accept the EPA's recommended 0.1 µg Hg/kg/day and only apply a correction factor based on the findings of Burbacher et al, the "less safe" Thimerosal basis factor is < 0.05 µg Hg/kg/day which, *for a 2 Kg newborn*, the Energix B injection still exceeds that "safe" level by a factor of 5.

Thus, *whichever of the defensible choices you elect to take*, the results indicate that, *for this "trace Thimerosal" vaccine*, the amount of mercury injected at birth exceeds the toxic level for this "2-kg newborn" by a factor of from "5" to "250."

Therefore, QED: For newborns weighting 2 kg (4.4 pounds), the mercury in the Energix B vaccine dose exceeds the Thimerosal's recommended daily intake limit (based on the EPA value for methyl mercury, the work of Burbacher et al, the recent review of the EPA's basis assumptions, and, respectively, a) a safety factor (10) appropriate for an unavoidable risk and b) a safety factor appropriate to poisons that are not required to be present) by 5 to 250 times.

"This load of mercury should be added to prenatal vaccine loads possibly given to mothers, and to other environmental sources of mercury, such as seafood."

Given a 20 to 30 year half-life for the "inorganic mercury" (the mercury compounds that are responsible for the delayed-onset, long-term toxic effects observed) "sequestered" in the brain, this reviewer agrees with you, each dose ("load**") of mercury administered "**should be added to prenatal

vaccine loads possibly given to mothers, and to other environmental sources of mercury, such as seafood**," water, air, and other foods.**

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

Here, this reviewer finds your statement confusing to the average person and would suggest that this sentence be revised to read:

"Since the dose (volume) of vaccine is not adjusted for the weight of the person receiving it and toxicity parallels the specific dose (dose per kilogram of mass), the risk of poisoning increases as the weight of the individual being inoculated decreases.

In addition, because the immune system's components, like those of the body's other more complex systems, only begin to mature as the fetus approaches the end of the gestation period, the risk of a clinical mercury poisoning outcome is increased for premature infants."

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

Here, your statement is again too simplistic and misleading.

Rather than deluge you with pages of documents that support the statements being made, this reviewer has chosen to attach a "pdf" file, 050821saveof_200x_BoydEHaleySlidesOnGenetic&OtherAggravatingFactors-HgPoisoning, from Dr. Boyd E. Haley, of 17 slides from his presentation, titled, "MERCURY TOXICITY: GENETIC SUSCEPTIBILITY AND SYNERGISTIC EFFECTS" by DR. BOYD E. HALEY, PROFESSOR AND CHAIR, DEPARTMENT OF CHEMISTRY, UNIVERSITY OF KENTUCKY**," that supports this reviewer's answers here. [Slide 01]**

To assist you in assessing this reviewer's remarks, the supporting slide number "nn" will be placed in bolded brackets at the end of each statement that this reviewer makes in addressing factors that affect a person's "susceptibility" to being poisoned by doses of Thimerosal. [Slide 01-17]

Factually, there is a body of evidence that demonstrates that from birth, the mercury excretion (detoxification) capabilities of babies differ. [Slides 03, 04]

Obviously, people of all ages who have reduced mercury excretion capabilities have a bigger risk of becoming mercury poisoned. [Slides 03, 12, 14]

However, absent additional mercury exposure, there is no added mercury poisoning. [Slide 14]

"But wait. Ethylmercury, the form of mercury found in thimerosal, is not as toxic as methylmercury; the EPA limits were based upon the more toxic form, and had a built-in safety margin. Recent studies also show that ethylmercury is removed more quickly than methylmercury and probably does not build up in the body, so doses would not have a cumulative toxicity."

Here again, you seem to have confused more rapid metabolism (dealkylation) with the build up of the species "bound inorganic mercury" responsible for the long-term poisoning observed.

Contrary to your misrepresentations, the sound toxicological studies that have looked at any the clinical toxicity of some "ethylmercury" compound versus some comparable "methylmercury" compound have found that the gross toxicities of these two series are similar[8,9,10].

In a recent study[11], Burbacher et al performed a comparative dosing and half-life study using baby monkeys and studying low-dose injected Thimerosal in vaccines as compared to ingested methylmecurihydroxide solutions.

The most important finding in that study is that for the same doses, the level of residual "inorganic mercury" trapped in the brains of the Thimerosal-injected monkeys (ThHg) was, on average, more than twice that found in the brains of the methylmecurihydroxide (MeHg) fed monkeys. [Note: The level of inorganic mercury in 7 of the MeHg monkeys was below, the MeHg-inorganic (n=10) ≈ 5.7 ng/g and the estimated level for the inorganic mercury was ThHg-inorganic (n=17) ≈ 12.3 ng/g (estimated from the graphs since the values were not reported). The true "ThHg-inorganic / MeHg-inorganic" ratio is obviously larger, or a "ThHg-inorganic / MeHg-inorganic" ratio of ~ 2.2. If the missing values were taken to be 0 ng/g, then the ratio ThHg-inorganic / "MeHg-inorganic" would be about ~ 12.3 to "~ 3.69" or " ~ 3.3." Thus, the true "ThHg-inorganic/MeHg-inorganic" ratio is between "~ 2.2" and ~ 3.3."]

On balance, the long-term clinical toxicity of Thimerosal's initial metabolite, ethylmecurihydroxide seems to be more than twice as toxic as the long-term toxicity of ingested methylmecurihydroxifde.

Finally, you have not cited any study that proves your premise and the applicable published studies that this reviewer has studied require this reviewer to reject your unsubstantiated premise, "Ethylmercury… is not as toxic as methylmercury**."**

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[8] K. A. Winship, "Organic mercury compounds and their toxicity," ***Adverse Drug Reaction Acute Poisoning Review***, **3**, pages 141-180 (1986).

[9] Laszlo Magos, A. W. Brown, S. Sparrow, E. Bailey, R. T. Snowden and W. R. Skipp, "The comparative toxicology of ethyl- and methylmercury." ***Archives of Toxicology***, **57**, pages 260-267 (1985).

[10] Leander Tryphonas and N. O. Nielsen, "Pathology of Chronic Alkylmercurial Poisoning in Swine," ***American Journal of Veterinary Research***, **34**(3), pages 379-392 (1973).

[11] Thomas M. Burbacher, Danny D. Shen, Noelle Liberato, Kimberly S. Grant, Elsa Cernichiari, and Thomas Clarkson, "Comparison of Blood and Brain Mercury Levels in Infant Monkeys Exposed to Methylmercury or Vaccines Containing Thimerosal," **Environ Health Perspect 113**, pages **1015-1021 (2005).**

"Plus, it seems that children have a greater capacity to metabolize mercury than adults."

Since this reviewer is unaware of any comparative capacity study that addresses the overall metabolism differences for mercury in an unspecified age range of "children**" to an unspecified age range of "**adults**," this reviewer respectfully requests you to furnish the reviewer with the peer-reviewed published article or articles that supports your assertions.**

Absent these studies, this reviewer must remain skeptical of your assertion here.

"There are other data and arguments, too complex to explain here."

Since this reviewer is not privy to the data and arguments of which you speak, this reviewer obviously <u>cannot</u> reject your assertion.

However, Dr. Haley's slides present a clear picture of the synergistic effects of other chemicals, including aluminum salts, antibiotics and testosterone that increase Thimerosal's toxicity and/or allude to a protective chemical, estrogen.

In addition, his slides clearly document the ongoing mercury poisoning that dental amalgam fillings may be inflicting upon those who have them.

Hopefully, the readers and you will find that Dr. Haley's slides adequately address the issues that you did <u>not</u> discuss.

"The bottom line is this: Yes, there is reason to believe that thimerosal, in sufficient doses, could be toxic and cause neurological damage."

In spite of the hundreds of thousands to millions of today's children exhibiting one or more of the symptoms of mercury poisoning and the hundreds of children whose primary DSM "autism" diagnosis has, after appropriate testing for proof of mercury or other heavy metal poisoning, been changed to "mercury intoxication" or "heavy metal intoxication," you have the temerity to only claim that Thimerosal "could be toxic and cause neurological damage**."**

Except for those who are, *for whatever reason*, deaf, dumb, and blind to the sea of mercury-poisoned children around them, *as you seem to be*, those scientists who, like this reviewer,

- **Have studied the applicable scientifically sound toxicological and medical literature and**
- **Have looked at these children and listen to those who speak for them because they are unable to speak, and**
- **Now speak out against an establishment that is, by choice, deaf, dumb, and blind to the catastrophic genocidal harm inflicted on the American public by the insidious severe poison, Thimerosal**

(49.55% mercury) knowingly concealed in some of the vaccines that are falsely touted as the safest drugs that medicine provides,

know that Don Imus is understating the magnitude of the harm when, as you put it, he rages against "a horrific crime against humanity**."**

As this reviewer and other scientists know, the real bottom line in America is:

- **All drugs that contain mercury should be immediately pulled from circulation and destroyed, and the use of mercury in all drug processes and dentistry totally banned;**
- **The:**
  - **DHHS, NIH, CDC, and the FDA should be immediately overhauled,**
  - **Mission of these agencies should be changed to only protecting the health of the public,**
  - **Managers having any culpability for this** "horrific crime against humanity" **should be prosecuted to the full extent of the law, and**
  - **Federal government should form and unleash a joint FBI/DOJ RICO taskforce on all firms, healthcare provider, and responsible persons who may be or are directly or indirectly involved in or have, in any way, aided this** "horrific crime against humanity"**;**
- **Any companies, and their senior managers who run them, who are found to have been and are, directly or indirectly, involved in or who profit from this genocidal poisoning of us all, should be prosecuted in the manner this reviewer has previously outlined and the money penalties assessed dedicated to helping heal those who have been mercury poisoned; and**
- **The federal and all state governments should:**
  - **Declare a medical state-of-emergency and provide, at no cost, the best proven curative therapies to all those who have been clinically mercury poisoned by vaccine programs that it recommended or mandated;**
  - **Outlaw the use of mercury in dentistry;**
  - **Declare a dental state-of-emergency, and**
  - **As rapidly as possible, provide free replacement of any dental amalgam filling with either a composite or, if the cavity is large a suitable inert porcelain or base-metal crown at no cost to any American citizen;**

    and
  - **Formally apologize to the American people for its complicity in the genocidal poisoning of us all.**

"But the best data we have so far indicates that thimerosal probably was not given in high enough dose to be neurotoxic, although there is room for reasonable doubt. So, given the uncertainty, the FDA did recommend the removal of thimerosal from childhood vaccines, and by 2002 the removal was complete, although it is still found is some flu vaccines and some multi-dose vaccine vials exported outside the United States."

Given that the facts, *which this reviewer has presented*, have already refuted the statements you make here, this reviewer sees no need to again review your less than accurate statements here.

"In any case, the biological data can illuminate a possible mechanism of damage, but it can never, by itself, prove that thimerosal actually did cause autism. That evidence must come from epidemiological studies. In other words, we need not only a theory of how thimerosal might be able to cause autism" "we need numbers to show that where there was thimerosal, there was autism. We always need both."

Again, you have gotten it backwards.

When there are valid appropriate animal-model experimental studies and in-depth patient studies, and the cause is found by experimental testing and/or experimental treatment studies that prove "A" causes "B," or, as is the case here, "repeatedly injecting poisonous doses of Thimerosal (49.55% mercury)" causes "mercury poisoning to the point that some exhibit the symptoms of clinical mercury poisoning," there is no need for any epidemiological study to confirm what experimental science has established is factually the case.

