

Facility Automation Management Engineering (FAME) Systems

33 Hoffman Avenue, Lake Hiawatha, NJ 07034 – Tel. 973 263-4843

Sunday, 27 July 2008

To All:

The text following this page is a draft review of the excerpted text from an article by Dr. Archana Chatterjee, titled: “**Vaccine safety: genuine concern or a legacy of unfounded skepticism?**”, which appeared in *Expert Reviews of Vaccines* 2008; 7(3): 275-277. [See: <http://www.future-drugs.com> for the journal information.]

The excerpted text of this article was transcribed from the original for review and comment.

FAIR USE NOTICE: The following review contains quotations from copyrighted (©) material the use of which has not been specifically authorized by the copyright owner. Such material is made available for educational purposes, to advance reader's understanding of human rights, democracy, scientific, moral, ethical, social justice and other issues. It is believed that the author's quoted statements are a 'fair use' of this copy-righted material as provided for in Title 17 U.S.C. section 107 of the US intellectual property law. This material is being distributed without profit.

The formal review, which is titled “**A Review of: ‘Vaccine safety: genuine concern or a legacy of unfounded skepticism?’**”, begins on the next page.

Introductory Remarks

First, *to simplify this review*, the statements in the article by the author, Dr. Archana Chatterjee, will be quoted in a “Times New Roman” font.

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

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

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

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

Respectfully,

<S>

Paul G. King, PhD,
Founder,

FAME Systems

33A Hoffman Avenue

Lake Hiawatha, NJ 07034-1922

Email: drking@gti.net

Tel. 1-973-331-0131, after 19:00 Eastern Time

[To whom all inquiries should be directed]

A REVIEW OF: “Vaccine safety: genuine concern or a legacy of unfounded skepticism?”

as transcribed by the reviewer, Paul G. King, PhD, on 5 July 2008

Since vaccine apologists, including this writer, are able to continually present their views, this reviewer, an advocate for: a) the safening of vaccines by banning the use of Thimerosal, or any other mercury compound, in the manufacture of any medicine and b) vaccine safety as well as for: c) government-supported vaccination programs only for vaccines that have been proven to be safe and medically cost-effective, will only address the “*genuine concern*” side of the “*Vaccine safety*” issues in this review.

Thus, this review presents factual information that exposes the weaknesses in, and/or exposes the apparent falseness of, the broad generalizations made by this writer.

Lest any take this reviewer’s remarks as those of someone who is anti-vaccine, this reviewer again reiterates that, *given the scientific information available*, he currently supports national vaccination programs for those vaccines that have truly been proven to be both generally safe and medically cost-effective, provided the individual parent’s constitutional right to “*due process of law*” is not abridged or ignored.

Having made his position as an advocate for:

- a. Banning the use of mercury compounds in medicine to safen vaccines,
- b. Vaccine safety, and
- c. Medically cost-effective vaccines

clear, this reviewer will now assess the statements made by the writer of the article, “*Vaccine safety: genuine concern or a legacy of unfounded skepticism?*”

“The impact of vaccination on the world’s health is difficult to exaggerate.”

This reviewer, as a *vaccine safety advocate*, notes that, *while the writer of this article and other vaccine apologists may believe this*, they certainly have never ceased trying to exaggerate the “*impact of vaccination on the world’s health*”.

Nor does this writer, as *this article clearly substantiates*, refrain from misrepresenting factual reality as, *and when*, it apparently suits her.

“The availability of vaccines to prevent many of the Earth’s worst killer diseases in the past centuries, has led to billions of lives being saved, decades of life-expectancy increase, enhancement of the quality of life and elimination of a huge burden of suffering and disability around the world.”

First, this reviewer notes that most of the historical increases in: **a)** lives saved, **b)** life expectancy, and **c)** the quality of life as well as **d)** the reduction of the burden of suffering and disability around the world has *actually* come from:

- Increases in sanitation and hygiene,
- The availability of clean, pathogen-free water for drinking and bathing,
- Increases in the quality and availability of shelter,
- Improvements in the availability of adequate safe nutritious food and dietary supplements, and
- The advent of effective antiseptics, antibiotics, anti-fungals, and, *most recently*, anti-viral drugs to treat infections.

To see the validity of this, we need only look at the decrease in deaths in the United States of America (USA) from measles, a highly contagious childhood disease.

To get a valid before-and-after picture, this reviewer suggests examining measles deaths from 1912 to 1993 (as shown in **Figure 1** on this page), a period which consists of five decades plus before the first “effective” measles vaccine was introduced in 1963 until roughly three decades after full national vaccination of children with a measles vaccine was achieved.

As the graph shows, *even though the population of the USA was rapidly increasing during most of this period*, more than 90 % of the declines in the annual numbers of deaths for contagious diseases endemic in the United States, other than smallpox, (e.g., cholera, measles, rubella, polio) occurred before there were vaccines for them.

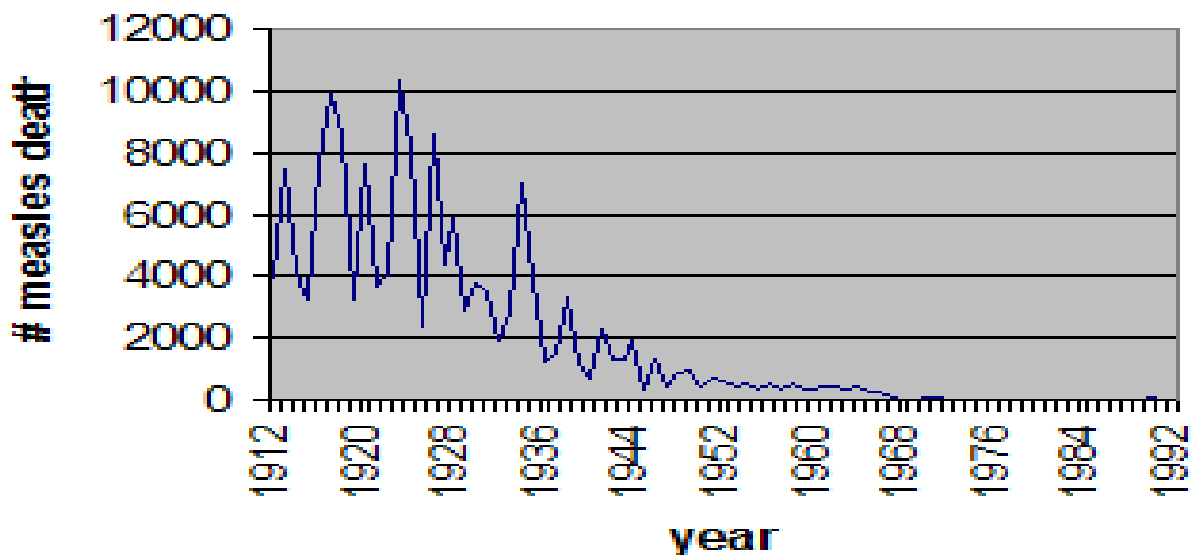
For example, the estimated annual average pre-vaccine cases and deaths from measles used by vaccine apologists touting the contributions of the measles vaccines to public health are generally based on the years 1953-1962,¹ the decade prior to the introduction of an effective measles vaccine in 1963.

By then (**see Fig. 1**), the annual number of deaths in the 1953-1962 period (<800 per year) had already dropped by more than 93% from the peak in the number of annual deaths in the 1915-1924 period (> 10,000 in 1924).¹

By ignoring the earlier years, the vaccine apologists *inaccurately* represent the magnitude of the decline in measles that is attributable to vaccination as the most significant factor.

However, the real major factors in the decline in measles deaths were pre-vaccine causes, such as significant increases in the availability of safe food and drinking water, and major improvement in sanitation, housing and nutrition as well as the introduction of antibiotics to treat the illnesses, like pneumonia, that children contracted after the measles virus had weakened their immune systems.

Figure 1. USA measles deaths by year, 1912 to 1993



¹ Centers for Disease Control (CDC). Reported Measles Cases, Deaths, Deaths-to-Cases Ratio and Estimated Population in the United States, 1912-1984. Provisional Data; Doc #0051m

In addition, current vaccine orthodoxy in the USA typically fails to emphasize the importance of giving a mega dose of fat-soluble vitamin A (typically, using Cod liver oil before the availability of single-vitamin supplements) at the onset of measles to minimize the disease's severity – though this was common practice before the vaccine.

Thus, though the magnitude of the effect is less than typically portrayed, the data from 1963 onwards do indicate that the measles vaccine has *apparently* been effective in significantly reducing measles deaths in the USA.

Lest the reader think that the impact of the measles vaccine, a very effective vaccine, on measles deaths is an isolated instance, this reviewer suggest that he or she read this commentator's January 2008 article, "A review of: 'Vaccinations are still needed for kids'"², in which both pertussis and polio are also discussed.

“Why then would anyone question the value of this wonderful preventative strategy?”

As a scientist, this reviewer questions “*the value of this wonderful preventative strategy*” because:

- Many of the “childhood” vaccines that have the greatest effectiveness actually consist of man-made (bioengineered) live-virus vaccine strains (e.g., measles, mumps, rubella, herpes varicella zoster [chickenpox and shingles], rotavirus, the genetically engineered influenza trivalent vaccine, and the trivalent Sabin polio vaccines [given in the USA from the 1960s to the mid-1990s]).
- When inoculated, these live-virus vaccines:
 - a. Infect those inoculated with one or more strains of the disease viruses they contain in an attempt to provide immunity to more virulent strains, and,
 - b. *When they are shed*, may also infect those who come into contact with the inoculated persons or their excretions,
- Our public health officials do not recognize, *much less count*, those inoculated with a live-virus as cases of the disease, as they should when, *shortly after inoculation*, the children inoculated:
 - a. Exhibit the symptoms of the disease or
 - b. Have the same severe side effects as the disease is known to cause (e.g., for the measles vaccine, where the package insert admits the vaccine can cause: death, atypical measles, vasculitis, diabetes mellitus, thrombocytopenia, leukocytosis, anaphylaxis and anaphylactoid reactions, encephalitis, encephalopathy, measles inclusion body encephalitis [MIBE], subacute sclerosing panencephalitis [SSPE], Guillain-Barré Syndrome [GBS], febrile convulsions, afebrile convulsions or seizures, ataxia, polyneuritis, polyneuropathy, ocular palsies, and paresthesia – in those inoculated with it).
- *Unlike the “lifetime” immunity that having the contagious childhood diseases one time confers in most all cases*, inoculation (with 2 or more doses of the corresponding vaccine) produces an immunity that:
 - a. Does not protect all of those who are inoculated with a live virus;
 - b. *In many cases (e.g., mumps, rubella, pertussis, and tetanus)* provides much less than lifetime immunity as we are becoming increasingly aware, and

² <http://mercury-freedrugs.org/docs/080127MegFisher1b.pdf>.

- c. *Increasingly*, “requires” additional “booster” doses even though:
 - i. The cost of these *boosters* often renders the vaccine not cost-effective on a public health basis and
 - ii. Each *booster* increases the risk of a vaccine’s severe adverse effects from these repeat challenges to the immune system (a reality medically known as “rechallenge”).
- The current national vaccination program contains several problematic vaccines that are not truly effective against all the endemic strains of the disease including, for example:
 - a. The various influenza vaccines that *admittedly* only provide limited-duration protection for 3 strains of human influenza, *though many strains are present*, and, *because the virus mutates rapidly*, new strains are continually being introduced into circulation;
 - b. The polysaccharide and diphtheria-toxoid-conjugated polysaccharide vaccines for *Neisseria meningitidis* (which cannot provide protection for the “B” strain that is found in 20% to 50 % of all typed cases) appear to:
 - i. Provide limited-duration [5-year or less] protection to no more than 85% of those inoculated and
 - ii. Seem to be shifting disease prevalence toward the “B” strain;
 - c. The rotavirus vaccines that simply infect all inoculated to varying degrees and have increased the rate of serious adverse outcomes (intussusception and, *for Merck’s RotaTeq®*, Kawasaki’s disease) to several times the reported rates before they reintroduced in 2006 (e.g., RotaTeq®) based on VAERS reporting³;
 - d. The HPV vaccines that not only have no proof of the claimed protection from developing cervical cancer 30-plus-years later and *apparently* only provide, *at best*, limited-duration protection against a few of the 100-plus strains of HPV that is provided by the bioengineered antigens that are contained in these vaccines, but also may have an unacceptable risk of serious harm and death as well as exhibit HPV-disease-promoting properties in those who have been exposed to the covered strains as well as some of the other strains of HPV; and
 - e. The pneumococcal vaccines for children and adults that, *in the long term*, seem to be shifting the spectrum of diseases in the vaccinated population to other strains of pneumonia and/or other diseases that are much more aggressive and/or harder to treat [e.g., MRSA].
- The present vaccination program permits severe underreporting of adverse vaccine-related events (where the CDC estimates that, *on average*, less than 10% of all vaccine-related adverse events are reported to VAERS).
- There is an ongoing recommendation of “universal” vaccination when the vaccine is clearly not medically cost-effective (as any vaccine should be before it is recommended for “universal” use) or even “societally” cost-effective (e.g., the influenza, HPV, herpes varicella zoster vaccines, and rotavirus vaccines, where, because of the vaccine manufacturer’s pricing or the need for an additional dose, reality pushes the vaccine from its initially claimed medically cost-effective or

³ Geier DA, King PG, Sykes LK, Geier MR. RotaTeq vaccine adverse events and policy. *Med Sci Monit*, 2008; **14**(3): PH9-PH16.

societally cost-effective status into public health costs that cannot be justified on any rational basis even when, as the costs estimates provided by the manufacturers do, the costs of the adverse effects are excluded).

Thus, the long-term in-use costs, which include the costs of the adverse vaccine reactions, clearly indicate that many of the current “universal” vaccination programs are neither medically cost-effective, as they should be, nor even societally cost-effective, which would make them public health cost neutral, clearly rendering such vaccination programs harmful to the public’s financial health.