Moreover, your statement "We always need both," is not only false but also scientifically absurd.

Since you claim science is the tool that needs to be used, then this reviewer suggests that, *based on your statements*, you need to go back to school and learn to properly use science.

"At the time of the IOM review in 2004, there were five published epidemiological studies on thimerosal and autism that showed no link. Together, they provide strong evidence that thimerosal does *not* cause autism. Subsequent to the IOM report, there has been one additional published study, for a total of six, from Great Britain, the United States, Sweden and Denmark, all showing a lack of correlation."

First, no matter whether the study designs are valid or not, the findings of epidemiological studies outside the U.S. that address different countries' populations, countries with significant to overwhelmingly lesser levels of maximum exposure and different exposure patterns (vaccination schedules) cannot validly be used to draw any compelling conclusions about epidemiological associations in the U.S. population.

Since five of the six studies are from population groups in countries (Great Britain, Sweden and Denmark) that have a lower (Great Britain; about half)) to a drastically lower (Denmark and Sweden; less than a third) levels of maximum Thimerosal exposure and all these countries have a significantly different dosing pattern than the dosing regimen recommended in the United States – ones that, in general, delay dosing so that:

- **The immune systems of their children are more mature and,**
- **For a given dose, the specific dose is lower because the timing delay makes their children older and, on average, older children weigh more,**

none of the findings from these five foreign epidemiological studies, even if the study designs and the study executions were scientifically sound, can validly be applied to judging the probability of a link of any kind in the U.S. population.

That having been said, qualified independent biostatisticians and lay scientists (like this reviewer), have reviewed the five foreign-population studies you cite and found that their study designs were flawed and that, in addition, their authors had significant concealed conflicts of interest that tainted the design of these studies outside of the United States.

Moreover, as far as this reviewer can ascertain, the authors have refused to make the original data available for independent age-range-corrected incidence-based epidemiological evaluation of the original datasets.

For these reasons, this reviewer must, on the scientific grounds declared, dismiss those foreign studies because they are not germane to the U.S. population's experience and, therefore, neither the IOM nor you can validly represent these foreign epidemiological studies as being relevant.

This leaves you and the IOM with the multi-iterated U.S. epidemiological studies, the so-called "Verstraeten Studies" on the "VSD Datalink database.

Except for the initial screening "Generation Zero" study, all of the subsequent "Verstraeten" iterations are scientifically unsound because they violate the primary rules of epidemiological study that explicitly prohibit the type of iterative adjustment of the datasets designed, *as the e-mails among the study members clearly show*, to adjust the decision bases and datasets until the desired odds ratio is obtained (in this case, the goal was to reduce the odds ratio for the odds of a causative "link" between Thimerosal dose and the risk of "autism," a "disorder" label used by the medical community to obscure the real risk, mercury poisoning).

If you want to see the "Generation Zero" odds ratio, you should visit the SafeMinds website (http://www.safeminds.org/) and read the findings reported there.

Unfortunately, apparently fearing the exposure of their treachery and scientific wrongdoing, some person or persons "lost" the original VSD Datalink datasets making it impossible to replicate their initial "Generation Zero" study or any of their subsequent iterations of the original datasets they used.

Based on the current state of affairs with respect to the Verstraeten Studies, this reviewer, and other scientists who respect adherence to the ethical practice of science's various disciplines, must reject the published findings because: a) they cannot be replicated and b) they are clearly the fruit of the unethical pseudo-scientific manipulation of the datasets and criteria designed to force the results that the "study's researchers" wanted to find.

Though there are many duplicitous examples that this reviewer could cite, the following three (3) are sufficient to illustrate this reviewer's points:

1. **The study group artificially set the 12.5 microgram dose as the "0" point**
2. **To further reduce the chance of finding a dose related effect, they then artificially truncated the maximum dose in the study at 62.5 micrograms when documented doses exceeding 200 micrograms were being administered.**
3. **Though their data tables showed that more than 80% of the confirmed DSM "autism" cases were male, they did <u>not</u> exclude females from the datasets when supposedly looking for the link between "Thimerosal dose administered" and "the risk of being diagnosed with DSM 'autism' subsequent to receiving a given total Thimerosal dose."**

Hopefully, you now understand that the <u>published</u> "Verstraeten Studies" are, from the point of view of sound science, the tool you claim must be used, <u>not</u> worth the paper they are written on.

"These studies were meticulously reviewed by Sarah Parker and others, who published their conclusions in the prestigious journal *Pediatrics* in September 2004."

While this reviewer does not doubt that Dr Parker and her colleagues "meticulously reviewed" the studies in question, this reviewer doubts that those who performed their reviews did so without predetermined goals firmly in mind and, *since none of the authors seem to be qualified biostatisticians nor could have reviewed the underlying datasets*, is compelled to question the scientific soundness of the reviews conducted.

In addition, based on the limited information on Dr. Parker's background, she most certainly does not seem to be a qualified biostatistician.

As to the prestige of the journal *Pediatrics*, this reviewer notes that, in spite of the unethical listing of Dr. Verstraeten as an employee of the CDC when Dr. Verstraeten had, in fact, been an European employee of the

vaccine manufacturer GlaxoSmithKline long before the final manuscript was accepted for publication, *Pediatrics* elected to publish, "Thomas Verstraeten, Robert L. Davis, Frank DeStefano, Tracy A. Lieu, Philip H. Rhodes, Steven B. Black, Henry Shinefield and Robert T. Chen; for the Vaccine Safety Datalink Team, 'Safety of Thimerosal-Containing Vaccines: A Two-Phased Study of Computerized Health Maintenance Organization Databases,' Pediatrics, 112(5), pages 1039-1048 (2003)," without disclosing his true employer or his obvious conflict of interest – to say the least, certainly not the ethical actions expected of a reputable journal or an ethical author.

"Parker also reviewed the only epidemiological studies that claim to show a link. They are all published by the same authors, the father-and-son team of Mark and David Geier. Parker and her coauthors concluded that these studies contained fatal methodological flaws rendering their conclusions either invalid or uninterpretable."

Since this reviewer has read and studied several of the Geiers' publications, including:

- **Mark R. Geier and David A. Geier, "Neurodevelopmental Disorders after Thimerosal-Containing Vaccines: A Brief Communication," Society for Experimental Biology and Medicine, pages 660-664 (2003).**
- **Mark R. Geier and David A. Geier, "Thimerosal in Childhood Vaccines, Neurodevelopmental Disorders, and Heart Disease in the United States," Journal of American Physicians and Surgeons, 8(1), pages 6-11 (2003).**
- **David A. Geier and Mark R. Geier, "An assessment of the impact of thimerosal on childhood neurodevelopmental disorders," Pediatric Rehabilitation, 6(2), pages 97-102 (2003).**
- **David A. Geier and Mark R. Geier, "A comparative evaluation of the effects of MMR immunization and mercury doses from thimerosal-containing childhood vaccines on the population prevalence of autism," Medical Science Monitor, 10(3), pages P133-P139 (2004).**

this reviewer, *recognized by some in the FDA as having a fundamentally sound understanding of statistical sampling and the statistical analysis of large populations*:

1. **Found no apparent serious, much less fatal, flaws in the epidemiological studies they published,**
2. **Notes that the journals in which these articles were published are peer-reviewed journals, and**
3. **Reports that the Geiers published, "David A. Geier and Mark R. Geier, 'A two-phased population epidemiological study of the safety of thimerosal-containing vaccines: a follow-up analysis,' Med. Sci. Monitor, 11(4), pp. CR160-170 (2005)," a follow-up analysis on their 2004 Medical Science Monitor publication which not only confirmed their finding in the VAERS database but a similar study**

on the VSD Datalink database also confirmed their original findings, and

4. **Observes that, for research medical scientists, the journal Medical Science Monitor, founded and supported by Eli Lilly and Company, is recognized as a reputable journal.**

Thus, this reviewer finds no credible evidence that the Geiers' published studies contained "contained fatal methodological flaws**."**

"Their final conclusion echoes the IOM report: 'Studies do not demonstrate a link between thimerosal-containing vaccines and [autism], and the pharmacokinetics of ethylmercury make such an association less likely. Epidemiological studies that support a link demonstrated significant design flaws that invalidate their conclusions.'"

Because the initial charge given to the IOM committee by the CDC as reflected in the transcript of the 2001 IOM's initial closed-door meeting clearly instructed the committee members to do essentially whatever is necessary to debunk the link between Thimerosal dose and the form of mercury poisoning labeled "autism," this reviewer is compelled to totally discount the findings reported in the reports issued by both the 2001 IOM and the follow-up 2004 IOM committees.

"To date there is not one well designed, peer-reviewed study that shows there is a link. Again, there still *could* be a link, but we have no reason to believe there is."

Contrary to your views, factually, *if it could be replicated*, the initial VSD Datalink database "Generation Zero" study and the Geiers' published studies, including their recently published one that studied the VSD Datalink database all probabilistically show "there is a link**."**

Moreover, toxicological and biochemical studies and analyses have clearly established proof that repeatedly injecting the slow-acting, bio-accumulative, severe poison, Thimerosal, into children causes some to become clinically mercury poisoned

"For the vaccine, autism-research and medical communities, the scientific case was all but closed."

Since this reviewer is a member of "the vaccine," "autism research," "regulatory compliance," and "analytical science" communities and works with several like-minded members of the "medical" communities, as this review of your commentary clearly establishes, the scientific case for injected Thimerosal causing mercury poisoning has been rapidly growing over the past six years and is continuing to grow – fed by the fertilizer that rains down upon it from the establishment and their well-compensated apologists.

Hopefully, after studying the information provided by this reviewer, you will clearly understand that the biological, toxicological, and case research has

already proven that repeatedly injecting Thimerosal-containing preparations mercury poisons all of that population to some degree and mercury poisons some to the point that they exhibit the symptoms of mercury poisoning that doctors, such as yourself, persist in labeling some "disorder," "syndrome" or "disease" that has no readily apparent or proven cause.

"But this has not ended the public controversy. Parent groups such as Moms Against Mercury and Safe Minds have not accepted this consensus. Critics like Kennedy continue to argue that the studies debunking a link are not reliable."

Again, you distort the facts by speaking of a non-existent "consensus**" and ignoring the fact that Mr. Kennedy is simply reporting the proven factual reality that the debunked studies are either not applicable to the U.S. experiences (the studies involving populations from the U.K., Sweden and Denmark) or not scientifically sound (the published U.S. Verstraeten study findings).**

"**5: Conspiracy Theories**

If the scientific data shows, according to a solid consensus of scientific opinion, that there is no reliable evidence for an autism epidemic, and that there is no statistical correlation between MMR and GI symptoms or autism, or between thimerosal and autism, how do believers maintain their claim?"

Since you begin with a false conditional premise, "If the scientific data shows… that there is no reliable evidence for an autism epidemic …**," the rest of your statement is meaningless.**

Having seen no poll of independent scientists who have no conflict of interest that could be clouding their judgment and being one of those scientists, this reviewer must dismiss your "solid consensus of scientific opinion**" as a fabrication that you have created to support: a) your position and b) the position of the establishment that seems to be employing you.**

Moreover, your question again betrays your feigned commitment to science when it lapses into realm of the religious and asks "how do believers maintain their claim?**"**

Were you a scientist, you would <u>not</u> have asked that question, but would have long ago accepted that the scientists, *whose position you seek to belittle*, might be correct and asked them, "What is the scientific evidence that has lead to your hypothesis and how are you testing its validity?"

If you were a scientist, you would have questioned why establishment scientists have refused, or been unable, for more than 30 years to conduct the requisite scientifically sound and appropriate toxicological studies to prove whether or not repeatedly injecting Thimerosal preparations does, or does not, cause some to be mercury poisoned to the point that they exhibit the clinical symptoms of mercury poisoning.

You, as this reviewer did, would have asked, "Why has the establishment 'dragged its feet' for more than 30 years rather than conducting and publishing the findings from the requisite toxicological studies?"

Had you asked that question, you might have found the answer be, *as a recent report asserts*, Lilly found that Thimerosal was toxic at 1/100th of the preservative dose in 1971 and, *probably to avoid liability*, exited the vaccines business, but, *to continue profiting from the licensing royalties it receives*, hid that information from the FDA and the public?

"Mostly by dismissing the scientific consensus as a result of bias, of conspiracy and of influence from the pharmaceutical industry."

Since:

- **Scientifically sound toxicological evidence, biological research, and case studies have established: "Repeatedly injecting toxic doses of a delayed-onset, bio-accumulative, severe poison, Thimerosal (49.55% mercury), mercury poisons those so injected to the point that some show the symptoms of clinical mercury poisoning," and**
- **Independent scientists and investigative researchers have established:**
  - **The epidemiological studies attacking this scientific reality are either <u>not</u> relevant and fatally flawed or intentionally biased, and were conducted by persons who had clear conflicts of interest that they concealed [clear proof of bias],**
  - **In knowing violation of the law, the pharmaceutical industry, government, and their paid "consultants" repeatedly held illegal meetings where the public was excluded and the participants "decided" how the obvious epidemic increase in harm would be "handled" and "concealed" from the public [clear proof of collusion and influencing],**
- **The history of the "handling" of Accutane, Vioxx, Bayxcol, and … as well as the effectiveness of the pharmaceutical industry "lobby" ability to "buy" influence and get legislation enacted that plainly puts the profit-making interests of the pharmaceutical industry above public health clearly indicate, the pharmaceutical industry's influence and greed-driven practices have successfully overcome and/or subverted the legislators and agencies, (who are supposed to regulate the pharmaceutical industry's activities in a manner that places protecting public health and safety above all other considerations) [proof of pharmaceutical industry influence],**

those Americans who have not yet been not subverted and/or severely mercury poisoned should reject your imagined "scientific consensus**" based on the documented factual evidence that proves that this "**consensus**" is built on a foundation of documented deceit, lies and corruption, which, by espousing this "**consensus,**" you seem to be actively supporting.**

"In the case of thimerosal and autism, believers argue that the FDA, CDC, IOM, the World Health Organization (WHO) and the American Academy of Pediatrics (AAP) are all involved in the cover-up: the FDA and CDC in order to hide their prior incompetence; the AAP because they cannot accept the horrible notion that vaccines could be harming children; the IOM, simply to please the CDC; and the WHO" "well, who knows, but all of them are influenced by the powerful pharmaceutical industry, whose only motive is to protect their profits."

Your initial "believers argue**" rhetoric again betrays your divergence from science – the tool you have posited is the one that must be used.**

Why is that?

Moreover, though you seek to dismiss them, you lay out, albeit inexactly, logical motives for the conduct observed for the agencies and industries that you and/or this reviewer have mentioned:

- **The CDC and the FDA** – **"**the FDA and CDC in order to hide their prior incompetence **— for it is human nature to want to hide your mistakes,**
- **The "**American Academy of Pediatrics (AAP)**"** – **"**the AAP because they cannot accept the horrible notion that**" they were and are harming children when they injected them with Thimerosal-containing vaccines that they now, at some level, have been mercury poisoning the children they took an oath not to harm – and thereby** – **"**harming children**" — for there are very few Josef Mengeles among pediatricians — even though the collective harm they have been and are participating in dwarfs, by orders of magnitude, the documented horrors of the infamous Dr. Josef Mengele,**
- **The Institute of Medicine (IOM)** – **"**the IOM, simply to**" fulfill the "outcome-expectation terms" in their contract with "**the CDC**" — since there are others in the advising government business, the IOM wanted to keep the CDC happy so that they would keep the CDC as a client,**
- **The pharmaceutical, medical, and healthcare industries – whose motives are "**to protect**" and, *by creating more patients*, increase** "their profits" **while protecting themselves from being held to account for the knowing harm they have and are causing, and**
- **The World Health Organization (WHO) to protect its reputation and itself (its very existence) from the backlash of emerging world and third-world action were it to be known that medicines, vaccines laced with concealed poisons, touted by the WHO as "the safest" and "lifesaving" were, in fact, "poisonous" and "life taking."**

"Josh Day, writing on the *Health and Beyond* website, captures the conspiracy attitude when he writes, referring to a CDC meeting at a site called Simsonwood, 'In a chilling Wannsee conference-style meeting, top brass in the pharmaceutical empire, FDA and CDC lackeys, and their scientist dogs have concocted their own Final Solution in "handling" the thimerosal problem.

These men met and decided to cover up a study that proved a connection between thimerosal and autism, as well as other serious disorders.' In other words, the CDC are like Nazis."

First, other than the rhetoric and the Nazis references, are not the facts correct?

Was not Simpsonwood the site of the 2000 meeting?

Wasn't the gathering a "conference-style meeting"?

Didn't the "top brass**" (key persons) "**in the pharmaceutical empire**" (industry),** "FDA and CDC lackeys" **(administrators deferential to the industry),** and their scientist dogs" **(CDC researchers and paid consultants) meet and decide "**to cover up a study that proved a connection between thimerosal and autism, as well as other serious disorders**"?**

Moreover, why have you failed to bring up and address their previous closed meeting, The NVAC's "Workshop on Thimerosal in Vaccines," held on August 11—12, 1999 in the Lister Hill Auditorium in Bethesda, Maryland where a similar group met and proceeded to suppress their discussions and findings?

Doesn't the "1999 Lister Hill" add to the pattern of conduct that substantiates the reality that there has been a concerted effort to manage and cover up the epidemic rise in clinical mercury poisoning cases in America?

"Now, to be fair, there are legitimate factors that have helped foster conspiracy theories. The CDC, for example, has made many statements that suggested they were trying to 'manage' the perception that vaccines are unsafe. They have also tried to hide preliminary evaluations of their data. Many of the experts at the CDC and FDA have ties to the pharmaceutical industry, have potential conflicts of interest, or even go back and forth between industry and government. These are all legitimate concerns, but they do not necessarily add up to a conspiracy."

First, this reviewer is glad to see that you admit that there is evidence of less than professional behaviors and incestuous relationships that, at a minimum, do add up to collusion among the parties – if not conspiracy.

In addition, CDC officials have repeatedly knowingly made false and misleading statements to the public and, in legislative hearings, to state legislators concerning the presence of Thimerosal in vaccines and the disease incidence and outcome numbers they speak of to the public.

Further, when confronted with proof of their misstatements and forced to admit they had lied, some of these CDC officials have tried to justify their actions by saying that, *because they were responsible for promoting the vaccination program*, they were justified in lying if the lie helped promote vaccination [the <u>end</u> (promoting vaccination) <u>justifies</u> <u>the</u> <u>means</u> (e.g., knowingly and deliberately lying to the American public about the annual disease rates, outcomes and outcome rates observed, and claiming

that Thimerosal had been removed from all childhood vaccines when they knew that it had not)].

Moreover, your rhetoric here supports:

- **The Robert F. Kennedy, Jr. statement you previously included in this opinion piece:**

  "Robert Kennedy Jr. writes, 'The story of how government health agencies colluded with Big Pharma to hide the risks of thimerosal from the public is a chilling case study of institutional arrogance, power and greed.'"

- **The reality that Mr. Kennedy's remark was a fair assessment of reality.**

Finally, this reviewer notes that you are the person who framed the present discussion in terms of "Conspiracy Theories" and, as Mr. Kennedy's statements show, not those who have studied the real issues.

"Let's look closer at the situation. The CDC is responsible for running, and therefore promoting, the vaccine program in the United States. They are also responsible for monitoring its safety. Some have argued that this is an inherent conflict of interest, and they have a point. For this reason, and in response to criticism, these two functions were recently separated at the CDC."

While this reviewer finds that your statements here represent the general course of reality, he notes that the budget for promoting vaccination is still more than an order of magnitude larger than the budget for ensuring that vaccines are safe.

In addition, this reviewer has seen no action by the CDC to experimentally determine what the safe level for Thimerosal is in each vaccine.

"But the CDC has to deal with a very serious dilemma. Anything that serves to undermine public confidence in the safety of vaccines may decrease compliance and thereby increase the rate of preventable diseases, causing harm and even death. In other words, if people begin to doubt vaccines, children may die.

Here, you strain at the proverbial gnat and swallow the camel.

As some of this reviewer's medical colleagues have warned the CDC and the FDA, the CDC's and the FDA's failure to be truthful has done and, since the CDC and the FDA are continuing to hide the truth, is doing more "to undermine public confidence in the safety of vaccines**" than the worst-possible truth (Thimerosal-containing vaccines have clinically mercury poisoned more than one child in six born between 1986 and 2005).**

This is the case because the American people can deal with the truth, but, once trust is lost, cannot, and will never again, trust governmental agencies to be truthful once they realize that those agencies have knowingly and cravenly lied to them about the safety and risks associated with each vaccine –

- **Not only to promote the national immunization program**
- **But also to assist the pharmaceutical industry in the industry's efforts to increase both its revenue yield, and the number of Americans who seek treatment for some "disorder," "syndrome," or "disease."**

Factually, because the American people have been brain washed to accept that their vaccines are the safest medicines and the Center for Disease Control and Prevention is only interested in preventing disease outbreaks and controlling disease outbreaks,

- **Millions of American children and adults have been unnecessarily harmed by an insidious poison, Thimerosal, which should <u>not</u> have been allowed to be used in any vaccine or other manufacturing process, or in vaccine or other medicine.**
- **Hundreds of thousands of Americans have some degree of clinical mercury poisoning from the Thimerosal-containing vaccines and other drugs they received, and**
- **Thousands have had their lives shortened and adversely impacted as a result of being unnecessarily mercury poisoned by the Thimerosal-containing vaccines and other Thimerosal-containing drugs they received**

"The CDC's job is to protect the public health, and that means doing what they can to quell false fears."

***Contrary to your assertion*, it is NOT the CDC's job, per se, "**to protect the public health**," that job belongs to the Department of Health and Human Services (DHHS) in which the CDC resides.**

Further, the DHHS has two arms, the Food and Drug Administration (FDA) and the Public Health Service (PHS) who have that charge.

The CDC's job is supposed to be to prevent disease and, in the event of a communicable disease outbreak, oversee the control of that out break.

Since, though the CDC is not the supposed to be a propaganda agency, its inflation and misrepresentation of the disease risks and disease-outcomes probabilities have turned the CDC into a proven, false-fear generating and fear-mongering agency.

Given this reality, this reviewer is surprised that you speak of the CDC's need to do "what they can to quell false fears.**"**

On this we both agree, except that you seem blind to the CDC's being the source of the "false fears**" that need to be stopped.**

"In order to accomplish this, they have chosen to play their cards close to their vest: to monitor vaccine safety in secret and then only make concerns public when they have been confirmed.