Further, because Thimerosal (49.55-wt% mercury) has never been proven to be safe at any level for injection into humans of any age, those vaccines that contain any level of Thimerosal mercury poison all of those inoculated with them to some degree.

Finally, those vaccines that contain a preservative level of Thimerosal (and, as of June 2008, there are 10 vaccines approved for use in children and/or adults, including pregnant women, that are Thimerosal-preserved vaccines) are adulterated drugs because the manufacturers have admitted to Congress⁴ that they have knowingly failed to comply with 21 C.F.R. Sec. 610.15(a), a current good manufacturing practice (CGMP) requirement minimum, where non-compliance renders those vaccines adulterated under 21 U.S.C. Sec. 351(a)(2)(B).

Hopefully, the writer now understands the major reasons why any knowledgeable scientist, or caring medical professional, should be questioning this “wonderful preventative strategy” as it exists today.

“Yet, in recent years, as vaccine-preventable diseases have disappeared from the public eye, particularly in developed countries, the specter of vaccines as a dangerous intervention has been raised by some people.”

Here, the writer begins with a general truth, “in recent years, as vaccine-preventable diseases have disappeared from the public eye, particularly in developed countries” that conceals two sad realities:

1. There has been a startling rise in many chronic childhood diseases (e.g., ASD, ADHD, ADD, diabetes [types 1 and 2], asthma and COPD, obesity, gastrointestinal disorders, multiple sclerosis [MS], cancer, severe food allergies, and other severe allergies) that, because they are long-term chronic medical conditions and not transient childhood diseases,
 - a. Have led to a general sickening of our children and
 - b. Are causing significant and increasing harm to public health, and
2. The attempted implementation of developed-country-vaccination programs in developing countries (e.g., India) has been much less successful than in they have been in America.

“To some extent vaccines have become a victim of their own success.”

First, since this reviewer finds this assertion in almost every article written by a vaccine apologist, as this writer clearly seems to be, this reviewer must conclude that it is one of the

⁴ Subcommittee on Human Rights and Wellness, Committee on Government Reform of the House of Representatives, “Mercury in Medicine Report,” Washington, DC, as published in the *Congressional Record*, pgs. E1011-E1030, May 21, 2003.

writer's core beliefs.

Based on the facts currently available to this reviewer, this “*success*” belief, *if legitimate*, is only valid for those effective legacy vaccines developed prior to the National Vaccine Injury Compensation Program⁵.

Second, given the steep/epidemic rise in chronic childhood disease, *which, in some cases (e.g., asthma), now generally exceeds 10% of our children*, it is clear to this reviewer that our children are increasingly the victims of the “*success*” of America's newer vaccination programs.

Third, the big successes for these newer vaccines have been the revenues they have generated for the vaccine makers, vaccine providers and vaccine professionals, *such as the author of this article*, and the increase in medical costs and treatment “opportunities” engendered by the chronic childhood diseases whose rates they clearly have increased to, *in many cases*, epidemic levels (> 1 in 1,000 [$> 0.1\%$] children).

Finally, only a vaccine apologist would even attempt to portray vaccines as “*a victim*” of anything.

“Attempts to vaccinate go back several centuries but the ‘golden age’ of vaccine development did not begin until the 1940s, with the development of cell-culture techniques.”

Here, this reviewer finds that the writer's “*golden age*” is another favorite phrase that vaccine apologists use.

But, this reviewer finds that the true “*golden age*” of vaccine development did not begin in the USA until the vaccine makers were shielded from liability in 1986, and, *later*, when the vaccine providers were also protected from being sued for the harm vaccinations inflict on some children.

Shielded from the prospect of being sued for vaccine-induced harm (an obvious drug safety issue for disease-preventive drugs) and the lack of effectiveness in “childhood” vaccines, the vaccine manufacturers, the US FDA and the US CDC have colluded to license and approve vaccines and vaccine usage programs with no real regard for:

- Their true safety and effectiveness (*e.g., for the Merck HPV vaccine, the FDA allowed Merck to pervert its short-term safety trials by allowing them to use essentially the aluminum-adjuvanted vaccine formulation without the four biological actives as the “placebo” in most of the short-term safety trials – thereby concealing the magnitude of the harm that the vaccine causes as compared to a sterile saline injection [the placebo “vaccine” that should be used as the control arm in all vaccine safety trials if you want to have a valid estimate for the vaccine’s potential to be harmful to those who receive it] or,*
- *In the case of Thimerosal-preserved vaccines, compliance with the applicable law governing the safety standard for preserved biological drug products as set forth in 21 C.F.R. Sec. 610.15(a).*

“Over the following few decades, vaccine development occurred in leaps and bounds, allowing public-health authorities to gain control of age-old scourges, such as smallpox, measles and polio.”

⁵ UNITED STATES CODE (U.S.C.), TITLE 42 - THE PUBLIC HEALTH AND WELFARE, CHAPTER 6A - PUBLIC HEALTH SERVICE, SUBCHAPTER XIX - VACCINES, Part 2 - National Vaccine Injury Compensation Program; 42 U.S.C. Sec. 300aa-10 through 300aa-34, originally enacted in late 1986.

In each case, rather than “*allowing public-health authorities to gain control of*” these diseases, the live-virus vaccines for the cited diseases infected, and infect, everyone inoculated with them with a man-made strain of a disease (i.e., a vaccinia virus strain for smallpox, a measles virus strain for measles, and, from 1963 to 1995, an oral trivalent polio virus vaccine for polio) that induced, *and induces*, a general level of “immunity” to these diseases in those who were inoculated. [Note: Lest the writer or any reader think that this “infection” view of live-virus inoculation is not generally accepted, this reviewer suggests that she or he read the interview response of Jay Gordon, MD, Assistant Professor of Pediatrics, UCLA Medical School and formerly, Senior Fellow in Pediatric Nutrition, Memorial Sloan-Kettering Institute to the question “*Why is there so much controversy specifically about the MMR vaccination?*”⁶ (with underlining added for emphasis):

“It’s a live-virus vaccine. A live-virus vaccine, in order to work, creates a little bit of an infection. And when you get measles, you get it through your nose and your throat, [which triggers a very specific immune response.] When we inject measles, we are bypassing that system and going right into the bloodstream. And we’re finding that yes, there can be some impact on the intestinal tract and to the brain from the measles vaccine. And it’s a vaccine of almost no benefit to American children, one by one. Now, in terms of public health, I don’t want to be the guy who said, ‘Boy, this vaccine stinks.’ It doesn’t stink. It works very, very well. The reason we don’t have measles in America is because the vaccine works great. But sit down, please. Let’s talk about the fact that your cousin and your other cousin both have autism. Or that your son has some questionable neurological issues, he seems to be speaking or walking a little later. I don’t want to mess with him.”]

Only in the case of smallpox, *where everyone was given a cowpox (vaccinia virus) inoculation*, could the infecting of everyone directly, or, *from viral shedding*, indirectly, with a man-made vaccinia disease be considered to have wiped out the disease caused by the related smallpox virus.

In the other cases, everyone was infected with man-made disease strains which simply displaced the endemic native strain (or strains) of the disease and provided effective protection of unknown duration against contracting the wild strains of the disease that are endemic to the USA (but not completely to measles or polio strains that are endemic or, by mutation, are developing in other areas of the world).

However, since the live-virus polio vaccines continue to be used in the developing world and the poliovirus is continually mutating, it remains to be seen how effective the current USA vaccination program for polio will be when the children who are currently getting an inactivated poliovirus vaccine grow up and, *in the mid-2010s and beyond*, are exposed to polio strains that are not covered by the vaccines they received, because, *in developing countries, like India*, repeated vaccination campaigns with live poliovirus vaccines have failed to eliminate polio cases.

“These early successes, however, have been tempered in recent years by the rising tide of fear that vaccines do more harm than good.”

Here the writer uses Orwellian “newspeak” to obscure the reality in the USA that, as a *whole*, some of today’s many vaccination programs obviously “*do more harm than good*”.

Moreover, *in general*, the public has only the words of the vaccine apologists to substantiate the claim that the early vaccination programs were “*successes*”.

This is the case because the articles published at the time the vaccination programs for the vaccine apologist’s flagship successes, “*smallpox, measles and polio*”, indicate that the

⁶ http://www.cookie-mag.com/entertainment/2008/07/vaccine_experts?currentPage=2, last visited on 22 July 2008.

early programs caused a significant increase in disease cases, which, *in the case of the early Salk inactivated-polio vaccines*, the health establishment has:

- Concealed the increase in cases by changing the definition of paralytic polio from partial paralysis of any duration to require the paralysis to continue for at least 30 days, and
- Hidden the reality that those receiving these vaccines were being infected with live animal viruses, including a monkey virus, SV-40, that has been shown to be a probable causal factor in certain aggressive brain cancers that develop decades later in some of those vaccinated from the 1950s until at least into the 1980s.

“Two major areas of concern have been the potential adverse effects, particularly neurodevelopmental disorders related to thimerosal (approximately 50% of which is ethylmercury), used as a preservative in some vaccines [1], and the reported but subsequently refuted, association between the measles component of the triple measles-mumps-rubella (MMR) vaccine and autism [2].”

Given the range of chronic childhood medical conditions in which Thimerosal, a *proven human carcinogen, mutagen, teratogen, and immune-system poison at exposure levels below 1 microgram per gram or milliliter*, is probably a causal factor, this reviewer is bemused by this writer’s:

- Describing the Thimerosal in Thimerosal-preserved vaccines as having “*potential adverse effects*”, then
- Limiting the scope of the harm, as vaccine apologists like to do, to “*neurodevelopmental disorders*”, a subset of Thimerosal’s “*potential adverse effects*” and finally
- Changing the discussion, as the reader will see, from all “*neurodevelopmental disorders*” to “*autism*”, which is only one of the many “*recognized*” Thimerosal-related “*neurodevelopmental disorders*”, which today include, *but are not limited to*: autism (autistic disorder), pervasive developmental disorder – not otherwise specified (PDD-NOS), Asperger’s, obsessive-compulsive disorder (OCD), attention deficit – hyperactivity disorder (ADHD), attention-deficit disorder (ADD), and tics.

In addition, this reviewer notes that the writer mischaracterizes the composition of Thimerosal, a trade name for sodium ethylmercurithiosalysilate, as “(*approximately 50% of which is ethylmercury*)” when Thimerosal is actually 49.55-wt% mercury and 56.73-wt% ethylmercury.

Further, this reviewer notes that Thimerosal is still used as a preservative in several vaccine formulations that are still approved for administration to children (humans from birth to age 18 years on the USA) as shown in this reviewer’s **Table 1**.

In addition, the CDC’s recommendations permit several Thimerosal-preserved influenza vaccines to be given to pregnant women without proof of safety to the fetus (these vaccines are “Pregnancy C” drugs indicating that fetal safety has not been established).

The CDC does not ban giving these Thimerosal-preserved vaccines to pregnant women even though published studies from the 1970s have established that giving Thimerosal-preserved flu shots to pregnant women led to statistically significant increases in some severe birth defects (cleft palate, pyloric stenosis and hydrocephaly) in the children born to pregnant women inoculated with such influenza vaccines during pregnancy⁷.

⁷ Heinonen OP, Slone D, Shapiro S. **Birth Defects and Drugs in Pregnancy**. Littleton, Massachusetts: Publishing Sciences Group, Inc., 1977.

Yet, even in the face of these facts, Dr. Chatterjee states, later in this article, that she is proud to lobby against state laws that would prevent healthcare providers from giving Thimerosal-preserved vaccines to children and pregnant women.

Turning to the writer's "the reported but subsequently refuted, association between the measles component of the triple measles-mumps-rubella (MMR) vaccine and autism [2]", this reviewer notes that this remark is a blatant attempt to rewrite history by:

- Confusing: **a)** a partial (by only 10 of the study's 13 authors) 2004 retraction of the interpretation (of the 1998 study being alluded to) with: **b)** a refutation of the "association between the measles component of the triple measles-mumps-rubella (MMR) vaccine and autism" theory, which the partial retraction was not, and
- Ignoring the reality that subsequent patient studies and an independent epidemiological study have confirmed a causal association between MMR vaccination and measles-associated regression into "autism".

Table 1. March 2008 FDA-licensed Thimerosal-preserved Vaccines for Children Revisited [Taken From: FDA CBER Table 3: Thimerosal and Expanded List of Vaccines - (updated 3/14/2008) Thimerosal Content in Currently Manufactured U.S. Licensed Vaccines]

No.	Vaccine	Trade Name	Manufacturer	Thimerosal Concentration[1]	Mercury
1	DT (available but not marketed [3])	No Trade Name	Sanofi Pasteur, Ltd [3]	0.01%	25 µg/0.5 mL
2	Td	No Trade Name	Mass Public Health	0.0033%	8.3 µg/0.5 mL
3	TT	No Trade Name	Sanofi Pasteur, Inc	0.01%	25 µg/0.5 mL
4	Influenza	Fluzone [6]	Sanofi Pasteur, Inc	0.01%	25 µg/0.5 mL (3 to 18 years of age) 12.5 µg/0.5 mL (6- to 35- months old)-
5	Influenza	Fluvirin	Novartis Vaccines and Diagnostics Ltd	0.01%	25 µg/0.5 ml (4 to 18 years of age)
6	Japanese Encephalitis [7]	JE-VAX	Research Foundation for Microbial Diseases of Osaka University	0.007%	35 µg/1.0mL (>3 years of age) 17.5 µg/0.5 mL (1 to 3 years of age)
7	Meningococcal	Menomune A, C, AC and A/C/Y/W-135	Sanofi Pasteur, Inc	0.01% (multidose)	25 µg/0.5 mL (9 to 18 years of age)

TABLE FOOTNOTES

1. Thimerosal is approximately 50% mercury (Hg) by weight. A 0.01% solution (1 part per 10,000) of Thimerosal, which nominally contains 50 µg of Hg per 1 mL dose, 25 µg of Hg per 0.5 mL dose or 12.5 µg of Hg per 0.25 mL dose.
2. Sanofi Pasteur's Tripedia may be used to reconstitute ActHib to form TriHIBit. TriHIBit is indicated for use in children 15 to 18 months of age.
3. This vaccine is not marketed in the US **but it is available.**
4.
5. ...
6. Children under 3 years of age receive a half-dose of vaccine, i.e., 0.25 mL (12.5 µg mercury/dose.)
7. JE-VAX is distributed by Aventis Pasteur. Children 1 to 3 years of age receive a half-dose of vaccine, i.e., 0.5 mL (17.5 µg mercury/dose).