This will avoid countless false alarms, which would constantly send waves of fear about vaccine safety across the country."

Again, you attempt to turn the CDC's unconscionable actions into something that is desirable.

Contrary to your views, history has shown that the CDC's secret actions have contributed to the suppression of confirmed vaccine safety problems long after the CDC's data clearly confirmed them.

Moreover, since the CDC continually engages in vaccine fear mongering that "constantly send waves of fear**" about some disease risk (e.g., "Swine Flu," and "Bird Flu"), false disease incidence and death rates (e.g., the grossly inflated influenza numbers and the failure to put them in proper context) and continually misleads the American public by grossly understating the vaccine side effects and side-effects risks, this reviewer finds that the CDC's acting in secret can no longer be tolerated because the CDC's actions have, and are, harming the health of the American public while you have the temerity to claim the CDC's job is to "**to protect the public health**."**

If protecting the public's health is the CDC's job, then the CDC needs to be fired.

"The downside to this, however, is that the necessary secrecy fosters distrust. Especially in the internet age, with well-meaning activists spreading rumors and exaggerations. The CDC must strike a delicate balance, but in the end theirs is probably a no-win situation."

You have not proven that there is any real need for secrecy and, in fact, *since your words indicate that secrecy is detrimental to the public trust that the CDC must have*, this secrecy is obviously <u>not</u> necessary.

If you believe that the CDC needs to be trusted, then "(e)specially in the internet age**," then the lies and distortions must be stopped and the secrecy relaxed to the point that credentialed independent scientists are encouraged to freely study the VSD Datalink database and share their findings with the CDC researchers so that, like Linux, the findings are "open sourced" so that all benefit equally.**

As with any agency living in the "information age," the CDC must transition to an open agency or it will die.

Further, *if you wish to walk in the world of science as you claim you do*, you need to stop using generalized and unsubstantiated rhetoric like your unnecessary and dismissive, "well-meaning activists spreading rumors and exaggerations**" when addressing groups or views with which you disagree.**

When you have legitimate concerns about specific individuals or groups, then gather evidence of their actions and motives as well as the factual evidence that clearly establishes the validity of your position on the issues you wished to raise, then, you should present your evidence, and

concerns to that individual or group and disseminate your views as widely as you see fit.

"Believers in a CDC coverup interpret all of the CDC's skittishness and statements about containment and perception as evidence of a conspiracy."

Once again, while claiming that science is the tool that should be used, you again step out of this world of science and into the world of religion when you speak of "Believers**".**

In the world of science, the CDC is judged by its actions and non-actions.

Operating in this world, this reviewer and the other scientists (who use the scientific method and Ockham's Razor to form their hypotheses and empirical observations to assess their accuracy and applicability), have determined beyond a reasonable doubt that:

- **The CDC lacks credibility because it continually lies to the American public.**
- **The CDC, by helping the pharmaceutical industry achieve its goals at the expense of the American public, is much less concerned about vaccine safety and public health than it is about helping sell more vaccines[12].**
- **The current National Immunization Program is broken and cannot be fixed by a government that, *at every level*, has been corrupted by**

[12] For example, let us consider the CDC's unsupported December 13, 2003 decision to include the influenza vaccine in the recommended childhood vaccination schedule for children 6-months to 4 years of age – a decision that could only benefit Aventis Pasteur, now a division of sanofi-aventis.
This decision was made even though the influenza vaccine has not been proven to be effective for children 2 and under.
This decision meant that, while claiming to be reducing Thimerosal dose in childhood vaccines, the CDC was adding back as much, if not more, by adding the "flu" vaccine, because most of the then and currently available licensed vaccine for that age group adds 12.5 mcg of mercury for each vaccination and the recommendation was for two vaccinations separated by 30 days initially, adding 25 mcg of mercury to most children's mercury load immediately and, for a child turning 6 months just after December 13, 2003, an additional worst-case total of up to 87.5 mcg of mercury by age 5.
Since the flu vaccine's lack of effectiveness has been raised as an issue, the CDC now justifies its administration on the grounds that giving it to children will somehow protect grandparents from the flu when nothing could be further from the truth.
Having made an unconscionable decision to accommodate a vaccine maker, the CDC has proven that it will tell any lie to keep mercury poisoning some so that sanofi-aventis's profits will increase and the mercury added by this back-door route help to keep the mercury poisoning incidence where it is so that the CDC can say, look, we took out or reduced the level of Thimerosal in vaccines p, q, r, s, t, u, v, w, x, y, and z and the level of mercury poisoning did not drop, the mercury poison cannot be causing the mercury poisoning observed while leaving out the fact that the flu shot put the mercury back and, in some cases, increased the dose.
Moreover, because the "flu" vaccine is only given in a part of the year and some children received the "trace Thimerosal" vaccine and, starting this year, will get the "Thimerosal free" vaccine make it much harder to sort out the mercury and mercury poisoning pattern from the added noise that such a wrongheaded decision has created.
Based on the preceding, it is clear that the CDC has NO real interest in protecting the health of the public – their interests clearly lie else elsewhere.
Yet, you say there is nothing fundamentally wrong here – guess your concerns lie elsewhere.

the pharmaceutical, healthcare, medical and insurance industries, whose greed demands that they be:

- **Allowed to freely experiment on the American public as they see fit and**
- **Protected from almost all liability for their actions.**

"However, all of this can also be interpreted as a sincere attempt to protect the public from an unwarranted fear that could lead to reduced vaccination and many, many sick children."

In the Orwellian world in which you appear to reside, "black" can "also be interpreted**" as "white."**

In your world, the millions of currently "sick children**" are ignored and the "public fear" focused on your "**an unwarranted fear that could lead to reduced vaccination and many, many sick children**."**

Dr. Novella, rather than worrying about outcomes that may never come to pass and ignoring the millions of sick mercury-poisoned Americans that have been harmed by the Thimerosal injected into them, you should use your energies to help heal all those who have been mercury poisoned.

"On close inspection, the conspiracy theories are not compelling, or even logical. But once the idea of a conspiracy is accepted, it can be used to dismiss all contradicting evidence, and to explain away the lack of confirming evidence. Conspiracy theorists quickly become insulated from any possible refutation creating a closed belief system reminiscent of cults."

Since you persist in raising the issue of "conspiracy theories**" and talking about them (without presenting any proof other than your rhetoric), it seems that, absent any evidence, you are certain that those, like this reviewer are somehow fixated on "**conspiracy theories**" rather than:**

- **Proving the harm and**
- **Making sure that all the possible corrective actions are taken.**

You seem to cling to this fixation, even when those, including this reviewer, have established that the problems they are concerned with are:

- **The repeated <u>unnecessary</u> and <u>illegal</u> injection of poisonous doses of Thimerosal-containing preparations [vaccines] into the American public under the guise of protecting public health has mercury poisoned, and is mercury poisoning, the American public.**
- **The administration of drugs, preparations, and treatments containing <u>unnecessary</u> Thimerosal and/or other mercury compounds has been, and is, contributing to the mercury poisoning of the American public, and**
- **The use of mercury in dentistry has been, and is contributing, to the unnecessary mercury poisoning of the American public.**

- **All use of mercury in the preparation of any medicine and in any dental procedure should be stopped immediately UNLESS, *with a safety factor of at least 1000*, the manufacturer thereof has proven (in scientifically sound acute and true long-term toxicology studies in two appropriate animal models) that the drug product is safe under the worst-case dosing regimen allowed in the product's labeling.**
- **All drugs, including vaccines, that are produced by any process in which, *by any means*, mercury or mercury compounds, including Thimerosal, have been added to the product should be removed from the market UNLESS, *with a safety factor of at least 1000*, the manufacturer thereof has proven (in scientifically sound acute and true long-term toxicology studies in two appropriate animal models) that the drug product is safe under the worst-case dosing regimen allowed in the product's labeling.**

"Also, grand-conspiracy theorists take a very black and white view of the world. David Kirby's book, *Evidence of Harm,* told largely from the point of view of activist parent groups, reflects this attitude. All of the thimerosal skeptics in his book are described as 'aloof,' 'cold,' 'arrogant,' and 'dismissive.' Believers are always charming, friendly, and sincere. Dark-suited pharmaceutical representatives are literally skulking in the background, talking into their cellphones in conspiratorial tones."

This reviewer only notes that your rhetoric is:

a. based on your perception of the world and

b. <u>not</u> substantiated by any factual studies or peer-reviewed publications that support the objective validity of your views.

In light of the preceding, this reviewer simply recommends that this passage be ignored.

"The weakest aspect of the conspiracy theories, however, is that the motivation of the 'villains' is simply not credible."

Again, like the instructions given to the IOM committees, you begin by telling everyone what, in your opinion, the reader should conclude.

"The IOM, for example, has no motivation that anyone can point to for not giving an honest report of the data."

Since the IOM never examined all the "data**," only publications based on the "**data**," this reviewer must dismiss your inference that the IOM reported on the data.**

As to your interesting "no motivation that anyone can point to**" assertion, this reviewer knows that satisfying the customer, the CDC, who paid the IOM**

to conduct the review and pre-instructed the committee as to what findings would be acceptable, is a powerful motivation.

Having named one of the common motivations, "to satisfy the customer," this reviewer trusts that you will concede this is a "motivation that anyone can point to**."**

"Also, they based their report on published data" "data any scientist in the world can review for herself**."**

Again, all the IOM committee, given their backgrounds, could review was the information, findings, and data excerpts, if any, in the publications that they reviewed.

Lacking access to the complete underlying data and parameter sets used, but not reported in the publication, all the committee could really do, was evaluate their perception of each paper and its perceived relevance within the framework of the charge that the CDC had given and the instructional guidance that the CDC had provided – instructions that, contrary to sound science, directed them to give the epidemiological studies precedence over the experimental studies.

Factually, all that "any scientist in the world can review for**" "his or" "**herself**" is what he or she can comprehend from reading what is published; just as, lacking access to all of your notes, all that this reviewer can address is what he understands, based on his knowledge and experience bases, from the words you have written.**

"If they gave a biased report, their malfeasance would be transparent to their colleagues, and their reputations would be ruined**."**

Given:

- **The current state of "science" in the U.S.,**
- **The fact that, as they knew, most of their colleagues would never read more than the abstract and summary of the report, and**
- **The report was actually prepared by non-committee members expert in preparing such in a manner where the voice is that of the "consensus" and not the individual members, should any issue be raised, they have the cloak of "plausible deniability" behind which to hide,**

no individual has anything to fear if the consensus report is a "biased report" – as, since you are a member of academia, you should be well aware.

"Further, if there were a thimerosal-caused autism epidemic, the truth would eventually come out; it could not be hidden from the world."

Since the "truth," injecting poisonous mercury causes mercury poisoning," has been known for some time, but, other than some of the CDC's personnel being stripped of their "power" and reassigned (e.g., Robert Chen), nothing of which this reviewer is aware has happened to the IOM committee members nor is likely to happen to them; and the critical population at issue in the United States today is the American population and not the world's.

As to the truth's coming out, this reviewer hopes that this review will contribute to the educating the American public about the truth of which you speak.

"When it did come out, the IOM committee members would be further disgraced. The same would be true of Sarah Parker and the other authors of the *Pediatrics* paper reviewing all the data. No scientist wants to be on the wrong side of history."

This reviewer sees no need to comment about what future holds for the IOM committee members, yourself, or, for that matter, himself, since this reviewer is a scientist and not a clairvoyant.

With respect to your "No scientist wants to be on the wrong side of history**," this reviewer notes that history tells us that many scientists have ended up being on the wrong side of science when all of the evidence required to prove whether "A" causes "B" – based on this reviewer's comprehensive understanding of the facts, "repeatedly injecting slightly toxic doses of an organic mercury compound, Thimerosal (49.55% mercury) that is a severe poison" causes "a) all to be mercury poisoned to some degree, b) some to be poisoned to the extent they are clinically mercury poisoned, and c) a few to be poisoned to death."**

"Officials at the CDC and FDA would also eventually be found out, and they know it. There have been regime changes at these institutions, giving the opportunity for newcomers to blame any wrongdoing on predecessors, yet no revelations have come."

Dr. Novella, the obvious answer to your observations is that there is a time for everything and the time for the events of which you speak has not yet come.

"The AAP is a professional organization, charged with improving health-care for children what possible motivation could they have for condemning millions under their watch to neurological damage?"

Besides the obvious monetary reason (vaccines provide a significant portion of a pediatrician's annual income), and the problem with accepting their personal responsibility for their role in harming of the very children they are supposed to be helping not harming, this reviewer notes that their members might stand to lose millions in the liability suits naming them as one of the parties who caused the harm.

All of these are obvious motivations to cover up the mercury poisoning.

Moreover, as with the previous case, where Calomel *mercury* in teething powders for babies clearly caused *mercury poisoning* and killed hundreds of children in the U.S., medical doctors called it "Pink Disease" and/or "Acrodynia" – but, did *not* call it what it was – *mercury poisoning*.

Today, depending on your point of view, history is either repeating itself or continuing the previous pattern, because, in spite of the truth that the "disease" is *mercury poisoning*, medicine has insisted on calling the current epidemic of *mercury poisoning* anything but *mercury poisoning* – often, *probably because it is the least frequent and most severe mercury poisoning*, the amorphous and ill-defined code label, "autism," is used to hide the underlying disease, *mercury poisoning*.

Since the AAP has bought into this "mislabeling" practice, the AAP is most certainly "involved in" a "cover up."

"Much of what is driving the conspiracy theories is based on a misunderstanding of the scientific process."

This reviewer notes that you seem to be confused.

From the rest of your comments it seems that you are imprecisely referring to the scientific sub-discipline, epidemiology, which is a branch of biostatistics (or biometry), which encompasses the set of statistical assessment tools applicable to the study of biological populations and how to properly use these tools.

For the rest of this discussion, this reviewer will presume you are discussing the practices that are, or are <u>not</u>, scientifically sound practices in biometry.

"Kirby reports on the argument that the CDC studies' being altered in response to comments from reviewers was 'suspicious.' But this alteration is almost universal practice" "part of the peer-review process."

Though what you state here is muddled, because, *as my biometry professor was fond of saying*, no one honest enough to be trusted with more than one adjustable parameter, epidemiology guards against less-than-honest manipulation of the findings to suit the outcomes desired (by the study's designers) by severely restricting the post-study "adjustments" that should be made to essential "none."

In epidemiology, the study team is supposed to carefully define and justify the study and all of the restrictions on the criteria for selection, grouping, the "no-dose" and 'highest dose" case, and the effects to be evaluated, including effects that should not be related to the responses observed, BEFORE the study is initiated with no provision for changes other than to providing for adding new-case like data into like categories.

Since Mr. Kirby is a journalist with little, or no, training in the fundamental precepts of sampling, population statistics, experimental statistical design, statistical data mining, and the rules governing their sound application, his statements are, as they must be, general in nature.

Similarly, your remarks seem to clearly indicate that your training in population sampling, data mining, statistical population assessment, and experimental design seems to be similarly limited.

That having been said, in epidemiology, your statement, "alteration is almost universal practice" "part of the peer-review process**," is patently false.**

In general, only new-case augmentation and study reiteration or sub population related factor study (like, the discovery of possibly sex-related effect) re-analysis should be conducted in a valid epidemiological study.

In general, following a database study where the validity of entry has not been verified before the data was entered, one should, as was originally proposed, conduct appropriate case interviews to confirm that the entry error bias found has not affected the outcomes observed.

Post-study peer review should be limited to assessing the validity of: a) the study design, b) factors assessed, c) the data included and its categorizations, d) the integrity and accuracy of the data used in the study, e) the statistical procedures used, and f) the appropriateness of the factors evaluated.

On this basis, your views are at odds and should be rejected as they have been by the independent statisticians who have reviewed all of the available information on the original Verstraeten "Generation Zero" study and its subsequent scientifically unsound iterations.

"Many parent groups cannot understand how preliminary data can show a link, and then later analysis show no link. But epidemiology and statistics are very complex enterprises. No study is perfect, and all involve choices that affect the outcome. Many rounds of analysis and peer-review are often required to achieve reliable results."

All that you seem to be doing here is repeating something that someone told you, because, for example, "rounds of analysis and peer-review**" are proscribed activities in epidemiology.**

Moreover, your pejorative "parent groups cannot understand**" overlooks the fact that some parents in those groups are statisticians, biostatisticians, and, yes, even, epidemiologists.**

"Finally, we must all be wary of 'confirmation bias.' It is human nature to look for evidence that confirms what we already believe."

While this reviewer agrees with you, he notes that the Verstraeten research team seemed to be oblivious to this reality, and continued their

iterative manipulations of the data and criteria until they found the outcomes that they were looking for.

However, for those who really are scientists, it is their ingrained nature to seek evidence that undermines their hypotheses – in other words, scientists seek the proverbial "exceptions that prove the rule."

Obviously, though are a medical doctor, you are words indicate that you are no scientist.

"Once someone believes in a link between mercury and autism, it's easy to collect all the data that seems to support a link and become increasingly compelled by the shear volume of evidence. It takes critical thinking, and some experience, to fight against this basic human tendency and to put all the data into some objective perspective."

Let this reviewer again remind you that, *as you said*, science is the tool that "we" need to apply to these issues and, as this reviewer has previously stated, what one "believes**" has no scientific value.**

Science is based on what:

- ✓ **Can be proved,**
- ✓ **Can be disproved, and**
- ✓ **Must be accepted as possible, because it is currently neither provable nor disprovable.**

Furthermore, this reviewer recommends that you take your own advice and go back and study all of the data that proves this reviewer's hypothesis:

- ❖ **"Repeatedly injecting small poisonous doses of a bio-accumulating severe poison, Thimerosal (49.55% mercury) into humans from birth onwards mercury poisons all to some extent and some to the extent that they exhibit the symptoms of clinical mercury poisoning," or, generalizing,**
- ❖ **"Repeatedly injecting small doses of any poisonous mercury compound 'causes' mercury poisoning."**

Further, this reviewer recommends that you consider the set of historical events in the United States (as shown in the table on the next two pages).

First, for some reason, though mercury is the most toxic of the common heavy metals known to man, mercury compounds (first inorganic and then organic) have been added to medicines without any real proof of safety for more than 100 years.

***For most of that period*, medicines for babies have been the "method of choice" for mercury poisoning Americans for more than 100 years.**

Though "committed," since 2000 to removing mercury from vaccines, the FDA has inexplicably <u>not</u> taken action to ban the use of Thimerosal in eye and ear preparations and has only "pushed" to reduce the level from 100 mcg per milliliter to "not more than 1" mcg per dose.

In addition to the mercury in vaccines, Thimerosal is used as a preservative in other serums and, more recently, *though not listed on the labeling or the products' published information*, "trace" Thimerosal seems to be being hidden (because the FDA doesn't test for and does not require the disclosure of, "impurities" in products if the level is significantly less than 0.1 %) in some of the newer monoclonal antibody drugs, which the FDA has begun approving.

Though the facts presented could be used to posit many a "conspiracy" theory, this reviewer only provides these facts as information for the reader' consideration.

"**6: What should we believe?**"

Again, Dr. Novella, you ask a question that has no place in science and fail to ask the question that you should have asked:

> **"What link, if any, does the historical (see: Ockham's Razor) and the recent valid experimental (see: Scientific Method) evidence support?"**

if, *as you claim*, science is the tool that should be used to decide such matters.

"We have to try to look at evidence as best we can."

Once again, you begin by asking a "religious" question and then suggesting that the "evidence**" needs to be looked at.**

Accurately, since the requisite observation-based evidence is now available, the valid experimental (toxicological, and biological) and patient-derived (valid parental observations, complete clinical symptomology, baseline test data, and case-study treatment "effects and outcomes" data) clinical evidence should be assessed.

Since, by their very nature, indirect retrospective epidemiological studies cannot prove or disprove a "link," such studies should not be considered whenever there is sufficient direct proof that "A" causes "B." [Note: For example, there is no need for an epidemiological study for the link between "secondhand cigarette smoke" and "lung cancer," because there is a body of direct evidence, in valid animal models and human case histories, which has adequately established that "breathing secondhand cigarette smoke" causes "lung cancer."

> **"What link, if any, does the historical (see: Ockham's Razor) and the recent valid experimental (see: Scientific Method) evidence support?"**

if, *as you claim*, science is the tool that should be used to decide such matters.