"Soon after these two hypotheses emerged, several crucial epidemiologic investigations were launched by different investigators and agencies, using a variety of designs, including cohort, case-control and ecologic, in different populations and countries."

Here, the writer's attempts to portray these studies as independent by using the phrase

“by different investigators and agencies” to conceal the reality that one agency, the US CDC, conducted, paid for, and/or exerted effective control over, all of the epidemiological studies that the writer deems as crucial, although:

- These studies have all been fully or partially discredited by independent reviewers and, *in the case of the US study*, the so-called “Verstraeten” studies, the US National Institute of Environmental Health Safety (NIEHS) and/or, *in the case of the writer’s “ecologic” studies*, by the CDC itself in a 2008 report to Congress,
- The “investigators and agencies” involved have refused to provide the original data sets, designs, and exclusion criteria for independent review and/or have claimed that the original datasets have been “lost”, and
- Internal documents, obtained under the US Freedom Of Information Act (FOIA), have clearly established that the CDC investigators (in the “Verstraeten” studies on U.S. children using the Vaccine Safety Datalink [VSD] database) manipulated the data sets, designs, and identification and selection criteria in a manner intended to minimize the magnitude of the causal links found between Thimerosal exposure and various neurodevelopmental outcomes, including autism, until the final apparent relative risk numbers were expressed in terms of the incremental risk for exposure to only 12.5 micrograms of mercury, in order to minimize the magnitudes of the relative risks found.
- In the published “Verstraeten” paper:
 - The “zero” exposure group was intentionally set to include those with exposures of up to 25 micrograms of mercury, and
 - The maximum exposure group was artificially limited to those with cumulative exposures to 62.5 micrograms of mercury by deliberately excluding those with higher mercury exposures that, *in some cases*, exceeded 235 micrograms of mercury [where the effect would be the greatest] from consideration

to further ensure that the relative risks reported in the published paper appeared not statistically significant for most all of the few specific neurodevelopmental conditions that this paper actually addressed.

“Except for studies conducted by one pair of authors [3], all others failed to reject the null hypothesis of no association [4].”

This reviewer accepts that this statement accurately reflects this writer’s myopic views about “studies” – a view that obviously excludes all but epidemiological studies because there were numerous peer-reviewed published animal, and human cellular and tissue toxicity studies by a variety of researchers that, in 2004, had clearly established the neural toxicity of Thimerosal to neurons at levels from 100 to more than 1,000 times lower than the 100-ppm level found in Thimerosal-preserved vaccines.

In addition, several subsequent epidemiological studies have clearly established statistically significant causal links between Thimerosal-preserved vaccines and various neurodevelopmental disorders, including autism.

Finally, when the statistical directions for the possible causal links between vaccine Thimerosal and various neurodevelopmental conditions, including autism, are considered in all of the epidemiological studies published up through mid-2008, the statistical reality is that they collectively point to the probability of a causal link between vaccine

Thimerosal and autism – when, *if there were no link*, about half of the epidemiological studies should have found a “zero” or negative association.

“The studies published by Geier and Geier [3] contain critical design flaws, such as using data from the Vaccine Adverse Event Reporting System (VAERS), a cooperative program for vaccine safety of the US CDC and the US FDA [101], VAERS is a passive surveillance system to which anyone may report vaccine-related adverse events, without determining causality.”

Having reviewed the paper in question and the criticisms raised against it, this reviewer finds that one key criticism (questioning the accuracy of the denominators used for the doses of each vaccine given) was not factually valid.

In addition, none of the other criticisms of this paper were critical to the outcomes found, other than to establish that the magnitudes of the statistical significance of the links found were underestimated because of inherent VAERS limitations.

While it is true that “*VAERS is a passive surveillance system to which anyone may report vaccine-related adverse events, without determining causality*”, the realities are:

- More than 95% of the reports during the study period in the paper question were submitted by medical professionals and/or drug-company representatives,
- The reports filed are “investigated” by VAERS personnel, and
- The study design and approaches were essentially the same as those used by, *and still being used by*, the CDC in its studies using VAERS to establish the possibility of a statistical causal link between a given adverse reaction to a vaccine and a given vaccine formulation (e.g., the recent putative link between vaccination with Sanofi-Aventis’ Menactra® and an increased risk for Guillain Barré syndrome).

Thus, the writer’s objection to using VAERS essentially becomes a claim that use of VAERS is only valid when the CDC oversees the epidemiological studies being conducted.

The writer espouses this view even though the current epidemiological credentials and experience of Dr. Mark R. Geier, Fellow of the American College of Epidemiology, seem to equal or, *in most cases*, exceed those for the individuals in the CDC who have conducted and published, and/or are still conducting, epidemiological studies using VAERS.

Moreover, this reviewer also notes that the Geier and Geier have conducted and/or have participated in studies in the VSD database that have found outcomes, which support their findings in their VAERS studies.

Finally, several recent case-control studies have established that children with an ASD diagnosis are mercury poisoned in instances where the bolus doses of mercury from the Thimerosal-preserved vaccines were the principal source of their mercury exposure.

“On the other hand, other studies that did not show any relationship between thimerosal and adverse neurodevelopmental disorders were statistically sound, well powered to detect even small effects and could adjust for background confounding factors.”

Since the writer has failed to identify the studies about which she is speaking here, this reviewer can only accept that this statement reflects the writer’s jaundiced view of reality.

“As for the study linking the MMR vaccine to autism, that too had major methodological flaws; of the 12 children in the study, some were found to have developmental disorders before they were vaccinated

and most were clients of a lawyer who was preparing to sue vaccine manufacturers [102].”

First, this reviewer must note that the writer has failed to reference any primary published scientific source to substantiate the validity of her statement.

Instead, she referenced the writings of another vaccine apologist, “Marjorie Ingall”, in a May 4, 2007 newspaper article titled, “Vaccine Nation”, that, *in turn*, failed to provide references to the credible peer-reviewed published papers that support that vaccine apologist’s views.

“In 2004, the Institute of Medicine Immunization Safety Review Committee reviewed all evidence available from biological, molecular and animal model studies and stated that ‘The committee concludes that the evidence favors the rejection of a causal relationship between thimerosal-containing vaccines and autism’ [5].”

First, though the 2004 “*Institute of Medicine Immunization Safety Review Committee*” (IOM-ISRC) did review evidence “*available from biological, molecular and animal model studies*” as well as the epidemiological studies alluded to by the writer previously, this committee did not, as the writer alleges, review all evidence.

Moreover, as instructed by the CDC who had hired the IOM-ISRC, this committee, having found pretexts to exclude the epidemiological evidence that had found support for a Thimerosal-neurodevelopmental link, chose to only consider the remaining CDC-directed epidemiological evidence and to restrict their statements to one neurodevelopmental disorder, “autism”, because even the CDC-directed studies had found evidence of a causal link between Thimerosal and some other neurodevelopmental disorder (e.g., tics) and, as far as the disclosed closed-meeting transcript indicates, the committee had been verbally instructed to find no causal links.

Thus, the report of the IOM-ISRC, charged with finding no links, does state: “*The committee concludes that the evidence favors the rejection of a causal relationship between thimerosal-containing vaccines and autism*”, as the writer states.

However, the writer fails to report that even the subset of the epidemiological evidence the IOM-ISRC considered should have led the committee to report that that evidence:

“clearly favored the acceptance of a causal relationship between Thimerosal-containing vaccines and tics”.

But, *because this committee was charged to find no links*, this clearly established linkage of Thimerosal-containing vaccines and tics was omitted from the IOM-ISRC report.

“Proponents of antivaccine legislation often quote a passage from this report that states that ‘the committee cannot rule out, based on the epidemiological evidence, the possibility that vaccines contribute to autism in some small subset or very unusual circumstances’, conveniently failing to complete the statement that continues, ‘however, there is no evidence to support this hypothesis either’ [5].”

First, this writer begins by falsely labeling those who oppose allowing any level of Thimerosal in vaccine formulations as “(p)roponents of antivaccine legislation”.

Since:

- Those who oppose the use of Thimerosal in vaccines or any other medicine are specifically opposing a vaccine ingredient that is only legally permitted to be there as a preservative,

- There are other compounds and compound mixtures that have been approved for use, and are used in, multiple-dose vaccine formulations, and
- There is no requirement that any vaccine be preserved unless it is packaged in a multiple-dose container,

all that proponents of no-Thimerosal vaccines are advocating is that vaccines be safened by removing Thimerosal from the manufacture of vaccines, because Thimerosal is a known bioaccumulative teratogen, mutagen, carcinogen and immune-system poison at levels below 1 ppm.

Further, because:

- These anti-mercury proponents are not opposed to vaccines, but only to their containing Thimerosal or any other mercury compound,
- The legislation they have proposed does not seek to ban any vaccine per se, and
- Vaccine makers have all repeatedly testified that they could manufacture all the no-Thimerosal doses needed if the government were to require them to cease using Thimerosal in the manufacture of any vaccine or component of a drug,

it is *clearly* false to label these vaccine-safety advocates as proponents of antivaccine legislation as the writer does here.

Second, accepting the reality of the report's "*the committee cannot rule out, based on the epidemiological evidence, the possibility that vaccines contribute to autism in some small subset or very unusual circumstances*" and the *precautionary principle* that medicine claims to revere, then, to protect "*some small subset*" and those inoculated in "*very unusual circumstances*", all use of mercury in medicine should have stopped in 2004 after this report was issued.

Third, speaking of epidemiological studies designed to find statistically significant evidence of a general population causal link between Thimerosal-containing vaccines and neurodevelopmental disorders, it is obvious that such epidemiological studies cannot provide "*evidence to support*" the hypothesis of the aforesaid link in "*some small subset or very unusual circumstances*".

"Two recently published studies have, again, addressed the issue of vaccine safety, particularly as it relates to autism [6] and other neuropsychological outcomes [7]. The study by Schechter and Grether uses an ecological design and data from the California Department of Developmental Services from January 1995 through March 2007 [6]. The authors have shown that prevalence rate of autism continued to climb during the period, despite the fact that thimerosal was discontinued as a preservative in childhood vaccines in 2001 [6]."

First of all, the cited studies are based on a false premise, the writer's "*the fact that thimerosal was discontinued as a preservative in childhood vaccines in 2001*".

This is a knowingly false misrepresentation of the facts because:

- The use of Thimerosal as a preservative in childhood vaccines and in vaccines given to pregnant women continues to this very day.
- The remaining in-date doses of the Thimerosal-preserved vaccines were not recalled and destroyed when, *beginning in late 2000*, the reduced-Thimerosal vaccines were introduced [with some in-date doses of these Thimerosal-preserved vaccine formulations *reportedly not* expiring until early 2005].
- *To offset the reduction in Thimerosal exposure*, in 2002 the CDC's Advisory Committee on Immunization Practice (ACIP) began officially recommending that:

- a. Pregnant women be given a flu shot during pregnancy (delivering a higher specific dose of Thimerosal to the fetus than a child previously received at birth from a Thimerosal-preserved hepatitis B vaccine) and
 - b. Children 6 months to 23 months of age also be given a flu shot
- because, *when these recommendations were made in early 2002*, the flu-shot doses that the FDA could approve for the 2002–2003 flu season were almost all Thimerosal-preserved.
- *In addition*, the CDC has:
 - Periodically increased the general age range for giving the flu shot to children,
 - Directed that “vulnerable” groups of children receive it, and
 - Decreed that children be given two doses separated by a short interval the first time the shot is given regardless of their age,until, in 2008, the Thimerosal-preserved flu shot is recommended each year for all children 6 months to 18 years of age.
 - *Based on the preceding*, the total maximum dose from all their vaccinations, mostly delivered in 25-microgram boluses, that some children may receive by 7 months of age is about 52 micrograms of mercury and, *by 18 years of age*, may exceed 500 micrograms of mercury (> 1000 micrograms of Thimerosal) [not including the doses of Thimerosal that a child may receive from Thimerosal-preserved eye and ear drops, nasal sprays and other drugs that may contain some level of Thimerosal or other mercury compound so that the total mercury exposure from vaccines and these drugs easily exceeds 900 micrograms and can, *in cases where there is prolonged or recurrent usage of these other Thimerosal-preserved/containing drugs*, exceed twice this level].
 - The reduction in Thimerosal level in some formerly Thimerosal-preserved childhood vaccine formulations beginning in late 2000 or, *beginning in 2004*, the “complete” removal of Thimerosal from the manufacturing processes for some of the reduced-Thimerosal childhood vaccines has, *in terms of specific dose exposure to a known bioaccumulative toxin like mercury*, been significantly offset by other changes in the recommended national vaccination program published by the CDC.

As proof of the continuing presence of Thimerosal-containing and Thimerosal-preserved vaccines that are still recommended for administration to children, the reader need only consult this reviewer’s **Table 2** on the next page.

In addition, *because of exemptions given in 2006 to the California law restricting flu shots to reduced-Thimerosal vaccines for pregnant women and children up to three years of age*, the 2007-2008 “flu season” was the first time that, *if the California law were rigorously adhered to*, pregnant women and children under three years of age in California would have received no Thimerosal-preserved influenza vaccine if vaccinated.

Since California does not even affirmatively classify children under age three as having a diagnosis of autism, the reported study, using “*data from the California Department of Developmental Services from January 1995 through March 2007*”, would have only included children born before March of 2004 when some children may still have been receiving the old (pre 2002) Thimerosal-preserved vaccine formulations as well as Thimerosal-

preserved influenza vaccinations and their mothers' could legally have been given a Thimerosal-preserved flu shot.