A Rough History Of Mercury Poisoning Of America By Teething Powders And Vaccines

Period	Medical Hg Sources	Narrative
1890-1940	**Calomel in teething powders** **Eli Lilly** **In mid 1930' Thimerosal in topical antiseptics (0.1%)** **&** **Tetanus Toxoid serums (0.01%)**	Teething powders were introduced and their use promoted as the use of these teething powders increased so did the form of mercury poisoning labeled "Pink Disease or "Acrodynia" by the medical establishment rather than mercury poisoning In the late 1930's the public began to demand that their doctors find the cause and the link between teething powders and "Pink Disease" or Acrodynia" was generally accepted. **After introduction of OTC Thimerosal & TT serums, "Pink Disease" / "Acrodynia" rate jumped in 1937-1939** In late 1939/early 1940, the drug makers pulled the Calomel-laced teething powders off the U.S. market though they continued to be sold in Australia into the 1950's.
1940-1945	**Eli Lilly & Others' Thimerosal uses as above**	"Pink Disease" (clinical mercury poisoning faded from view) but sub-clinical poisoning from Thimerosal continues.
1945-1950	**Eli Lilly & Others' Thimerosal uses as above**	**1948** JAMA paper strongly warned of toxicity of Thimerosal & recommended that it not be used in vaccines & serums BUT WARNING IGNORED Eli Lilly continued to promote Thimerosal's use based on a bogus 1930's study that Lilly claimed proved safety.
1950-1960	**Eli Lilly & Others' Thimerosal uses as above**	**1950** Annals of the New York Academy of Sciences paper by Frank B. Engley, Biological Dept., Chemical Corp, Camp Detrick, MD, "EVALUATION OF MECURIAL COMPOUNDS AS ANTISEPTICS," found Thimerosal was not a good antiseptic; but Lilly continued to market Merthiolate® (0.1% Thimerosal) to the American public.
1960-1970	**Eli Lilly & Others' Thimerosal uses as above**	**In 1968**, 21 CFR 610.15(a) approved requiring preservatives to be proven safe but NOT enforced for Thimerosal In 1969, deaths from 0.1% Merthiolate (a/k/a Thimerosal) use as a topical antiseptic on umbilical stumps were reported to Lilly and the FDA.
1970-1980	**Others' Thimerosal uses as above** **Eli Lilly exits vaccines & serums business but licenses other drugs to use Thimerosal as a preservative in**	**In 1970**, the FDA demanded Lilly provide all the toxicological and safety data on Thimerosal to them and Lilly again gave then the bogus 1930's study, again representing that Thimerosal was safe at preservative levels (0.003% to 0.01%) and for use a topical antiseptic. Recently, it was reported that a Lilly study completed in **1971**, but apparently not shared with the FDA or published, found Thimerosal was toxic at 1/100th the preservative level or at ***0.0001%*** **In 1975**, Eli Lilly abruptly exited the vaccines and serums business, but continued to promote the use of Thimerosal (Merthiolate) in topical products and licensed its use as a preservative in OTC drug and biological products, including vaccines even though it apparently knew it was toxic at 1/100th the preservative level. Other vaccine makers impressed with Thimerosal's hidden benefit [Lister Hill 11 Aug 1999, Dr. Englhardt, Eli Lilly & Company, Inc, "Also as mentioned earlier**, thimerosal is a very exquisite antigen**, not only in people but also in guinea pigs and rabbits, (page 95, lines 19-21)"] and "unaware" of its concealed toxicity, used it in their vaccines.
1980-1985		**In 1982**, an FDA panel studying the benefits/risks of topical Thimerosal found it caused more tissue damage than it promoted healing and recommended it be removed from OTC topical products but nothing was done to implement that recommendation.
1985-1995		**In 1986**, 42 U.S.C. 300aa-27(a)(2) enacted requiring adverse events in childhood vaccines to be reduced by whatever means required. **In 1988**, U.S. Supreme Court rules government administrators have no latitude in complying with any clear statute, law or policy.
1995-1998		**In 1998**, FDA bans future OTC's with Thimerosal but does not recall all in-date products available until 2002 or after [2005 internet survey found Butt Balm, listing Thimerosal as an ingredient but not disclosing its level (<=0.1%) though illegal, was still being made and sold]

A Rough History Of Mercury Poisoning Of America By Teething Powders And Vaccines

Period	Medical Hg Sources	Narrative
1998-2000		**By 1999**, Lister hill 187.5 mcg at 6 months or, if flu vaccine given, 200 mcg) 4X increase Hg leads to 10 X increase in toxic symptoms but other sources of mercury also rising and being used. **In late 1999**, first "trace Thimerosal" vaccines licensed.
2000-2002		**By Jan 2000**, epidemic levels confirmed and pledge to remove Thimerosal as soon as possible starts to be effected. However, because no recall mechanism is put in place, Thimerosal-preserved vaccines continue to be administered to babies and young children. **In 2000**, the illegal "Simpsonwood" conference is held, the "Thimerosal" problem is discussed and government and industry agree that this problem needs to be handled. **In 2001**, first IOM committee is charged to investigate the "vaccine safety" but not to find evidence of a link between "vaccines" and either the "MMR" vaccine or "Thimerosal" and writes a report that indicates no proof of either "link" but does recommend more research on "vaccines" / "autism" link.
2002-2004		**In Jan. 2002**, NVIC "citizen petition" asking recall of "Thimerosal preserved" vaccines when "trace Thimerosal" replacements available is filed requiring a response from FDA within 180 days (July 2002). In Sept. 2002, last "Trace Thimerosal" vaccine licensed. **In 2003**, "Generation Seven" Verstraeten findings published and immediately challenged as being manipulated data and less than proper because lead author's conflicts-of-interest (including his employer during the last iterations of the study) were not disclosed. **In Dec 2003**, Influenza vaccine inexplicably added to childhood schedule even though most doses are "Thimerosal preserved."
2004-2006		**In Feb. 2004**, IOM committee reconvened studies additional evidence (improperly focused on epidemiological studies) that reports no evidence of a "vaccine-autism link" based on the studies reviewed. **In July 2004**, CoMeD discovers NVIC "citizen petition" to FDA (FDA Docket #: 2002P-0025) has never been answered. **In Aug. 2004**, CoMeD files "citizen petition" (FDA Docket #: 2004P-0349) that, among other things, demands the requirements of 21 CFR 610.15(a) be met and, as required by law, FDA comply with 42 U.S.C. 300aa-27(a)(2) **In Oct. 2004**, Chiron "flu" vaccine contamination – UK MCA pulls license; Only 6% of Aventis, Inc.'s doses are "Trace Thimerosal" doses. **In Dec. 2004**, Aventis "Thimerosal free vaccine licensed. **In Feb. 2005**, CoMeD receives interim response from FDA that FDA is still studying the issues because they are complex. **In March 2005**, CoMeD replies that 2 of the issues, 21 CFR 610.15(a) and 42 U.S.C. 300aa-27(a)(2) are NOT complicated – they are clear legally binding requirement minimums. **In July 2005**, Aventis 'promises' ~12 % of its 2005-6 "flu" doses will be "Thimerosal free – too few for all children; Chiron return supply not assure; at best, only about half of the expected doses will be available. IOM committee studying VSD Datalink database confirms the original datasets from the Verstraeten studies have been deliberately deleted from the database making it impossible to confirm what real links were or replicate Verstraeten's work – critical data that U.S. taxpayers paid tens of millions for was deliberately "lost." Investigation of the payments made for VSD Datalink database found costs to be inflated and payments made to bogus companies – persons in CDC who are involved reassigned but, to date, not prosecuted. **In Aug. 2005**, parents still reporting Thimerosal-preserved vaccines that, according to CDC's latest position, "expired" in 2003.

"We have to try to look at evidence as best we can."

Once again, you begin by asking a "religious" question and then suggesting that the "evidence**" needs to be looked at.**

Accurately, since the requisite observation-based evidence is now available, the valid experimental (toxicological, and biological) and patient-derived (valid parental observations, complete clinical symptomology, baseline test data, and case-study treatment "effects and outcomes" data) clinical evidence should be assessed.

Since, by their very nature, indirect retrospective epidemiological studies cannot prove or disprove a "link," such studies should not be considered whenever there is sufficient direct proof that "A" causes "B." [Note: For example, there is no need for an epidemiological study for the link between "secondhand cigarette smoke" and "lung cancer," because there is a body of direct evidence, in valid animal models and human case histories, which has adequately established that "breathing secondhand cigarette smoke" causes "lung cancer."

Since recent key peer-reviewed studies have established:

- **Parents are valid observers for assessing the timeframes for the onset of initial regressive behavior [2005],**
- **Following exposure to Thimerosal (49.55% mercury) reflecting the United States' childhood immunization schedule (i.e., the dose and stage of development), SJL/J mice developed symptoms mirroring childhood mercury poisoning, the form of mercury poisoning labeled "autism," including: [2004]**
  - **Growth delay;**
  - **Reduced locomotion;**
  - **Decreased numbers of Purkinje cells;**
  - **Exaggerated response to novelty;**
  - **Significant abnormalities in brain architecture, affecting areas subserving emotion and cognition; and**
  - **Densely packed, hyperchromic hippocampal neurons with altered glutamate receptors and transporters, and**
- **Repeatedly (at 4 equally-spaced intervals) injecting baby monkeys with weight-corrected Thimerosal-preserved-vaccine doses (20-mcg/kg) resulted in measurable levels (between 1 ng/g and 20 ng/g) of the recognized mercury poison ("inorganic mercury") to bio-accumulate in the monkey's brains with no evidence, over the 30-day washout period, that this "inorganic mercury" level declines significantly [2005], and**
- **Parents consistently report that the regressive symptoms observed occur shortly after some vaccination with a Thimerosal-preserved vaccine or vaccines from as early as the 3-months vaccinations to as late as the pre-college multi-dose Menomume® (Aventis, Inc) vaccination at "18" years of age**

- **When children labeled as having "autism" are comprehensively tested for evidence of mercury or general "heavy metal" poisoning (intoxication), including the inability to efficiently excrete mercury and other heavy metals, evidence of some level mercury poisoning is found.**
- **Controlled mercury detoxification case studies have established that the detoxification procedures used:**
  - **Recover mercury and other associated heavy metals**
  - **Reduce the severity and number of mercury-poisoning symptoms that the patient exhibits, and**
  - **Improve the patient's functional capabilities,**

it is clear that repeatedly injecting Thimerosal-preserved vaccines causes some to:

- **Developmentally regress and**
- **Exhibit the classical clinical symptoms associated with mercury poisoning including the set of symptoms that cause the affected children to be "classified" as having "autism."**

Further, comparison of the incidence rates in the elderly between those who receive the "flu" vaccine and those who do not, indicate that repeated vaccination with the Thimerosal-preserved "flu" vaccine increases the risk of a subsequent diagnosis of Alzheimer's up to 11 fold for those so vaccinated over those who are not (private communication).

"And there is now adequate scientific evidence to conclude that there is no epidemiological association between either MMR or thimerosal and autism."

Based on the direct scientific evidence, there is a proven causal link between injecting Thimerosal (49.55% mercury) and mercury poisoning, including the mercury-poisoning "symptoms set" that is diagnosed (labeled) as "autism," <u>contrary</u> to what you assert (based on the reported findings of the now non-relevant epidemiological studies you incorrectly accept as being valid).

"At present, the evidence strongly suggests that the autism 'epidemic' is largely an artifact of increasing diagnosis. But there is room for the possibility of a real increase in this disease, and if that's the case, then searching for the real cause or causes of autism is critical."

Contrary to your rhetoric, the California data on included, confirmed, "autism" cases clearly has established that, in spite of a slight widening of the diagnosis criteria for "autism" ("DSM" to "CDER status 1") and, in July 2003, the narrowing of the inclusion criteria (by adding a requirement for demonstrated significant functional limitation in at least 3 of 7 defined areas [where year-to-year, 2002-2003 to 2003-2004, there was an apparent 1% decline in included "autism" cases; in contrast to the 60%,

59% and 29% declines seem for cerebral palsy, epilepsy, and mental retardation, respectively]),

- **The epidemic incidence in the rate of "autism" is real and**
- **A major cause of the mercury poisoning diagnosed as "autism" has been established as the repeated injection of poisonous doses of Thimerosal-containing vaccines into developing humans.**

"Regardless of this evidence, many countries have removed thimerosal from childhood vaccines" "the United States phased it out by 2002."

Your statement is not accurate.

Because the U.S. FDA has:

- **Not revoked the license for the Thimerosal-preserved vaccines,**
- **Not recalled all Thimerosal-preserved vaccine doses in 2002 when the last "trace Thimerosal" replacement was licensed for the Thimerosal-preserved vaccines, and**
- **Chosen to allow "trace Thimerosal" vaccines rather than "Thimerosal free" vaccines to replace the "Thimerosal preserved" vaccines, and**
- **Allowed the Thimerosal-preserved "flu" shot to be administered to children as young as 6 months of age and required two doses to be given initially, even though the evidence is the "flu" vaccine is not effective in children 2-years-old and younger,**

the United States has not phased Thimerosal out of vaccines given to children.

Factually, at best, "the United States has only phased it**" down, and, for those children unlucky enough to be given doses from the remaining in-date Thimerosal-preserved vaccines in all cases, has, *by adding the "flu" shot in 2003*, actually increased the total dose that these unlucky children may receive when they are most vulnerable by 23 to 31 micrograms of mercury.**

"This removal will provide a final test of the thimerosal-autism hypothesis."