Thus, all of the children with autism in this California study could still have received Thimerosal-preserved vaccines.

Moreover, this reviewer notes that the "autism" numbers for children older than 8 were also increasing.

This indicates that there was significant underascertainment in prior years and/or an influx of children with autism from other states and/or nations.

Table 2: Thimerosal Content In Currently Manufactured U.S. Licensed Thimerosal-Containing Vaccines That Are Approved For Administration To Children
[From The FDA's "Table 3: Thimerosal and Expanded List of Vaccines - (updated 3/14/2008)"]

Vaccine	Trade Name	Manufacturer	Thimerosal Concentrat'n[1]	Mercury
DTaP	Tripedia[2]	Sanofi Pasteur, Inc	≤ 0.00012%	≤ 0.3 µg/0.5 mL dose
DTaPH (Tripedia + ActHIB [2])	TriHIBit	Sanofi Pasteur, Inc/SA	≤ 0.00012%	≤ 0.3 µg/0.5 mL
DT	No Trade Name	Sanofi Pasteur, Inc	< 0.00012% (single dose)	< 0.3 µg/0.5mL dose
		Sanofi Pasteur, Ltd[3]	0.01%	25 µg/0.5 mL dose
Td	No Trade Name	Mass Public Health	0.0033%	8.3 µg/0.5 mL dose
	Decavac	Sanofi Pasteur, Inc	≤ 0.00012%	≤ 0.3 µg mercury/0.5 ml dose
TT	No Trade Name	Sanofi Pasteur, Inc	0.01%	25 µg/0.5 mL dose
HepA/HepB	Twinrix	GlaxoSmithKline Biologicals	< 0.0002%	< 1 µg/1mL dose
Influenza, inactivated	Fluzone[6]	Sanofi Pasteur, Inc	0.01%	25 µg/0.5 mL dose
	Fluvirin	Novartis Vaccines and Diagnostics Ltd	0.01%	25 µg/0.5 ml dose
	Fluvirin (Preservative Free)	Novartis Vaccines and Diagnostics Ltd	< 0.0004%	< 1 µg/0.5 mL dose
Japanese Encephalitis[7]	JE-VAX	Research Foundation for Microbial Diseases of Osaka University	0.007%	35 µg/1.0mL dose; 17.5 µg/0.5 mL dose [If 1 to 3 years old]
Meningococcal	Menomune A, C, AC and A/C/Y/W-135	Sanofi Pasteur, Inc	0.01% (multidose)	25 µg/0.5 dose

Table Footnotes

1. Thimerosal is approximately 50% mercury (Hg) by weight. A 0.01% solution (1 part per 10,000) of thimerosal contains 50 µg of Hg per 1 ml dose or 25 µg of Hg per 0.5 ml dose. The **bolded** entries are for vaccines that are Thimerosal-preserved.
2. Sanofi Pasteur's Tripedia may be used to reconstitute ActHib to form TriHIBit. TriHIBit is indicated for use in children 15 to 18 months of age.
3. This vaccine is not marketed in the US **but it is available**.
4. ...
5. ...
6. Children under 3 years of age receive a half-dose of vaccine, i.e., 0.25 mL (12.5 µg mercury/dose.)
7. JE-VAX is distributed by Aventis Pasteur. Children 1 to 3 years of age receive a half-dose of vaccine, i.e., 0.5 mL (17.5 µg mercury/dose).

Given the preceding factual realities, all that the study by Schechter and Grether actually demonstrated is that, *for children born between January 1992 and March 2004 who were*

then in the California system for tracking children with a regional-center-confirmed and included diagnosis of autism, the apparent prevalence rate for autism in California could have continued to increase because Thimerosal was not removed from the vaccines that these children might have received.

“The study by Thompson *et al.* examined 42 neuropsychological outcomes (excluding autism-spectrum disorders) in children between 7 and 10 years of age from four health-maintenance organizations that participate in the CDC’s Vaccine Safety Datalink [7].”

Since this study excluded those with “*autism-spectrum disorders*”, other than to mislead the less-than-knowledgeable reader, this reviewer sees no value in including this study in a discussion of vaccine safety where the prior focus was on Thimerosal-preserved vaccines or the MMR vaccine and autism.

“The authors conclude that their study does not support a causal association between exposure to mercury from thimerosal-containing vaccines and immunoglobulins, and deficits in neurophysiological function at the ages of 7—10 years [7].”

Despite the authors stated conclusion, this reviewer finds that, *even though more than two-thirds of the potential patients selected were excluded from the study including all those with an ASD diagnosis*, the study did find statistically significant effects for some measures for tics for prenatal (**see** the cited article’s “**Table 2. Association between Prenatal Thimerosal Exposure and Neuropsychological Outcomes**”), and 1- and 7- month (**see** the cited article’s “**Table 3. Association between Thimerosal Exposure and Neuropsychological Outcome, According to Age Range**”) exposure to varying levels of Thimerosal.

Thus, this study clearly indicates that increased levels of pre- and/or post- natal exposures to Thimerosal probably produce increased neuropsychological harm in a subgroup of the children with “tics”.

“Despite the growing body of scientific literature refuting any association between thimerosal in vaccines and neurodevelopmental disorders in children, and the link between the MMR vaccine and autism being debunked after the Lancet retracted the report by Wakefield et al. and ten of its 12 authors disavowed its findings, powerful, well-funded advocacy groups continue to keep the antivaccine movement alive.”

The Link Between Vaccine-Triggered Mercury Poisoning And Neurodevelopmental Disorders, Including Autism, As Well As Other Chronic Childhood Developmental And Behavioral Conditions

Here, the writer begins by ignoring the truth that there is an ever growing body of evidence published after the 2004 IOM-ISRC’s report that, *in spite of the efforts of the Establishment to suppress it*, continues to strengthen the association between Thimerosal-containing vaccines and not only neurodevelopmental disorders but also a range of childhood medical conditions that, *before the 1970s (when the Thimerosal load recommended in the national vaccination programs began to increase significantly)*, were either uncommon (e.g., childhood COPD, precocious puberty/hyperandrogeny, and severe chronic gastrointestinal disorders) or virtually unknown (childhood type 2 diabetes and childhood IDCM).

That evidence includes:

- A November 9, 2007 medical concession, *before the case was scheduled to be heard in 2008 and even before the petitioners' experts were scheduled to file their expert reports*, in ***Hannah Poling v. Sec. HHS*** (Vaccine Injury Compensation Case: 02-1466V, which was filed as a “Thimerosal in vaccines causes autism” case and scheduled to be heard in 2008 as a test case in the Omnibus Autism Proceeding for that theory [“**Theory 2**”]) by medical professionals in the US Department of Health and Human Services that Hannah Poling’s 19-month vaccinations *more-likely-than-not* caused the symptoms that led to her autism and seizure disorder diagnoses,
- Several published case-control studies involving children with an ASD diagnosis that established that these children were mercury poisoned by the Thimerosal in their vaccines,
- Animal-model Thimerosal-vaccine-dosing studies mimicking the 1999 US or the current early childhood vaccination schedule in Peru, using rats and monkeys in the US studies or, in the Peruvian study, Gold-Syrian hamsters:
 - a. Induced behavioral symptoms similar to those seen in children with neurodevelopmental disorders and/or
 - b. Found accumulation of mercury in the brain and/or
 - c. Showed changes in brain morphology similar to those seen in post-mortem studies of the brains of deceased individuals that had been diagnosed with an ASD,
- Numerous in vitro studies using neuroblastoma, glioblastoma/astrocytoms, and/or developing fetal cells that have shown:
 - a. The deleterious effects of Thimerosal and/or its metabolite, ethylmercury hydroxide, on the developing cell systems studied and
 - b. Changes in cell morphology similar to the changes seen in the post-mortem brains of children with an autism diagnosis,and
- Studies on children with an ASD diagnosis showing that their controlled chelation with chelating drugs (e.g., DMSA and DMPS), which are recognized to be somewhat mercury-selective, reduced the level of mercury poisoning in those who had established mercury poisoning and, more importantly, improved their capabilities and/or socialization.

In addition, the writer’s “*growing body of scientific literature refuting any association between thimerosal in vaccines and neurodevelopmental disorders in children*” mostly consists of epidemiological studies designed to refute previous studies showing a link by manipulating and/or distorting the data (including as the Thompson *et al.* study cited by the writer [the writer’s reference “7”], excluding those with an ASD diagnosis or, in the recent Miles and Takahashi study⁸, excluding many of the children with an autism diagnosis and including cases where there was no Thimerosal exposure.

The Link Between The Vaccine Measles Virus And Neurodevelopmental Disorders, Including Autism, As Well As Chronic Childhood Gastrointestinal Conditions

The writer’s “*the link between the MMR vaccine and autism being debunked after the Lancet retracted the report by Wakefield et al. and ten of its 12 authors disavowed its findings*” begins by falsely

⁸ Miles JH, Takahashi TN. Lack of Association Between Rh Status, Rh Immune Globulin in Pregnancy and Autism. ***Am. J. Med. Genetics Part A*** 2007; **143A**: 1397-1407.

asserting, “*the link between the MMR vaccine and autism being debunked*” when the underlying link, the link between the vaccine strain of the measles virus and regressive autism that sometimes develops after the administration of the measles or MMR vaccines usually in children who have previously been given Thimerosal-preserved vaccines and, *in many cases*, are concomitantly given Thimerosal-containing vaccines, has not been refuted.

As evidence of this “debunking”, the writer alleges, “*after the Lancet retracted the report by Wakefield et al. and ten of its 12 authors disavowed its findings*”.

Factually, the writer’s assertion concerning the 1998 paper by Wakefield et al.⁹ is wrong on several counts:

- Six years after the report in question was published and apparently because of pressure being applied by the British medical establishment, ten of its thirteen (13), not 12, authors only retracted the “Interpretation” of the report’s findings¹⁰: they did not disavow “*its findings*” as the writer claimed,
- *The Lancet* did not retract the Wakefield et al. paper she referenced,
- Subsequent studies have supported the findings in the cited Wakefield et al. report, and
- Independent peer-reviewed published epidemiological studies support a probable causal link between the MMR vaccine and neurodevelopmental disorder, including those in the “ASD/pervasive developmental disorders” spectrum.

The Misrepresentation Of Vaccine-Safety Advocacy Groups

Completing an eloquent example of Orwellian newspeak, the writer intentionally misrepresents reality by stating, “*powerful, well-funded advocacy groups continue to keep the antivaccine movement alive*”.

Factually, the vaccine-safety advocacy groups of which the writer is actually speaking are neither powerful nor well funded nor antivaccine per se.

IF these advocacy groups were powerful and well funded, *as the writer alleges*, THEN, *at a minimum*, there would be no FDA-licensed and/or FDA-approved Thimerosal-containing vaccines or other drugs that contain any level of Thimerosal or other mercury compound.

However, *as this reviewer’s Table 2 clearly shows*, the preceding is not true in today’s America.

Moreover, IF there truly were “*powerful, well-funded*” antivaccine advocacy groups and an “*antivaccine movement*”, *as the writer alleges*, THEN, *at a minimum*, all of today’s vaccines that are approved for administration to healthy individuals would:

- Have been toxicologically proven to:
 - a. Be lifetime safe, non-carcinogenic, non-mutagenic, and non-teratogenic, and
 - b. *If approved for use in women of childbearing age*, have no adverse effect on reproduction or the fetus,

⁹ Wakefield AJ, Murch SH, Anthony A, Linnell J, Casson DM, Malik M, Berelowitz M, Dhillon AP, Thomson MA, Harvey P, Valentine A, Davies SE, Walker-Smith JA. Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children. *Lancet*. 1998 Feb 28; **351**(9103): 637-41.

¹⁰ Murch SH, Anthony A, Casson DH, Malik M, Berelowitz M, Dhillon AP, Thomson MA, Valentine A, Davies SE, Walker-Smith JA. Retraction of an interpretation. *Lancet*. 2004 Mar 6; **363**(9411): 750.

- All vaccines included in the national recommended vaccination program would have been proven to be both:
 - a. Effective and
 - b. *Medically* cost-effective in independently verified studies where the costs of the adverse events are included in computing the cost-effectiveness before these vaccines were included in said program,
- The system for reporting adverse events to VAERS would be mandatory for all health professionals with appropriate monetary and, *for a pattern of non-compliance*, criminal penalties for the failure to report any possibly adverse reaction to any vaccination to VAERS within 3 business days of the person exhibiting the adverse outcome(s) being seen or reporting any such, and, last but not least,
- Any vaccine that generates more than twice as many “adverse event” reports on an annualized for a serious medical condition as the background rate prior to that vaccine’s being recommended for general use would have its recommendation for general use revoked and, *if the incidence of these serious conditions does not drop to the former baseline within 3 years after being suspended from the recommended national program*, this vaccine would be removed from the protections afforded by the US Vaccine Injury Compensation Program.

Since this reviewer finds that none of the preceding is true, it is obvious that, *in today’s America*, there:

- Are no “*powerful, well-funded*” antivaccine advocacy groups and
- The vaccine-safety advocacy groups are not an “*antivaccine movement*”.

Therefore, the writer’s statement here is an obvious Orwellian fabrication.

“Conspiracy theories generated by these groups portray respected investigators, vaccine manufacturers and public-health agencies as public enemies [8].”

First, this reviewer failed to find any use of the words “*conspiracy*”, “*theory*” or “*theories*”, and “*enemy*” or “*enemies*” in the writer’s reference “8”.

Moreover after reading that article, it is clear that the writer has simply wrote this statement to suit her purposes and attached a reference, “[8]”, in an attempt to add substance to her fabrication by citing a “supporting” article – trusting that most would not bother to verify whether or not the referenced supported the writer’s statement.