Given the preceding realities, Thimerosal has not been removed from all vaccines.

In addition, the U.S. FDA currently has:

- **Permitted other approved OTC and licensed or approved prescription drugs that contain Thimerosal, including some with undisclosed levels of Thimerosal, to remain of the market, and**
- **Allowed "banned" topical OTC drugs to remain on the market after 1998 when the use of Thimerosal in topical drugs was banned (by not mandating the recall of all such and not monitoring all OTC products produced (e.g., Butt Balm).**

Furthermore, the FDA has not banned the use of Thimerosal or other mercury compounds in the manufacturer of medicines or other medical procedures.

Until all mercury use is banned, all in-date added-mercury medicines are recalled and destroyed, and the use of mercury outlawed, your "thimerosal-autism hypothesis**" cannot be given the "**final test**" of which you speak. -**

"If there is a real epidemic caused by thimerosal, then autism numbers should drop precipitously to, or near, 1990 levels, back before the increase in the vaccine schedule resulted in higher thimerosal doses."

Because the reality of the "epidemic caused by thimerosal**" has been established, your "**If**" should be changed to "Since."**

Given that this reviewer has established that there are other unregulated Thimerosal-containing medicines whose usage has not been addressed much less banned and those in-date medicines have not been banned and recalled, and there is no universal bar to the use of other mercury compounds in the manufacture of medicine, it is premature t speak of a your postulated "autism numbers should drop precipitously to, or near, 1990 levels**."**

If you really want to see a precipitous drop in the incidence of clinical mercury poisoning from medicines, including your "autism numbers**," then this reviewer suggests that you contact both of your U.S. Senators and urge them to introduce and, with some slight improvements, pass the "Mercury-free Drugs Act of 2005" draft that was hand delivered to their Washington, DC offices in late 2004 or early 2005.**

Factually, the California data seem to indicate that the case rate for includable confirmed "autism" cases has leveled off and, for those children born in 2002, <u>may</u> have declined slightly.

However, the addition of "inclusion" criteria may account for some of that slight decline

"Kennedy is already declaring victory on this count, citing 'yet to be published' data by none other than Geier and Geier, the father-son authors of so many flawed studies, to suggest a drop in autism numbers."

Since all of the studies published by the Geiers were published in peer-reviewed journals and, *except for rhetoric*, this reviewer has seen no proof that any of their published studies are "flawed" in any material manner, this reviewer must caution you that your "by none other than Geier and Geier, the father-son authors of so many flawed studies**" remark not only has no place in a scientific discussion but also, *since you have widely published it*, constitutes an actionable libel on their good names unless you have scientific proof, not opinion, that your remark is true.**

"Kirby also gives a preliminary report of a trend downward in the California numbers, but he agrees it's too early to tell (and autism experts feel these numbers are unreliable)."

While this reviewer agrees with Kirby, he finds your repeated reference to unidentified "autism experts**" tedious and knows that these unidentified experts are wrong about the data from the California Department of Developmental Services which is being discussed here.**

"It will probably take another two years before epidemiological studies conclusively show the true effect of removing thimerosal from American childhood vaccines."

Since, as this reviewer has established, Thimerosal has not been removed "from American childhood vaccines**, only reduced, Thimerosal and other mercury compounds have not been banned from being used, and examining the trend in California's included, confirmed, "autism" cases does <u>not</u> an epidemiological study make, your assertion here is "confused" and unsupported by the factual realities concerning Thimerosal in American vaccines and other medicines.**

Hopefully, the reduction in the total level of Thimerosal in vaccines will translate into a reduction in the incidence of clinical mercury poisoning cases and, after all uses of mercury in medicine are banned, the clinical mercury poisoning rates will drop to the levels that would have been seen if the only sources for population-wide mercury-poisoning risks were the air we breathe, the water we drink, and the food we eat.

Unfortunately, for more than a hundred years in America, we have been, and are being, "sold" medicines that have UNNECESSARILY increased our collective risk of being harmed by the low-level mercury poisoning of the public under the guise of providing them with helpful medicines.

If you, Dr. Novella, would like to return America to that condition, then this reviewer again urges you to write your Senators and otherwise lobby Congress to enact the comprehensive "Mercury-free Drugs Act of 2005."

"Vaccines are a safe and effective public health measure, and they deserve broad public support. Because they are given to such a large segment of society, and are in fact mandatory in the United States for those attending school, it is vital that we have in place mechanisms to ensure both the safety of vaccines and public confidence in them."

Here, this reviewer <u>almost</u> agrees with you.

Safe and effective vaccines can be a "a safe and effective public health measure**."**

Safe and effective vaccines "deserve broad public support**."**

However, vaccines that contain UNNESSARY components, which, like Thimerosal, are intrinsically harmful, are <u>not</u> safe and these should <u>not</u> be touted as a "a safe and effective public health measure**."**

Similarly, because all vaccines have adverse reaction risks, vaccines that are not truly effective in a given population group (e.g., the influenza vaccine for children 2 years of age and under) or unnecessary to protect a given population group (e.g., Hepatitis B for all children under the age of 10 years) should not be administered to that population group.

In addition, unlike the present reality, the facts about vaccines that provided limited protection (e.g., the current Menomune® and Menactra™ vaccines produced by Aventis, Inc., that provide no protection against the "B" variant of infectious organism, *Neisseria meningitides*, that is responsible for about 50% of the cases in the U.S. each year) and the alternative equally or more-protective health measures that can be taken to minimize infection risk (e.g., improved hygiene especially in "dormitory settings" since *N. meningitidis* is a dirt/dust-borne organism) should be disclosed and each person, not the government, allowed to decide whether they or their children should receive that vaccine.

Further, the excess risks (e.g., higher risk of "rare" conditions) over the childhood diseases that a) the vaccines protect against and b) have low life-threatening complication and fatality rates, like chicken pox, should be fully disclosed (e.g., the varicella, chicken pox, carries with it an increased risk of "childhood shingles" that is virtually absent in children who only contract the "wild" varicella disease) each person, not the government, allowed to decide whether they or their children should receive that vaccine.

In other words, the public needs to be fully informed about the real risks and benefits and their true probabilities and, for those vaccines that are not fully population or subpopulation protective, each responsible person should be allowed to decide whether he or she or his or her children receive those vaccines – not the government.

Unfortunately, the preceding "shoulds" are not the case today.

"Zero risk is an impossible standard, as everything in life comes with some risk. It is more reasonable to consider risk versus benefit."

This reviewer completely agrees with your statements.

However, to properly consider "risk versus benefit":

A. All of the real risks and their true incidence rates should be disclosed, and

B. All of the real benefits and their probabilities of attainment should be disclosed.

Unfortunately, neither "A" nor "B" is true today for vaccines.

"What we can say about vaccines is that any potential risk is very low, and the benefits are both substantial and proven. In short, the benefits clearly far outweigh the risks."

Based on the facts presented, your statements here are not supported by the reported statistical data and real-life confirmed adverse-event reports, submitted mostly by healthcare professionals, which fill the FDA CBER's Vaccine Adverse Events Reporting System (VAERS).

"Vaccine controversies, real or imagined, can do real harm to the public."

This reviewer must disagree with you, because the harm in this case is <u>not</u> from the "controversies" — the proven harm here is the mercury poisoning from the unnecessary bio-accumulating, severe poison, Thimerosal (49.55% mercury), added to vaccines and other medicines at levels that have never been proven safe and, *based on the clinical mercury-poisoning outcomes seen*, levels that were <u>not</u> and are <u>not</u> safe.

"There was a time in this country, before we had the vaccines we have now, when people regularly suffered, even died, from influenza, smallpox, measles and polio."

Yes, we have traded that time for a time where babies die from mercury poisoning and, for those who survive, if the CDC is correct, more than 1 child in 6 is mercury poisoned to the extent that those poisoned children exhibit one or more of the clinical symptoms of mercury poisoning.

Given this reality, we may have been better off then. [Note: Of course there were no rich and powerful, pharmaceutical, healthcare, insurance and medical industries then to profit from all of the patients their medicines could create.]

"Barely more than 50 years ago, going to the beach during a polio epidemic was dangerous and terrifying.**"**

Having grown up in the time of which you speak and going to the beach in the South with no concern about polio because it was rare that anyone infected was seriously ill, this reviewer's greatest worry was getting sunburned because the sunscreens in those days weren't as long-lasting and effective as they are today, and, though this reviewer is 1/8th Choctaw, the fair skin this reviewer inherited makes sunburn a real concern.

Since this reviewer has discussed the "illusory" and/or "harmful" benefits of the polio vaccines ("killed/inactivated" and "live"), he sees no need to comment further on that matter here.

"Vaccines have changed our lives for the better, profoundly."

Since this reviewer is aware of no scientifically sound American studies comparing the health outcomes for groups who do <u>not</u> vaccinate (such as the Amish) to the health outcomes of matched populations who do vaccinate and who live in the same geographical areas of America, your statement is a hypothesis that, at present, <u>cannot</u> be rejected.

Perhaps when the government compares the "autism" rates for the unvaccinated Amish to a matched local population that does vaccinate, as has been suggested, that study can be expanded to cover a general "vaccines/no vaccines" comparison of the outcomes for all diseases for which we have vaccines so that your hypothesis can be scientifically tested — perhaps this is one reason that no such studies have been conducted.

As a scientist, this reviewer would be interested in and support such a study provided qualified researchers, who have no conflict of interest in the outcomes observed, conducted the study — perhaps a qualified Japanese research team.

"Vaccines are also one of the great social justice achievements. Poor people suffer much more when they're sick than rich people do; when a population manages to reduce or eliminate the incidence of a disease, it's poor and oppressed people whose lives change most for the better."

This reviewer sees no place for your pejorative and disingenuous rhetoric here.

Your words betray you and your rhetoric overlooks the reality that the poor and oppressed bear the bulk of the burden of the harm caused by vaccination for a disease since they cannot afford to have their children treated for the adverse side effects from mass vaccination while the rich not only can afford the treatments, but they can also afford to pay for the safest vaccines whenever, as is the case today, different vaccines (e.g., "Thimerosal preserved," "trace Thimerosal" and "mercury free" are available in America but, in general, because they are the cheapest, the children of the poor receive the least costly ("Thimerosal preserved"), and the rich and powerful receive the most costly but safest ("mercury free") vaccines.

After all, is it a just a coincidence that, in 1998 (at least 2 to 3 years before they were generally available), "trace Thimerosal" childhood vaccines were administered to children at the Bethesda Naval Hospital in Bethesda, Maryland — the hospital where the President, Vice president, etc., and their families receive their healthcare?

Or do you really think that flu-vaccine that President George W. Bush received last year was a Thimerosal-preserved vaccine?

"So while it's always important to question our medical and scientific establishments, asking the hard questions, it's also important not to throw out the great progress we have made."

This reviewer agrees with you that, "it's always important to question our medical and scientific establishments, asking the hard questions**," but fails to see that you have asked any "**hard questions**" in your current endeavor.**

In addition, this reviewer agrees with you that, "it's also important not to throw out the great progress we have made**," but notes that you have left out the fact that, "it's critical to learn from the past so that we do not repeat our past mistakes."**

It is clear that, in the case of Thimerosal, somebody failed to learn keep mercury out of our medicines even though the previous wide-spread American mercury-poisoning incident (wide-spread mercury poisoning of American children by Calomel [mercury(I) chloride] added to teething powders for our babies) was occurring when Eli Lilly and Company, Inc. started using Thimerosal in their Tetanus Toxoid serums. [Note: *Who knows*, perhaps someone in Lilly may have recognized that sub-clinical mercury poisoning would provide more "business opportunities" (patients) in the future.]