Since the article is easily located using PubMed (<http://www.ncbi.nlm.nih.gov/sites/entrez>) and entering the search terms: “epstein ra, vaccine” and, when the abstract of the article loads, clicking on the link to the article, this reviewer suggests that interested or skeptical readers verify the accuracy of this reviewer’s preceding remarks.

Therefore, *since the writer’s views appear to be her unsubstantiated personal beliefs*, this reviewer recommends that the readers simply ignore this venomous fabrication.

“When their efforts at promoting legislation to restrict access to vaccines failed at a federal level, these groups resorted to lobbying state legislators to pass bills that would ban thimerosal-containing vaccines and limit public-health agencies and private providers from providing many vaccines to children.”

Again ignoring the facts, this writer misrepresents those seeking to have the FDA impose an orderly ban on Thimerosal-containing vaccines and other drugs containing any level of

Thimerosal or other mercury compound used in their manufacture with exceptions for emergencies and vaccines proven toxicologically “sufficiently nontoxic ...” (an explicit CGMP minimum requirement for all preserved biological drug products [see: 21 C.F.R. Sec. 610.15(a)]) as “*promoting legislation to restrict access to vaccines*” when the laws proposed in the USA in the early 2000s were not intended to restrict access to vaccines but rather to force the government, pediatricians and vaccine makers to keep their joint pledge to remove Thimerosal from vaccines as soon as possible that they had made in 1999, but had and have not yet kept.

Moreover, since the vaccine makers have repeatedly testified that they can provide all of the needed U.S. doses of vaccines in a “no Thimerosal” formulation or, *even safer*, in a single-dose vial or syringe where no preservative is required if the government were to require them to do so and, *to back up these claims*, they have obtained licenses for “no Thimerosal” single-dose formulations of several of the formerly Thimerosal-preserved vaccines.

While the writer’s “*groups resorted to lobbying state legislators to pass bills that would ban thimerosal-containing vaccines*” is factually correct, the writer omits the reality that these laws, cognizant of the vaccine makers’ need for time and allowing for emergencies, only phased out the use of Thimerosal-preserved vaccines in most cases or, *in some cases*, followed the phase-out of the Thimerosal-preserved vaccines with a phased ban on vaccines containing any level of Thimerosal.

Thus, the writer’s “*and limit public-health agencies and private providers from providing many vaccines to children*” is another obvious misrepresentation of the facts.

Finally, this reviewer is compelled to recognize the venality of anyone who would oppose the removal of an unnecessary (because other preservatives can be used or no-preservative formulations can be packaged in single-dose containers) highly toxic compound, Thimerosal (49.55-wt% mercury) from a vaccine formulation when, at levels more than 1,000 times lower than the 0.01% level in a typical preserved-vaccine formulation, Thimerosal is:

- A proven bioaccumulative human teratogen, mutagen, carcinogen, immune-system poison, and systemic toxin, and
- Like penicillin, known to cause life-threatening anaphylactic shock in sensitive/sensitized individuals.

Given the proven harmful nature of Thimerosal, this reviewer wonders how any medical professional can oppose banning the use of this compound in all drugs, including, most especially, vaccines given to pregnant women, or to developing children, who have been proven to be more sensitive to mercury poisoning than adults.

“Unfortunately, such efforts have been at least partially successful in a few states.”

Since removing Thimerosal from a vaccine formulation or reducing its level by 50-fold or more obviously makes the vaccine safer, this reviewer is surprised that this writer would state: “*Unfortunately, such efforts have been at least partially successful in a few states*”.

Given her rhetoric, this writer believes that it is “unfortunate” that the developing fetus and developing children up to 3 years of age, *or, in some cases, 8 years of age*, “*in a few states*” have been given some protection from being mercury poisoned by Thimerosal-containing vaccines.

“Having gone before the Health and Human Services Committee of my home state to testify against these bills for several years, I have heard some of the most egregious misinformation spread by those who continue to delude the public of the possible harm caused by vaccines.”

First, given the writer’s initial remark, “*Having gone before the Health and Human Services Committee of my home state to testify against these bills for several years*”, it is clearly apparent to this reviewer that the writer puts the preservation of her status quo right to inject Thimerosal-preserved and Thimerosal-containing vaccines into pregnant women and developing children above the safening of the vaccines that pediatricians, *a group to which she clearly belongs*, and other medical professionals administer.

In this regard, this reviewer again asks:

“Why would the Establishment continue to lie about the removal of Thimerosal from vaccines if they have not recognized, *on some level*, that injecting Thimerosal-containing vaccines into pregnant women and children mercury poisons all of them to some degree?”

“I am proud to say that this bill has not been passed into law in my state.”

While this reviewer accepts that the writer is proud, he finds it odd that anyone would be so positive when the legislation, *if passed*, would most certainly make the current Thimerosal-preserved vaccines safer if it *immediately* required them to be replaced by “reduced Thimerosal” vaccines and later required “no Thimerosal” vaccines replace the “reduced Thimerosal” ones.

After all, these changes would not reduce the number of vaccines recommended in her state’s vaccination program, but only make some of them safer.

“However, charlatans offering false hope to desperate parents and caregivers continue to peddle ‘tests’ to confirm mercury poisoning and alternative, sometimes dangerous ‘treatments’ for autism such as chelation therapy, hyperbaric oxygen and testosterone suppression [9].”

First, this reviewer generally expects that the reference cited at the end of a statement, *the writer’s reference “[9]” in this instance*, will provide supporting evidence for the assertions made in that statement.

However, the article cited by the writer as reference “[9]” here appears not to support any of the claims, “*continue to peddle ‘tests’ to confirm mercury poisoning*” and “*sometimes dangerous ‘treatments’ for autism ...*”, but rather this study reports the results from small clinical trial involving 11 children with a diagnosis of autism or PPD-NOS who also had diagnosed mercury toxicity and abnormal androgen levels.

This study found that the combined treatment with an appropriate chelating drug, vitamin and mineral supplementation, and an androgen-lowering drug for a median period of 4 months (range 2 to 7 months) led to:

“A significant ($p < 0.01$) overall improvement from the 70–79th percentile of severity (median baseline score=87) at baseline to the 40–49th percentile of severity (median end of study period score=63) at the end of the study was observed for patients treated for a median of approximately 4 months. Significant improvements in sociability, cognitive awareness, behavior, and clinical symptoms/behaviors of hyperandrogenemia were also observed. Significant decreases in blood androgens and increases in urinary heavy metal concentrations were observed. Minimal drug adverse effects were found”.

Unless the writer has proof that the authors of this article falsified the data, then this

study shows that, *for children with a diagnosis of autism or PPD-NOS who also had diagnosed mercury toxicity and abnormal androgen levels*, the combined androgen suppression/chelation/supplementation treatment protocol not only lowered these children's apparent body burden of mercury and reduced blood-androgen levels but also significantly improved the children's sociability, cognitive awareness, and behavior – in other words the children's health improved.

Since the writer uses “[9]”, a published peer-reviewed research study by David A. Geier, BA and Mark R. Geier, MD, PhD, ABMG, DABFM, FACE, titled, “*A clinical trial of combined anti-androgen and anti-heavy metal therapy in autistic disorders*”, as a reference that supports her claims, it appears that the writer is:

- Indirectly, labeling the Geiers as “*charlatans offering false hope to desperate parents and caregivers*” and,
- *Since she presents no factual evidence to substantiate her claims and the data in the referenced Geier paper does not support these claims, not so subtly libeling the Geiers' good name and reputation.*

Given the USA laws governing libel and the penalties that apply unless, *prior to publication*, the editors had medical proof substantiating this writer's claim, this reviewer is surprised that the editors of the journal that published this article allowed this statement to be made especially given the reference the writer appended to it.

Moreover, returning to the claims the writer makes here, this reviewer finds:

- She has neither provided nor cited published documents that have established the truth of her views, *in general*, or, *since she references a published study by the Geiers*, the actions of the Geiers, *in specific*, and
- On its face, the peer-reviewed published article the writer referenced refutes her “*sometimes dangerous ‘treatments’ for autism*” claim with respect to “*chelation therapy*” and “*testosterone suppression*”.

Since the writer is a fellow MD (of Dr. Geier), this reviewer also thinks that the writer's statement here may be a violation of the standards of conduct that most state physician licensing boards expect of their physicians.

Finally, after:

- Reviewing the medical safety literature on non-IV chelation using DMSA,
- Recognizing that the Geiers pre-screened these children for evidence of adverse reactions to the androgen-lowering drug they used before using it for treatment, and
- Understanding that the Geiers appropriately monitored the health of these children during the study,

the editors of ***Expert Reviews of Vaccines*** will at least issue a written apology to the Geiers for what appears, *because their study does not support the writer's “charlatans ...” allegations*, to be an untoward attempt to link the Geiers to “*charlatans offering false hope to desperate parents and caregivers*”.

“Since autism was first described in the 1940s, multiple unfounded theories of causation and corollary ‘treatments’ have been offered [10].”

All that this reviewer can support is the writer's generalization:

“Since autism was first described in the 1940s, multiple unfounded theories of causation and corollary ‘treatments’ have been offered”.

Table 3. March 2008 FDA-licensed Thimerosal-containing Vaccines

[Taken From: FDA’s “Table 3: Thimerosal and Expanded List of Vaccines - (updated 3/14/2008) Thimerosal Content in Currently Manufactured U.S. Licensed Vaccines” & recent approvals]

No. [8]	Vaccine	Trade Name	Manufacturer	Thimerosal Concentration ^[1]	Mercury
1	DTaP	Tripedia ^[2]	Sanofi Pasteur, Inc	≤ 0.00012%	≤ 0.3 µg/0.5 mL
2	DTaPH (Tripedia + ActHIB ^[2])	TriHIBit	Sanofi Pasteur, Inc/SA	≤ 0.00012%	≤ 0.3 µg/0.5 mL
3	DT	No Trade Name	Sanofi Pasteur, Inc	< 0.00012% (single dose)	< 0.3 µg/0.5mL
4/ 1	DT (available but not marketed ^[3])	No Trade Name	Sanofi Pasteur, Ltd ^[3]	0.01%	25 µg/0.5 mL
5/ 2	Td	No Trade Name	Mass Public Health	0.0033%	8.3 µg/0.5 mL
6	Td	Decavac	Sanofi Pasteur, Inc	≤ 0.00012%	≤ 0.3 µg /0.5 mL
7/ 3	TT	No Trade Name	Sanofi Pasteur, Inc	0.01%	25 µg/0.5 mL
8	HepA/HepB	Twinrix	GlaxoSmithKline Biologicals	< 0.0002%	< 1 µg/1mL
9/ 4	Influenza	Afluria	CSL Limited	0.01% (multidose)	24.5 µg /0.5 mL
10/ 5	Influenza	Fluzone ^[6]	Sanofi Pasteur, Inc	0.01%	25 µg/0.5 mL (3 yrs & older) 12.5 µg/0.5 mL (6- 35- months old)-
12/ 6	Influenza	Fluvirin	Novartis Vaccines and Diagnostics Ltd	0.01%	25 µg/0.5 ml
13	Influenza	Fluvirin (Preservative Free)	Novartis Vaccines and Diagnostics Ltd	< 0.0004%	< 1 µg/0.5 mL
14	Influenza	Fluarix	GlaxoSmithKline Biologicals	< 0.0004%	< 1 µg/0.5 mL
15/ 7	Influenza	FluLaval	ID Biomedical Corporation of Quebec	0.01%	25 µg/0.5 mL
16/ 8	Japanese Encephalitis ^[7]	JE-VAX	Research Foundation for Microbial Diseases of Osaka University	0.007%	35 µg/1.0mL (>3 years of age) 17.5 µg/0.5 mL (1 to 3 yrs of age)
17/ 9	Meningococcal	Menomune A, C, AC and A/C/Y/W-135	Sanofi Pasteur, Inc	0.01% (multidose)	25 µg/0.5.mL
18/10	Avian Influenza ^[9]	Influenza Virus Vaccine, H5N1	Sanofi Pasteur Inc.	0.0098% (multidose with dosing at 0 & 2mnths)	49 µg/1.0.mL (98 µg in 2-dose regimen; 18 - 64 yrs of age)

TABLE FOOTNOTES

8. Thimerosal is approximately 50% mercury (Hg) by weight. A 0.01% solution (1 part per 10,000) of Thimerosal contains 50 µg of Hg per 1 ml dose or 25 µg of Hg per 0.5 ml dose. Vaccines with a nominal “preservative” level of mercury have **bolded** mercury values.
9. Sanofi Pasteur’s Tripedia may be used to reconstitute ActHib to form TriHIBit. TriHIBit is indicated for use in children 15 to 18 months of age.
10. This vaccine is not marketed in the US **but it is available**.
11.
12. ...
13. Children under 3 years of age receive a half-dose of vaccine, i.e., 0.25 mL (12.5 µg mercury/dose.)
14. Aventis Pasteur distributes JE-VAX. Children 1 to 3 years of age receive a half-dose of vaccine, i.e., 0.5 mL (17.5 µg mercury/dose).
15. The numbers in **red** are the count for the current Thimerosal-preserved vaccine formulations that have FDA approval.
16. Approved April, 17 but not in “Table 3” because it is currently only licensed for use in a pandemic outbreak; approvals for children are pending or deferred.)

Moreover, the reviewer must reject the use of the cited reference, “[10]”, “*Fombonne E. Thimerosal disappears but autism remains. Arch. Gen. Psychiatry 65, 15-16 (2008)*”, because, contrary to the cited article’s title, “*Thimerosal disappears ...*”, Thimerosal has not been removed from all of the U.S.-approved vaccines (**see** reviewer’s **Table 3** on the prior page) or, *for that matter*, all Canadian-approved vaccines nor from the U.S. vaccines recommended to be given to pregnant women.

“On a personal note, having grown up with a brother who was autistic, I remember the many years of anguish my mother suffered thinking that somehow her ‘neglect’ led to his condition.”

Here, the reviewer accepts the validity of this reviewer’s memories.