Moreover, the 1948 JAMA paper by Harry E. Morton et al.[13] clearly established that Thimerosal was not suitable for use as a vaccine preservative, but was apparently ignored by the vaccine makers of the day.

"*Dr. Steven Novella is president of the New England Skeptical Society and an assistant professor of neurology at Yale; snovella@theness.com <mailto:snovella@theness.com>.*"

This reviewer notes that Dr. Novella failed to disclose some of his other key affiliations[14].

In addition to the information available on his web page[15], this reviewer, Dr. Paul G. King is the New Jersey Representative of 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 a Citizen Petition, posted in the FDA Public Docket 2004P-0349 and wrote and submitted CoMeD's response to the FDA's 180-day response letter.

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[13] Harry E. Morton, Leon L. North and Frank D. Engley, "THE BACTERIOSTATIC AND BACTERIOCIDAL ACTIONS OF SOME MERCURIAL COMPOUNDS ON HEMOLYTIC STREPTOCOCCI In Vivo and in Vitro Studies," ***JAMA* 136**(1), pp 37-41 (1948).

[14] http://www.quackwatch.org/09Advisors/medadvbd.html, Member **QuackWatch** Medical Advisory Board; http://www.chirobase.org/10Bio/advbd.html, **Chirobase**, Your Skeptical Guide to Chiropractic History, Theories, and Practices, Scientific Advisor; Dr. Novella, 33 covers scientific and medical frauds. **The Connecticut Skeptic** is running his series on chiropractic, which, he writes, "remains in the realm of pseudo science," contending that few chiropractors limit their practice to treatments that have been proved effective. He has also tried to debunk claims about homeopathic medicine (the administration of unproved cures in infinitesimal doses), the use of bee venom for multiple sclerosis and the disproven therapy of psychomotor patterning in treating mental deficiencies.

[15] http://www.dr-king.com.

In addition, Dr. King has drafted the "Mercury-free Drugs Act of 2005," the "Federal Drug Safety Act of 2005," and a comprehensive substitute for Congressman Burton's H.R. 1297, titled, "The `National Vaccine Injury Compensation Program Improvement Act of 2005" that because it proposed a comprehensive overhaul of the National Vaccine Program, was re-titled, "The National Vaccine Program Improvement Act of 2005."

Finally, Dr. King has provided various groups with his analysis of various other Congressional bills, resolutions, and treaty documents.

APPENDIX A

Comparison Of:
The Characteristics of "Autism" To Those For Mercury Poisoning

Information derived from postings on: http://www.extremehealthusa.com/autism.html

"**Table I: Summary Comparison of 'Traits' of Autism & Mercury Poisoning**"
"(ASD references in bold; Mercury Poisoning references in italics)" **Part A**

Psychiatric Disturbances
Social deficits, shyness, social withdrawal (**1,2,130,131;** *21,31,45,53,132*
Repetitive, preservative, stereotypic behaviors; obsessive-compulsive tendencies (**1,2,43,48,133;** *20,33-35,132*)
Depression/depressive traits, mood swings, flat affect; impaired face recognition (**14,15,17,103, 134,135;** *19,21,24,26,31*)
Anxiety; schizoid tendencies; irrational fears (**2,15,16;** *21,27,29,31*)
Irritability, aggression, temper tantrums (**12,13,43;** *18,21,22,25*)
Lacks eye contact; impaired visual fixation (HgP)/ problems in joint attention (ASD) (**3,36,136,137;** *18,19,34*)
Speech and Language Deficits
Loss of speech, delayed language, failure to develop speech (**1-3,138,139;** *11,23,24,27,30,37*)
Dysarthria; articulation problems (**3;** *21,25,27,39*)
Speech comprehension deficits (**3,4,140;** *9,25,34,38*)
Verbalizing and word retrieval problems (HgP); echolalia, word use and pragmatic errors (ASD) (**1,3,36;** *21,27,70*)
Sensory Abnormalities
Abnormal sensation in mouth and extremities (**2,49;** *25,28,34,39*)
Sound sensitivity; mild to profound hearing loss (**2,47,48;** *19,23-25,39,40*)
Abnormal touch sensations; touch aversion (**2,49;** *23,24,45,53*)
Over-sensitivity to light; blurred vision (**2,50,51;** *18,23,31,34,45*)
Motor Disorders
Flapping, myoclonal jerks, choreiform movements, circling, rocking, toe walking, unusual postures (**2,3,43,44;** *11,19,27,30,31,34,39*)
Deficits in eye-hand coordination; limb apraxia; intention tremors (HgP)/problems with intentional movement or imitation (ASD) (**2,3,36,181;** *25,29,32,38,70,87*)
Abnormal gait and posture, clumsiness and incoordination; difficulties sitting, lying, crawling, and walking; problem on one side of body (**4,41,42,123;** *18,25,31,34,39,45*)

"Table I: Summary Comparison of Traits of Autism & Mercury Poisoning"
(ASD references in bold; Mercury Poisoning references in italics)" **Part B**

Cognitive Impairments
Borderline intelligence, mental retardation - some cases reversible (**2,3,151,152;** *19,25,31,39,70*)
Poor concentration, attention, response inhibition (HgP)/shifting attention (ASD) (**4,36,153;** *21,25,31,38,141*)
Uneven performance on IQ subtests; verbal IQ higher than performance IQ (**3,4,36;** *31,38*)
Poor short term, verbal, and auditory memory (**36,140;** *21,29,31,35,38,87,141*)
Poor visual and perceptual motor skills; impairment in simple reaction time (HgP)/ lower performance on timed tests (ASD) (**4,140,181;** *21,29,142*)
Deficits in understanding abstract ideas & symbolism; degeneration of higher mental powers (HgP)/sequencing, planning & organizing (ASD); difficulty carrying out complex commands (**3,4,36,153;** *9,18,37,57,142*)
Unusual Behaviors
Self injurious behavior, e.g. head banging (**3,154;** *11,18,53*)
ADHD traits (**2,36,155;** *35,70*)
Agitation, unprovoked crying, grimacing, staring spells **3,154;** *11,23,37,88*)
Sleep difficulties (**2,156,157;** *11,22,31*)
Physical Disturbances
Hyper- or hypotonia; abnormal reflexes; decreased muscle strength, especially upper body; incontinence; problems chewing, swallowing (**3,42,145,181;** *19,27,31,32,39*)
Rashes, dermatitis, eczema, itching (**107,146;** *22,26,143*)
Diarrhea; abdominal pain/discomfort, constipation, "colitis" (**107,147-149;** *18,23,26,27,31,32*)
Anorexia; nausea (HgP)/vomiting (ASD); poor appetite (HgP)/restricted diet (ASD) (**2,123;** *18,22*)
Lesions of ileum and colon; increased gut permeability (**147,150;** *57,144*)

"Table II: Summary Comparison of Biological Abnormalities in Autism & Mercury Exposure" Part A

Mercury Exposure	Autism
Biochemistry	
Binds -SH groups; blocks sulfate transporter in intestines, kidneys (40,93)	Low sulfate levels (91,92)
Reduces glutathione availability; inhibits enzymes of glutathione metabolism; glutathione needed in neurons, cells, and liver to detoxify heavy metals; reduces glutathione peroxidase and reductase (97,100,161,162)	Low levels of glutathione; decreased ability of liver to detoxify xenobiotics; abnormal glutathione peroxidase activity in erythrocytes (91,94,95)
Disrupts purine and pyrimidine metabolism (10,97,158,159)	Purine and pyrimidine metabolism errors lead to autistic features (2,101,102)
Disrupts mitochondrial activities, especially in brain (160,163,164)	Mitochondrial dysfunction, especially in brain (76,172)
Immune System	
Sensitive individuals more likely to have allergies, asthma, autoimmune-like symptoms, especially rheumatoid-like ones (8,11,18,24,28,31,111,113)	More likely to have allergies and asthma; familial presence of autoimmune diseases, especially rheumatoid arthritis; IgA deficiencies (103,106-109,115)
Can produce an immune response in CNS; causes brain/MBP autoantibodies (18,111,165)	On-going immune response in CNS; brain/MBP autoantibodies present (104,105,109,110)
Causes overproduction of Th2 subset; kills/inhibits lymphocytes, T-cells, and monocytes; decreases NK T-cell activity; induces or suppresses IFNg & IL-2 (100,112,117-120,166)	Skewed immune-cell subset in the Th2 direction; decreased responses to T-cell mitogens; reduced NK T-cell function; increased IFNg & IL-12 (103,108,114-116,173,174)
CNS Structure	
Selectively targets brain areas unable to detoxify or reduce Hg-induced oxidative stress (40,56,161)	Specific areas of brain pathology; many functions spared (36)
Accumulates in amygdala, hippocampus, basal ganglia, cerebral cortex; damages Purkinje and granule cells in cerebellum; brain stem defects in some cases (10,34,40,70-73)	Pathology in amygdala, hippocampus, basal ganglia, cerebral cortex; damage to Purkinje and granule cells in cerebellum; brain stem defects in some cases (36,60-69)
Causes abnormal neuronal cytoarchitecture; disrupts neuronal migration, microtubules, and cell division; reduces NCAMs (10,28,57-59,161)	Neuronal disorganization; increased neuronal cell replication, increased glial cells; depressed expression of NCAMs (4,54,55)
Progressive microcephaly (24)	Progressive microcephaly and macrocephaly (175)

"Table II: Summary Comparison of Biological Abnormalities in Autism & Mercury Exposure" Part B

Neuro-chemistry	
Prevents presynaptic serotonin release and inhibits serotonin transport; causes calcium disruptions (78,79,163,167,168)	Decreased serotonin synthesis in children; abnormal calcium metabolism (76,77,103,179)
Alters dopamine systems; peroxidine deficiency in rats resembles mercurialism in humans (8,80)	Either high or low dopamine levels; positive response to peroxidine, which lowers dopamine levels (2,177,178)
Elevates epinephrine and norepinephrine levels by blocking enzyme that degrades epinephrine (81,160)	Elevated norepinephrine and epinephrine (2)
Elevates glutamate (21,171)	Elevated glutamate and aspartate (82,176)
Leads to cortical acetylcholine deficiency; increases muscarinic receptor density in hippocampus and cerebellum (57,170)	Cortical acetylcholine deficiency; reduced muscarinic receptor binding in hippocampus (83)
Causes demyelinating neuropathy (22,169)	Demyelination in brain (105)
Neurophysiology	
Causes abnormal EEGs, epileptiform activity, variable patterns, e.g., subtle, low amplitude seizure activities (27,31,34,86-89)	Abnormal EEGs, epileptiform activity, variable patterns, including subtle, low amplitude seizure activities (2,4,84,85)
Causes abnormal vestibular nystagmus responses; loss of sense of position in space (9,19,34,70)	Abnormal vestibular nystagmus responses; loss of sense of position in space (27,180)
Results in autonomic disturbance: excessive sweating, poor circulation, elevated heart rate (11,18,31,45)	Autonomic disturbance: unusual sweating, poor circulation, elevated heart rate (17,180)

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