“Only in the past few years, with the convergence of rapidly advancing genomic technologies, the completion of the Human Genome Project and successful collaborative efforts to obtain DNA samples from autistic parents for study, have the first solid clues regarding the genetic origins of autism begun to emerge [11-13].”

While this reviewer understands that some small percentage of those with a diagnosis of an ASD may have a condition that produces the symptoms used to diagnose an ASD that is purely genetic, this reviewer notes that, *to date*, even the largest studies have failed to find a probable purely genetic common abnormality in the study group of affected children’s DNA at a level above 1%.

To sort out the role of genetics, this reviewer highly recommends that those who are interested read Richard Lathe’s 2006 book, **Autism, Brain, and Environment** (published by Jessica Kingsley Publishers; ISBN 1 84310 4385), which provides an in-depth discussion of the roles of both genetics and environmental factors, *including vaccines*, in autism.

“Instead of continuing to conduct studies to demonstrate that vaccines do not cause autism or other neurodevelopmental disorders, it is time to refocus our intellectual and monetary resources on further defining the genetic basis of these terrible diseases, develop scientifically proven therapies and provide succor and support to the patients and families who are affected by these disorders.”

In 2007, knowledgeable experts in the US Department of Health and Human Services (DHHS) conceded there were links between “Thalidomide, Lead, Ethanol, ‘Retinoids’, Valproic Acid, Thimerosal”¹¹ (*in April*) and, *in November*, “vaccinations”¹² [the causal factors], and autism spectrum disorders [the symptom-based diagnostic outcomes seen in many children with a neurodevelopmental disorder].

Therefore, this reviewer agrees with the writer that there is no need “*to conduct studies to demonstrate that vaccines do not cause autism or other neurodevelopmental disorders ...*” because:

- Knowledgeable federal experts have admitted that “vaccinations” and “Thimerosal” can cause “*autism or other neurodevelopmental disorders*, ” and
- There is a body of toxicological, clinical, case, and epidemiological studies that has established:

¹¹ April 2007 (PowerPoint Presentation) by Dr. Larry Needham, Chief, Organic Analytical Toxicology Branch, Nat’l Center for Environmental Health, CDC, “Exposure (To Stressors) and Autism Spectrum Disorders” to the IOM.

¹² Hannah Poling v. Sec. HHS, VICP case 02-1466V, DHHS medical professionals conceded vaccinations as a causal factor in child’s autism in a report filed with the “Vaccine Court” on November 9, 2007.

- Thimerosal-preserved vaccines and
- *To a lesser extent*, the man-made measles virus in the MMR vaccine formulation matrix (usually, in children who have previously received Thimerosal-containing vaccines and, *in some instances*, received a Thimerosal-containing vaccine shot along with the MMR inoculation

do cause the set of symptoms used to diagnose autism, other neurodevelopmental, and some other developmental and behavioral disorders in some children who are administered such vaccines according to the current CDC-recommended vaccination programs for both **a)** children, and **b)** pregnant and lactating women.

Since these causal links have been established, this writer's:

“it is time to refocus our intellectual and monetary resources on further defining the genetic basis of these terrible diseases, develop scientifically proven therapies and provide succor and support to the patients and families who are affected by these disorders”

flies in the face of the conceded realities of the established causal vaccine linkages and clearly reveals that this writer is a vaccine apologist who is attempting to:

- Deny the conceded facts simply because they reveal the lack of adequate safety for some vaccine formulations and/or vaccination program recommendations, and
- *Though the largest genetic studies have failed to find any probable genetic cause at a level higher than 1% in those diagnosed with autism and genetic epidemics are unknown*, forlornly call for the public to: **a)** deny what has been conceded and **b)** continue to waste *“our intellectual and monetary resources on further defining the genetic basis of these terrible diseases”*

In addition, rather than:

- Demanding a ban on the use of Thimerosal, *a known bioaccumulative mercury poison*, or any other bioaccumulative mercury poison in all vaccines,
- Recommending a delay in the start of vaccination to and a spreading out of the recommended vaccinations,
- Demanding that only vaccines that are medically cost-effective be included in the US recommended vaccination program, and,
- *To further safen vaccines*, insisting that all US-licensed vaccine formulations:
 - Be dispensed in a preservative-free single-dose presentation, and
 - Contain:
 - No adjuvant, or
 - *Until it is possible to make a safe and effective vaccine without an adjuvant*, the minimum level of only an aluminum adjuvant that has been proven to dissolve completely in the body within *not more than* 45 days after the vaccine dose is injected into the human body to minimize the risk of chronic activation of the macrophagic immune system,

the writer:

1. Skips taking these obvious steps to make the current vaccines and vaccination programs safer and
2. Jumps to *“develop scientifically proven therapies and provide succor and support to the patients and families who are affected by these disorders”* –

continuing to act as if the conceded vaccine safety issues do not exist.

Noting that new cases of similar “disorders” with an “unknown” cause, which were prevalent in the early 1900s (i.e., Pink disease, acrodynia, erythredema, Feer-Swift disease, and Young's syndrome), virtually disappeared a few years after Calomel, mercurous chloride (84.98-wt% mercury), was voluntarily removed from the US formulations of teething powders and other medicines by the US drug makers in the early 1940s, this reviewer understands that most new cases of an ASD, many other neurodevelopmental disorders, as well as some other chronic developmental (childhood) disorders and diseases and behavioral disorders will similarly disappear a few years after all use of Thimerosal, ethylmercuriethiosalicylate, sodium salt (49.55-wt% mercury) and any other organic mercury compound (e.g., phenylmercuric acetate) is prohibited in any medicine.

Unlike the writer, this reviewer understands that there already are some empirical “*scientifically proven therapies*” that have been shown to improve the health and behavior of those having an ASD diagnosis or an ASD diagnosis complicated by severe gastrointestinal disorders.

Furthermore, *before any more therapies are proven and initiated*, there is a pressing need for a well-defined diagnostic screening protocol that is capable of finding all of the health issues that an affected child has so that appropriate holistic hierarchical treatment regimens may be established for each group of affected children, which will, *in the appropriate order*, address and remediate all of the affected systems in each child.

Again, the writer appears to be oblivious to the need for an appropriate comprehensive diagnostic protocol.

Finally, though this reviewer agrees with the writer that there is a need to “*provide succor and support to the patients and families who are affected by these disorders*”, this reviewer notes that this is a need:

- To which most pediatricians seem to give little more than lip service, and
- Which is better addressed by our social service infrastructure.

“Providers of healthcare to children need to familiarize themselves with current recommendations for the identification, evaluation and management of children with autism-spectrum disorders that have been published by the American Academy of Pediatrics [14, 15].”

First, the writer’s “*identification, evaluation and management of children with autism-spectrum disorders*” rhetoric indicates that the current recommendations published by the American Academy of Pediatrics (AAP) are *apparently* focused on:

- Ignoring the reality that multiple vaccinations, Thimerosal, and MMR are all fundamentally unmet vaccine safety issues that should be *immediately* addressed,
- “Autism-spectrum disorders” (ASD) rather than a holistic evaluation to identify and, *in an appropriate order*, implement patient-appropriate recuperative therapies,
- Medical-condition “management” rather than proactive preventive measures and restorative therapies, and
- Continuing to:
 - a. Knowingly misinform the public about the presence of Thimerosal in vaccines and other vaccine risks,
 - b. Hype the benefits of vaccines,

- c. Gloss over the limitations in strain coverage, immunity, and immunity duration for each vaccine, and
- d. Intentionally underreport and/or misreport possible adverse reactions to vaccination,

all while repeating the vaccine mantra: “Vaccines are the safest medicines” – even though there are no studies that prove this assertion, and/or some variant of the vaccine mantra: “*Vaccines are among the greatest achievements ...*” as the writer next states.

“Vaccines are among the greatest achievements of biomedical science and public health [16].”

IF by “*among the greatest achievements*” this writer means the greatest public-health propaganda successes, THEN this reviewer could agree with the writer’s “*greatest achievements of ... public health*” view.

However, given:

- This reviewer’s journeyman’s understanding of the complexities of the human immune system¹³ that most vaccine apologists either ignore or gloss over, and

¹³ A Journeyman’s View of the Human Immune System

The Immune System is the name of a collection of compounds, cells, and organs whose complex interactions form an efficient system that is usually able to protect an individual from both outside invaders and its own abnormal cells, which, when not properly handled, can lead to cancer.

The immune system is a multi-layer wide-area network of subsystems distributed in the lymphoid tissues and organs of the body. Although the lymphoid tissues are widely distributed, they are concentrated in bone marrow, lymph nodes, spleen, liver, thymus, and Peyer’s patches scattered in the linings of the GI tract.

The lymphoid system is encompassed by the system of mononuclear phagocytes (equivalent to a reticuloendothelial system [RES]). Lymphocytes are the predominant cells, but macrophages and plasma cells are present also. Lymphocytes are cells, which are continually circulating — alternating between the circulatory blood stream and the body’s lymphatic channels.

The immune system’s components can also be viewed as belonging to one of two general categories, non-specific (also known as [a/k/a] innate immunity or non-adaptive immunity) and specific (a/k/a acquired or adaptive immunity). The breakdown of the immune system into non-specific and specific components is only valid for classification purposes because there is a constant and complex interaction, coordination and communication among all the components of the immune system. The non-specific components provide the majority of the body’s immune resistance to outside invaders and altered internal cells.

The outermost layer of the immune system’s defenses are the non-specific physical barriers (e.g., the skin, mucosal membrane, tears, ciliary elevators, and urine) and the chemical barriers (e.g., sebum, sweat, stomach acid, mucosal secretions, metallothionens, and lysozymes).

The second layer of the immune system is also a non-specific defense layer that includes the macrophage system, complement, fever, interferon and inflammation.

The macrophage system attacks and consumes pathogens by engulfing them, a process known as phagocytosis. Complement cooperates with macrophages by attaching to foreign cells and initiating the ingestion of the cells in phagocytosis. Interferons are a class of proteins; activated by fever, which prevent viral replication in surrounding cells and also inhibit the growth of cancer cells. Fever is a powerful part of the immune system, as it interferes with pathogen growth, inactivates many pathogen toxins, and facilitates a more intense immune system response.

Whether caused by bacteria, viruses, or by physical means, when any tissue injury occurs, the injured tissues respond by releasing “inflammatory” substances such as bradykinins, complement, and histamines. This process is called inflammation and it strongly activates the macrophage system to remove damaged cell tissue. Inflammation is a vital part of the healing and repair process of the immune system and, whenever it is delayed or inhibited, healing and repair are generally incomplete and/or abnormal.

The immune system’s third defense layer, the specific immune subsystems (a/k/a acquired or adaptive immunity), consists of B cells (for humoral immunity), and T cells (for cell-mediated immunity). The B and T cells have mechanisms for selecting a precisely defined target and for developing memory for a targeted antigen, so that the immune response to subsequent exposures to this antigen will be more efficient and effective. In a healthy immune system, these two branches of the specific immune subsystem are “balanced”.

Every standard definition of immunity depends on the overall competence of both the non-specific and specific components of the immune system to recognize, isolate and eliminate foreign pathogens. This competence also involves the ability of the immune system to properly distinguish between self and non-self. Thus, at its foundation, immunity is the body’s ability to establish and maintain its biological identity.

Consequently, given the preceding realities, there is a vast difference between true immunity, a prerequisite for bodily health, and the absence of any disease symptoms.

- The realities that:
 - The most successful childhood vaccines are the man-made live-virus contagious-disease vaccines that deliberately infect the person inoculated with the disease,
 - Neither the healthcare providers nor public health officials count the disease conditions that result from vaccination with live-virus as disease cases as they should, and
 - These healthcare providers and public health officials allow these vaccine-induced disease cases to be: **a)** grossly underreported and **b)** misreported as “adverse events” rather than mild to severe cases of the man-made disease strain(s) in the live-virus vaccine,

this reviewer understands:

- *At their best*, some of our current recommended childhood vaccines (e.g., the DTaP, inactivated polio, and MMR vaccines) are still somewhat problematic achievements of a biomedical science that does not yet truly understand the human immune system and,
- *At their worst*, many of the current vaccines in our current recommended national vaccination program are not:
 - Sufficiently nontoxic (e.g., the hepatitis B, rotavirus and HPV vaccines), or
 - Medically cost-effective (e.g., the pneumococcal and meningococcal vaccines), or
 - *In a some cases*, even societally cost effective (e.g., the herpes varicella zoster vaccines), or
 - *In a few cases*, even effective (e.g., the influenza vaccines and the now-discontinued Lyme-disease vaccine).

Hopefully, after studying the preceding information and reviewing the actual performance of vaccines with the inclusion of a minimum of 10 times the reported number of serious adverse reactions in VAERS as vaccine disease cases whenever any vaccine is given, then the reader should have a better understanding the realities of the current FDA-licensed vaccines with respect to safety.

“A recent study compares the morbidity and mortality before and after widespread implementation of national vaccine recommendations for 13 vaccine-preventable diseases in the USA [17].”

This reviewer accepts that the article cited presents the pro-vaccine Establishment’s biased views of disease morbidity and mortality – views that fundamentally do not include the underascertainment-corrected morbidity and mortality attributable to the vaccine, as they should.

“There was a greater than 92% decline in cases and a 99% or greater decline in deaths due to vaccines against diphtheria, mumps, pertussis and tetanus [17].”

Having briefly scanned the cited paper and carefully looked at the explanations provided in the “**Boxes**”, this reviewer finds that this statement roughly reflects what its authors stated.

However, the data clearly seems to have been manipulated to improve the reported reductions in some cases.

“Endemic transmission of polioviruses, measles and rubella viruses has been eliminated in the USA and smallpox has been eradicated worldwide [17].”

First, since the “**Results**” section in the cited article’s “**ABSTRACT**” stated:

“Endemic transmission of poliovirus and measles and rubella viruses has been eliminated in the United States; smallpox has been eradicated worldwide”,

this reviewer finds that the writer should have quoted the text as follows:

“‘Endemic transmission of poliovirus and measles and rubella viruses has been eliminated in the United States’ and ‘smallpox has been eradicated worldwide’”,

so that it was clear that most all of the words in this statement, *except the “and”*, were taken verbatim from the original article or have rewritten the citations statement in the writer’s own words as she did in the next two statements.

“Declines of 80% or greater for cases and deaths have been noted for hepatitis A, acute hepatitis B, invasive *Haemophilus influenzae* type b and varicella [17].”

Since the “**Results**” section in the cited article’s “**ABSTRACT**” stated:

“Declines were 80% or greater for cases and deaths of most vaccine-preventable diseases targeted since 1980 including hepatitis A, acute hepatitis B, Hib, and varicella”,

the writer’s statement reflects what the article stated.

However, examining the cited article’s “**Box 2. Explanation of Variables for Table 2**” notes for “**Varicella**”:

^b Annual number of cases estimated from the National Health Interview Survey⁷⁶ using a general question concerning any medical conditions during the 2 weeks before the interview. The 2-week case counts were adjusted to represent annual case counts and averaged over the 5-year period.

^c Annual number of hospitalizations shown in the table for the prevaccine era was estimated using the National Hospital Discharge Survey.⁷⁷ Using the Nationwide Inpatient Sample, Davis et al provided alternative estimates of 13 746 hospitalizations per year during 1993-1996, and 3729 per year during 2001, or a decrease of 64.9%.⁹⁵

^{d,f} Varicella mortality.⁷⁹ Varicella is very rare among elderly individuals. An unknown but large proportion of deaths attributed to varicella among individuals aged 50 years and older are likely to be herpes zoster or causes other than varicella. Disregarding data for individuals aged 50 years and older, there were 84 deaths annually attributed to varicella during 1990-1994 in individuals aged 0 to 49 years.

^e Peak number of varicella cases was estimated from the product of an estimated incidence rate of 21.8 cases per 1000⁷⁶ and a total residential population of 245 807 100.⁸⁰

^g Varicella vaccine was licensed in March 1995.⁸¹

^h Cases reported to NNDSS for 2006.⁵⁸ In 2005, 31 states reported 32 242 cases to NNDSS, but in 2006, 33 states reported 48 445 cases.

ⁱ After the varicella vaccine program was implemented, the NNDSS passive surveillance system and the Varicella Active Surveillance System (VASP) demonstrated an approximately 85% decline in the incidence of varicella. Percent decline is the average decline in VASP in the 4 states (Michigan, West Virginia, Texas, Illinois) that have consistently reported varicella data through NNDSS. Applying (1-0.85) to the annual number of cases in 1990-1994 yields an estimated 612 768 cases in the postvaccine era. NNDSS data compare 2006 data to 1993-1995 data.^{58, 60, 68, 82} VASP data cover 1995-2005.

^j Estimated reduction in hospitalizations represents MEDSTAT percent reduction applied to National Hospital Discharge Survey data for annual number of hospitalizations.⁸³ From the prevaccination period to 2002, hospitalizations in the MEDSTAT data set due to varicella declined by 88%.

^k Deaths reported in 2004.⁵⁹ Varicella is very rare among elderly individuals. An unknown but large proportion of deaths attributed to varicella in individuals aged 50 years and older are likely to be herpes zoster or causes

other than varicella.⁸⁴ Disregarding data (2004) for individuals aged 50 years and older, there were 8 deaths in 2004 attributed to varicella, for a decline of 90.5%”

this reviewer notices that the authors of this paper have:

- Knowingly misclassified chickenpox and shingles as if they were two different diseases, “varicella” and “herpes zoster”, *respectively*, when both these diseases are caused by the same herpes virus, *herpes varicella zoster*, and
- Then used this erroneous classification to inappropriately exclude the cases and deaths reportedly from shingles and shingles-related causes from the totals for cases and instances related to *herpes varicella zoster*.

Obviously, the authors in the study cited by the writer seem to have generated results based on a deliberate distortion of the data for herpes varicella zoster cases and deaths.

However, lacking the raw data, this reviewer, *based on his understanding that vaccination of the children significantly increased cases of shingles, a medical condition which is much more serious and much more likely to be fatal in the elderly than chickenpox (referred to by the authors of the study the writer cited as “varicella”)*, can only surmise that, the percentage reductions observed would have been much smaller than the values reported in the cited study provided the excluded “herpes zoster” cases had been included, as any unbiased assessment would have.

Moreover, given the large number of serious adverse events filed in VAERS for Merck’s licensed chickenpox vaccine, Varivax®, it may well be that, were these serious adverse events to be appropriately corrected for underascertainment and the underascertainment-corrected values added to the corrected totals for “*herpes varicella zoster*” cases and instances, there would have been either:

- a. No net reduction in “varicella”, or
- b. An increase in “varicella”.

Turning to *Haemophilus influenzae* type b (Hib), this reviewer notes that he has previously examined the “success” of Hib in his 2008 review a review of an online article, “**Vaccinations are still needed for kids**”, by “DR. MEG FISHER” that this reviewer found and downloaded on December 30, 2007 from:

<http://www.courierpostonline.com/apps/pbcs.dll/article?AID=/20071230/OPINION/712300316/1047>

That formal review, posted in the “**Documents**” web page posted on the CoMeD website: <http://www.mercury-freedrugs.org>, and titled, “**A Review of: ‘Vaccinations are still needed for kids’**”, contained the following statement from that article and this reviewer’s review response concerning the Hib vaccine:

““Since the use of *Haemophilus influenzae* type b vaccine in the mid-1980s, this infection has almost disappeared; it was a major cause of brain, airway, joint and skin infection in young children.”

Based on this reviewer’s previous published reviews that include a review of the “*Haemophilus influenzae type b vaccine*” (the “Hib” vaccine), the writer has inflated: a) the cases of Hib infections before the vaccine and b) the vaccine’s effect on the outcomes observed in children.

Consulting the CDC’s “**Summary of Notifiable Diseases – United States, 2002**” report,¹⁴ “this reviewer finds the following for reported “*Haemophilus influenzae*” cases:

¹⁴ <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5153a1.htm> last visited 31 December 2007. *MMWR* 2004 April 30; **51**(53): 1-84.

'Haemophilus influenzae, Invasive Disease

In 2002, 331 cases of invasive *Haemophilus influenzae* disease in children aged <5 years were reported; 34 (10%) were reported as *H. influenzae* type b (Hib), 144 (44%) were reported as other serotypes or non-typeable isolates, and 153 (46%) were reported with serotype information unknown or missing. The continued remarkably low number of invasive Hib infections in children (down from an estimated 20,000 cases annually in the prevaccine era) is a result of the successful delivery of highly effective conjugate Hib vaccines to children, beginning at age 2 months (1,2).

Because discrepancies in serotyping results have occurred between laboratories, CDC requests that state health departments obtain and send all invasive *H. influenzae* isolates from children aged <5 years to CDC for serotype confirmation (3,4).

1. CDC. Progress toward elimination of *Haemophilus influenzae* type b disease among infants and children---United States, 1998--2000. *MMWR* 2002; **51**: 234-237.
2. Zhou, F, Bisgard KM, Yusuf H, et al. Impact of universal *Haemophilus influenzae* type b vaccination starting at 2 months of age in the United States: an economic analysis. *Pediatrics* 2002; **110**: 653-661.
3. LaClaire LL, Tondella ML, Beall DS, et al. Identification of *Haemophilus influenzae* serotypes by standard slide agglutination serotyping and PCR-based capsule typing. *J Clin Microbiol* 2003; **41**: 393-396.
4. CDC. Serotyping discrepancies in *Haemophilus influenzae* type b disease---United States, 1998--1999. *MMWR* 2002; **51**: 706-707.'

Moreover, this report's 'Table 1' lists 1,743 cases of invasive *Haemophilus influenzae* and the total reported cases for children under 5 is 331.

In addition, the 2002 report's 'down from an estimated 20,000 cases annually in the prevaccine era'" statement reveals that the government had no solid data for cases of *Haemophilus influenzae*, or disease prevalence data for the Hib strain in children under 5 before the current Hib vaccines were introduced on the 1980s.

Next, consulting the CDC's "**Summary of Notifiable Diseases – United States, 2005**" report,⁵ this reviewer finds the following for reported "*Haemophilus influenzae*" cases:

- Oddly, there is no paragraph discussing *Haemophilus influenzae* in the report.
- However, this "2005" report's "**Table 1**" lists:
 1. 2,304 cases of invasive *Haemophilus influenzae*; a 32% increase from 2002.
 2. For children under five:
 - a. 9 serotype B cases (a 70+ % decrease from 2002),
 - b. 135 nonserotype B cases (a 6+ % decrease from 2002),
 - c. 217 unknown serotype cases (a 42 % increase from 2002), and
 - d. 361 total cases (a 9% increase from 2002).

Given the increase in unknown serotype cases,

- The CDC's 2002 request 'that state health departments obtain and send all invasive *H. influenzae* isolates from children aged <5 years to CDC for serotype confirmation' was ignored, and/or
- The CDC did not confirm the serotyping or serotype the majority of the isolates submitted as 'unknown serotype cases,' and/or
- New strains of this disease were emerging that, *lacking suitable anti-sera*, the states and/or the CDC could not serotype.

Subsequently, consulting the CDC's '**Notice to Readers: Final 2006 Reports of Nationally Notifiable Infectious Diseases**,'"¹⁵ "this reviewer finds in its '**Table 2**' the following data are reported for '*Haemophilus influenzae*' cases:

1. 2,436 cases of invasive *Haemophilus influenzae*; a 6% increase from 2005 cases.
2. For children under five:
 - a. 29 serotype B cases (a 320+ % increase from 2005)
 - b. 175 nonserotype B cases (a 30 % increase from 2005),
 - c. 179 unknown serotype cases (an 17+ % decrease from 2005),
and
 - d. 383 total cases (a 6 % increase from 2005).

Based on all the published CDC data available to this reviewer, it appears that the Hib vaccines are shifting the distribution of serogroups toward other serogroups.

Furthermore, recent reports indicate that other organisms that are more difficult to treat than Hib are beginning to fill the bacterial "niche" left by the Hib vaccine.

In addition, studies have reported that there is a 'causal relationship between the haemophilus vaccine and the development of insulin dependent diabetes ... 3 – 4 years after four doses of Hib.'"¹⁶

"Since the cost impacts of the short-term adverse effects were not considered in the initial licensing of the Hib vaccines and the long-term adverse effects to health (e.g., insulin-dependent diabetes) and the rise in infections by other microorganisms filling the niche left by the Hib vaccine, rather than continuing this line of reasoning, which looks to modify the strains in the vaccine, the public needs to reconsider whether or not a vaccine for Hib is *medically* cost-justifiable because the published data seem to indicate that this is not the case".

Given this reviewer's previous findings, this reviewer would, *at a minimum*, ask the writer to either: **a)** provide independent scientific studies that refute: **i)** the CDC's published data and **ii)** the reported longer-term "insulin-dependent diabetes" risk or **b)** revise her remarks concerning the decrease in Hib cases.

"Significant declines in deaths and diseases due to invasive *Streptococcus pneumoniae* have also occurred [17]."

Here, this reviewer finds that the writer's statement is consistent with the "**Results**" reported in the cited *JAMA* article's "**ABSTRACT**":

"Declines in cases and deaths of invasive *S pneumoniae* were 34% and 25%, respectively"

Overall, since the writer's statements appear to be based on the text in the abstract, it seems that the writer may not have read the article or, *if she did*, not have noticed that the authors of that paper seemingly distorted the numbers of cases in some instances (e.g., the "**Varicella**" data).

"This impressive record of success of vaccine programs in the past may lead to complacency regarding these killer diseases."

Since this reviewer has provided evidence that the writer's "*impressive record of success of vaccine programs in the past*" assertion is, *at least in some instances*, apparently based on distortion of the facts and/or omissions of key realities, this reviewer finds that it is more likely that, *if anything*, pro-vaccine propaganda may be leading vaccine apologists, like

¹⁵ <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5633a4.htm> last visited 31 December 2007. *MMWR*, 2007 August 24; **56**(33): 851,853-863.

¹⁶ <http://www.vaccines.net/newpage112.htm> last visited 31 December 2007.

this writer, “*to complacency regarding*” problems associated with the vaccine programs for many mostly childhood infectious and/or communicable diseases that the writer chooses to characterize as “*these killer diseases*” in a transparent effort to instill fear in those who read statements such as the writer made here.

“A sobering fact is that young children continue to die in Europe as a result of the MMR-autism scare, and unfounded concerns about vaccine safety continue to pose a risk from vaccine-preventable diseases to children in the USA, as exemplified by the recent measles outbreak [18].”

First, this writer’s:

“A sobering fact is that young children continue to die in Europe as a result of the MMR-autism scare”

appears to be a twisting of historical reality to conform to this writer’s orthodoxy, an orthodoxy which simplistically treats all vaccines as beneficial and those who question any aspect of vaccine safety as apostate deniers, who are to be blamed for any and all deaths in the unvaccinated (the writer’s “*young children continue to die in Europe as a result of the MMR-autism scare*”).

Historically, this reviewer must point out, as *the UK vaccine-safety advocates repeatedly have pointed out*, that the rates of uptake for the MMR vaccine in the UK were dropping before the article that the writer ties to the “*MMR-autism*” hypothesis was published.

Moreover, that MMR uptake rate was dropping because of the UK health officials’ decision to approve the use of an MMR vaccine that contained a strain of the mumps virus, the “*Urabe*” strain, that was more virulent than the strains of the mumps virus in other MMR vaccines, even though Canadian authorities, *who had initially approved its use*, had recognized the vaccine-induced harm from the vaccine containing the “*Urabe*” strain of mumps and switched to another MMR vaccine that was significantly safer.

Thus, this vaccine apologist is attempting to direct the reader away from the real reason MMR uptake was dropping in the UK, *a too toxic MMR vaccine*, and blame this uptake drop, *and the resultant increase in measles cases*, on an article that only noted a possible association between children who had a diagnosed neurodevelopmental condition and the vaccine strain of the measles virus in the MMR vaccine that the researchers apparently found in the tissues and spinal fluid of some of these children who also had severe gastrointestinal disease.

With respect to the writer’s:

“unfounded concerns about vaccine safety continue to pose a risk from vaccine-preventable diseases to children in the USA, as exemplified by the recent measles outbreak [18]”,

this reviewer simply notes, as *his discussions about the varicella (chickenpox) and Hib vaccines have established*, the public’s “*concerns about vaccine safety*” are well founded and what poses the bigger risks come from vaccine apologists’ ongoing misstatements about the removal of Thimerosal from vaccines and/or the safety of each FDA-approved vaccine as well as the continual publication of articles by vaccine apologist that are Orwellian propaganda pieces intended to instill unfounded disease fear in the public and, *without scientifically sound substantiation that supports their views*, hype the wonders of vaccines.

“The motivations of a minority of individuals who prey upon the fears of poorly informed parents and caregivers for personal financial gain and notoriety must be exposed.”

Not content to present the facts that establish the validity of her views, the writer uses another device employed by those who use the tools of Orwellian newspeak in their writings on vaccines, the writer attacks the “*motivations of a minority of individuals*” – apparently having forgotten that she had previously characterized this “*minority of individuals*” she is attacking here as “*powerful, well-funded advocacy groups*”.

IF those groups advocating for a ban on all use of Thimerosal (49.55-wt% mercury) and other mercury compounds in medicines and/or for safer vaccines were only a “*minority of individuals*”, THEN there would be no need for the writer, as she does here, to attack their “*motivations*” or to impugn these individual’s integrity by claiming, *without any substantiation*, that some unidentified “*individuals prey upon the fears of poorly informed parents and caregivers for personal financial gain and notoriety must be exposed*”.

While this reviewer admires the writer’s skillful attempt to attribute the motivations of vaccine-safety advocates to greed, the writer’s “*prey upon ... for personal financial gain*”, and, *by using the negative-connotation word “notoriety” rather than the neutral word, “recognition”*, further cast vaccine-safety advocates in a demeaning light, this reviewer notes that the writer is simply using the standard tactics of those who cannot attack the validity of the message – she attacks the imputed motivations (integrity) of the messengers.

Moreover, the writer’s: “*... fears of poorly informed parents and caregivers ...*” not only paints parents and caregivers as fearful but also implies these individuals are simply “*parents and caregivers*”, who lack the knowledge (her: “*poorly informed*”) required to challenge the writer’s views on vaccines – a not-so-subtle attempt to obscure the reality that many of those who are vaccine-safety advocates are also doctors, lawyers, and/or researchers, such as this reviewer is.

Given the reviewer’s understanding of the facts, the writer’s statement here amounts to a finger-pointing exercise and compels this reviewer to suggest that she remove the proverbial “log” from her own eye before attempting to remove the “speck” from the eyes of those who are, *among other things*, vaccine-safety advocates.

“Unfounded theories about vaccine safety based on flawed studies must not be allowed to trump well-designed, scientifically and statistically sound research conducted by respected investigators and published in renowned, peer-reviewed journals.”

Since it is the validity of the science and not: **a)** who published it or **b)** where it is published that should be determinative, this reviewer can only agree with the first part of the writer’s assertion here:

“*Unfounded theories about vaccine safety based on flawed studies must not be allowed to trump well-designed, scientifically and statistically sound research*”.

Further, scientifically sound and appropriate theories and the studies that support them stand on their own merits.

Contrary to the writer’s stated views, they do not require the imprimatur of “*respected investigators*” or publication in “*renowned, peer-reviewed journals*” to validate their findings.

Moreover, this reviewer accepts that “*theories about vaccine safety based on flawed studies must not be allowed to trump*” theories based on “*well-designed, scientifically and statistically sound research*”.

However, *unlike the writer*, this reviewer has found (and, *in some instances in this review*, has provided the evidence that supports his findings) that the studies upon which the

writer relies are *fundamentally* flawed by intentional iterative manipulations of the data, study design, and exclusion criteria as well as, *in some cases*, misstatements of fact and/or selective reporting designed to ensure their reported findings agree with the predetermined outcomes desired.

In sharp contrast, most all of the studies that the writer and other vaccine apologists have attempted to debunk (while providing little more than their pronouncements to support the validity of their views) are, *in fact*, well designed, not iteratively manipulated, scientifically sound, and, *in most cases*, robust to the point that their limitations and the potential confounding factors are not only stated but also, *where possible*, the estimated magnitude of their effect on any of the findings is reported.

“For the gains of the last century to continue in the future, vaccine providers in the USA and around the world must continually update their knowledge of the issues surrounding vaccine safety and reassure concerned parents and caregivers that vaccines remain a life-saving intervention and that there is no scientific evidence to implicate them in a causal relationship with autism or other neuropsychiatric disorders.”

Here, this reviewer finds that the writer is simply wrong.

Boiled down to it essentials, this writer is recommending that “*vaccine providers*” should only be concerned with (with underlining added by this reviewer for emphasis):

- Continually updating “*their knowledge of the issues surrounding vaccine safety*” – not, as *they should be*, continually updating their understanding of vaccine safety,
- Reassuring “*parents and caregivers that vaccines remain a life-saving intervention*” and
- Telling “*parents and caregivers ... that there is no scientific evidence to implicate them in a causal relationship with autism or other neuropsychiatric disorders*” – even though: in 2007, DHHS medical professionals had conceded a causal relationship between vaccinations and autism in the **Poling** case.

In essence, this writer is telling “*vaccine providers*” to:

- a. Support the status quo and
- b. Deny the scientific evidence supporting the conceded causal relationship between vaccinations and autism.

Obviously, recommending that “*vaccine providers*” stonewall the public's growing vaccine safety concerns and mislead “*parents and caregivers*” about their vaccine safety concerns (which DHHS medical professionals have conceded are real) will only further undermine the American public's confidence in not only the current vaccination programs but also in the “*vaccine providers*” themselves.

IF the true gains of the last century that have been provided by vaccines are to continue, THEN, *at a minimum*, “*vaccine providers in the USA*” should:

- Fully inform American parents and caregivers, who have the right to know, about:
 - All of the risks and contraindications associated with each vaccine and
 - Each vaccine's probable benefits and the estimated duration of those benefits

so that the appropriate decision makers, the writer's “*parents and caregivers*”, can make an informed decision to allow that vaccine to be given or to withhold it.

- Demand that the vaccine manufacturers and the DHHS, as required by law,¹⁷ continually work to improve the safety of all vaccines,
- Proactively recommend that parents and caregivers not give O-T-C painkillers to children before vaccination or immediately thereafter, carefully monitor the each vaccinee’s health for at least 30 days after each vaccination, and immediately report all adverse reactions that may be associated with a given vaccine to both VAERS and the vaccine’s manufacturer,
- Refuse to vaccinate children who are obviously ill or have a history of immune system problems, and
- Shun giving the vaccine formulations licensed after 1980 that lack proof that they:
 - Are not mutagenic or carcinogenic,
 - Have no adverse impact on the fertility or reproductive capability,
 - Have been proven to be effective,
 - Have an estimated overall cost, including the worst-case estimated lifetime adverse event costs, that is below 75 percent of the cost where giving the vaccine to all children ceases to be societally cost-effective, and,
 - When they are approved for administration to pregnant women, have no adversely impact on the developing fetus.

Reviewer’s Postscript

On June 27, 2008, the Special Masters in the Omnibus Autism Proceeding in the United States Court of Federal Claims granted¹⁸ the Justice Department’s request to withdraw the expert reports of the two recognized toxicologists (Drs. Magos and Clarkson), which were the key reports upon which the government was heretofore relying to rebut the petitioners’ toxicological evidence that Thimerosal in vaccines causes mercury poisoning that manifests as autism and other neurodevelopmental disorders.

This action is another, *albeit indirect*, admission by key toxicology experts (who were nominated to testify against “**THEORY 2**” [the proposition that Thimerosal {49.55-wt% mercury} in vaccines is causally linked to autism] and filed expert reports supporting this view) that the ever-growing body of scientifically sound toxicological evidence clearly supports the causal link between Thimerosal-containing vaccines and autism.

“Archana Chatterjee, MD, PhD, Creighton University School of Medicine, Division of Pediatric infectious Diseases, Department of Pediatrics, 601 N. 30th Street Suite 2321, Omaha. Nebraska 68131, USA. Tel.: +1 402 280 1238 – Fax: +1 402 280 1234 – Email: achatter@creighton.edu.”

¹⁷ **42 USC Sec. 300aa-27. Mandate for safer childhood vaccines** [See: Sec. 300aa-27(a)(2):

“(a) General rule

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

(1) ...

(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.”

¹⁸ http://www.uscfc.uscourts.gov/sites/default/files/autism/7_03_08_autism.pdf “**AUTISM MASTER FILE ORDER CONCERNING THEORY 2 GENERAL CAUSATION REBUTTAL**”.

Financial & competing interests disclosure

Grants/research: Abbott Labs, Bayer, Bristol-Meyer Squibb, GlaxoSmithKline, MedImmune, Merck, Novartis, Sanofi-Pasteur and Viropharma. Speaker's bureau: Abbott labs, AstraZeneca, GSK, MedImmune, Merck, Pfizer, Sanofi-Pasteur and Wyeth. The author has no other relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript apart from those disclosed. No writing assistance was utilized in the production of this manuscript."

This reviewer received no financial compensation for this review.

Apart from his advocacy for mercury-free drugs and safer vaccines and his assistance in preparing relevant papers for publication and, in some cases being listed as one of the minor authors thereon, this reviewer has no conflicting interests.

Outside of having his colleagues review sections of this draft for grammatical correctness and accuracy, the evidenced-supported views expressed in this review are this reviewer's own.

This reviewer's credentials can be found on his web-site: <http://www.dr-king.com/>.

“References

1. Ball Lk, Ball R, Pratt D. An assessment of thimerosal use in childhood vaccines. *Pediatrics* 107, 1147-1154 (2001).
2. Wakefield AJ, Murch SH, Anthony A *et al*. Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children (partially retracted in: *Lancet* 363, 750 [2004]). *Lancet* 351, 637-641 (1998).
3. Geier DA, Geier MR. An assessment of the impact of thimerosal on childhood neurodevelopmental disorders. *Pediatr. Rehabil.* 6, 97-102 (2003).
4. Doja A, Roberts W. Immunizations and autism: a review of the literature. *Can J. Neurol. Sci.* 33, 341-346 (2006).
5. Institute of Medicine. Immunization Safety Review: Vaccines and Autism. National Academy Press, Washington DC, USA (2004).
6. Schechter R, Gerther JK. Continuing increases in autism reported to California's developmental service system. *Arch. Gen. Psychiatry* 65, 19-24 (2008).
7. Thompson WW, Price C, Goodson B *et al*. Early thimerosal exposure and neuropsychological [sic; neuropsychological] "outcomes at 7 to 10 years. *N. Engl. J. Med.* 357, 1281-1292 (2007).
8. Epstein RA. It did happen here: fear and loathing on the vaccine trail. *Health Aff. (Milwood)* 24, 740-743 (2005).
9. Geier DA, Geier MR. A clinical trial of combined anti-androgen and anti-heavy metal therapy in autistic disorders. *Neuro Endocrinol. Lett.* 27, 833-838 (2006).
10. Fombonne E. Thimerosal disappears but autism remains. *Arch. Gen. Psychiatry* 65, 15-16 (2008).
11. Gupta AR, State MW. Recent advances in the genetics of autism. *Biol. Psychiatry* 61, 429-437 (2007).
12. Hu-Lince D, Craig DW, Huentelman MJ, Stephan DA. The autism genome project: goals and strategies. *Am. J. Pharmacogenomics* 5, 233-246 (2005).
13. Szatrnari P, Paterson AD *et al.*; Autism Genome Project Consortium. Mapping autism risk loci using genetic linkage and chromosomal rearrangements. *Nat. Genet.* 39. 319-328 (2007).
14. Johnson CP, Myers SM. Identification and evaluation of children with autism spectrum disorders. *Pediatrics* 120, 1183-1215 (2007).
15. Myers SM, Johnson CP. Management of children with autism spectrum disorders. *Pediatrics* 120, 1162-1182 (2007).

16. US CDC. Impact of vaccines universally recommended for children – United States, 1990-1998. MMWR Morb. Mortal. Wkly Rep. 48, 243-248 (1999).
17. Roush SW, Murphy TV. Historical comparisons of morbidity and mortality for vaccine-preventable diseases in the United States. JAMA 298, 2155-2263 (2007).
18. Parker AA, Staggs W, Dayan GH *et al.* Implications of a 2005 measles outbreak in Indiana for sustained elimination of measles in the United States. N. Engl. J. Med. 355, 447-455 (2006).

Websites

101. The Vaccine Adverse Event Reporting System www.vaers.hhs.gov.
102. The Jewish Daily Forward www.forward.com/articles/vaccine-nation”

Filename: 20080725_drftRevu_VaccineSafety_GenuineConcernOr-
br1.doc
Directory: C:\AE_out
Template: C:\WINDOWS\Application
Data\Microsoft\Templates\Normal.dot
Title: A Review Of: 'Vaccine safety: genuine concern or a legacy
of unfounded skepticism?'rchana Chatterjee, MD, PhD (pediatrician)
Subject: Vaccine Safety, Effectiveness and Cost-effectiveness
Issues
Author: Dr. King
Keywords: Vaccine, safety, effectiveness, cost-effective, mercury,
Thimerosal, MMR
Comments:
Creation Date: 7/28/08 01:29
Change Number: 4
Last Saved On: 7/28/08 01:34
Last Saved By: Dr. King
Total Editing Time: 10 Minutes
Last Printed On: 7/28/08 01:34
As of Last Complete Printing
Number of Pages: 39
Number of Words: 16,960 (approx.)
Number of Characters: 96,672 (approx.)