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Monday, 29 October 2007

To All:

This article is a review of an October 23, 2007 article by Michael Fumento titled, "**'Suffer the Little Children' No More**," which was located and then downloaded on 24 October 2007 from:

http://www.tcsdaily.com/article.aspx?id=102307A

After some introductory remarks, the formal review, titled "**No Proof Of Safety for Thimerosal in Vaccines –** A Rebuttal to the Doublespeak in: 'Suffer the Little Children' No More**,**" begins on the next page.

Introductory Remarks

First, *to simplify this review*, the comments by the writer, Michael Fumento, 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 mentions, or quotes from, a federal statute or regulation; these items will be in a "Lydian" font.

Further, when this reviewer quotes from statements made in the writer's column, an *italicized* "*Times New Roman*" font will be used.

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

With these things in mind, this review of "**'Suffer the Little Children' No More**," begins on the next page.

Respectfully,

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No Proof of Safety for Thimerosal in Vaccines

A Rebuttal to the Doublespeak in: 'Suffer the Little Children' No More,"

By Paul G. King, PhD in Analytical Chemistry, MS in Inorganic Chemistry, ACS-certified BA in Chemistry

"The vaccine preservative thimerosal has jumped the safety hurdle. Again. So indicates the Sept. 27, 2007 issue of the New England Journal of Medicine. The 'again' is the problem, though. One huge study after another has cleared thimersorosal [sic; Thimerosal] as a cause of child developmental disorders, but there is a powerful lobby that couldn't care less."

Plainly, this opinion piece is an obvious vaccine apologist's rant that misrepresents and twists the facts.

Factually, the epidemiological study in "*the Sept. 27, 2007 issue of the New England Journal of Medicine*," like the others to which this author alludes, cannot prove the ***safety*** of any chemical.

All that such studies can do is provide some statistical probability of a link between some factor, "Thimerosal used as a preservative in vaccines" (the author's "*vaccine preservative thimerosal*" in this case) and some observed outcome ("*child developmental disorders*" in this instance.

Moreover, epidemiological studies cannot prove that the factor evaluated is the "*cause of*" any observed outcome.

To ***prove safety***: scientifically sound and appropriate large-scale toxicity studies must be conducted in some animal model system that has been proven to mimic the behavior of humans exposed to the compound of interest, Thimerosal in this instance.

When properly designed and conducted, these toxicity studies can establish the no-effect level in each exposed population in the animal model system.

Then, an appropriate safety factor, typically, a factor of 10 for systems where the animal model is a primate and, *absent a high incidence rate in humans exposed to the chemical*, a factor of 100 for systems where the animal model is a rodent species.

To date, as the U.S. FDA has repeatedly testified to Congress, ***none*** of the safety studies required to establish the "**sufficiently nontoxic** ..." level of safety ***required*** by FDA law (**21 C.F.R. Sec. 610.15(a)**[1]) have been reported and/or published by the vaccine makers or the U.S. National Institutes of

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[1] "Sec. 351. Adulterated drugs and devices
A drug or device shall be deemed to be adulterated -
(a) Poisonous, insanitary, etc., ingredients; adequate controls in manufacture
(1) …; or
(2) (A) …; or
(B) if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess;"

Health (NIH), the U.S. Centers for Disease Control and Prevention (CDC), FDA, academic or independent research FDA scientists.

Absent the required proofs of safety ***required*** by law, all Thimerosal-containing vaccines and other drugs where the level is in the "preservative range" (100 parts per million [ppm] to 1 ppm Thimerosal) are ***clearly adulterated*** under **21 U.S.C. Sec. 351(a)(2)(B)** and, by statute[2], are illegal to be on the market in the United States.

Thus, the story that this writer should be discussing is:

"Why is the U.S. government knowingly colluding with vaccine makers to permit adulterated vaccines to be marketed in the U.S. and elsewhere?"

If this author or any reader wants a detailed accounting of the realities of the toxicity of Thimerosal and the perfidy of the vaccine makers and U.S. government officials, that person can read the citizen petition that CoMeD, the Coalition for Mercury-free Drugs, filed on 24 August 2007 with the FDA Division of Dockets Management (FDA Docket # 2007P-0331)[3].

"Thimerosal, used in vaccines since the 1930s, comprises about 50 percent ethyl mercury."

Factually, Thimerosal:

- Is:
  1. A highly toxic compound and proven human teratogen, mutagen, carcinogen, and immune-system disruptor at levels below 1 ppm (levels more than 100 times lower than the 100-ppm level found in the typical Thimerosal-preserved vaccine),
  2. 49.55 % mercury by weight and
  3. 56.73 % "*ethyl mercury*" by weight,
- Has been:
  1. Used as a preservative "*in vaccines since the 1930s*"
  2. Used without the drug maker's providing general proof of safety in any drug formulation approved or licensed after 1938,
  3. Used without the required specific proof of safety for all biological drug products, including vaccines, set forth in **21 C.F.R. Sec. 610.15(a)** since the late 1960s and
  4. Illegally allowed by the FDA to be present as a preservative in drugs licensed and/or approved after the U.S. Supreme Court *unanimously* held in 1988 that a government administrator has no "administrative discretion" with respect to any official policy, law or statute[4], and

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[2] **21 U.S.C. Sec. 331 Prohibited acts.**

[3] A copy of the citizen petition CoMeD filed as well as other pertinent petition-related information can be found in the "Documents" section of the CoMeD website: http://mercury-freedrugs.org.

[4] Kevan BERKOVITZ, a Minor by his Parents and Natural Guardians Arthur BERKOVITZ, et ux., et al., Petitioners, v. UNITED STATES No. 87-498. Argued April19. 1988. Decided June 13. 1988. 108 S.Ct. 1954, 100 L.Ed.2d 531, 56 USL W 4549 (Cite as: **486 U.S. 531, 108 S.Ct. 1954**.)

- At a preservative level, renders any drug product containing it adulterated under **21 U.S.C. Section 351(a)(2)(B)** since **21 C.F.R. Sec. 610.15(a)** is a current good manufacturing practice (CGMP) requirement *minimum* that must be met before a drug product can legally be accepted for release into commerce.

"It neither contains nor degrades into the pollutant methyl mercury that pregnant mothers are warned about in fatty fish. (That said, the Maternal Nutrition Group, a coalition of nutrition groups and experts including several federal agencies, has just released a report calling on pregnant women to eat far more fatty fish than they do, citing in part a low risk from methyl mercury.)"

While the author's first statement is true, Thimerosal both contains and, in the human body, degrades into "ethyl mercury" compounds that have been shown to bioaccumulate in the developing brain to a greater extent than "*methyl mercury*" hydroxide as tissue-bound "inorganic mercury"[5].

Thus, based on the preceding reality, Thimerosal is more toxic to the developing brain than "*methyl mercury*."

In addition, the "*Maternal Nutrition Group*" appears to be a group supported by the fish industry to represent that industry's interests and, *in spite of their pronouncements*, the U.S. government has not changed it official position that pregnant women should restrict their intake of fish and avoid those seafood species known to accumulate the highest levels of mercury.

"The thimerosal fearmongers comprise three groups."

Rather than discuss the issue of the toxicity of Thimerosal, the author thinks that he must attack the messengers because he apparently knows he cannot attack the message, "there is no proof of safety for any level of Thimerosal in any medicine."

"The first is the far left as represented the Environmental Working Group and individuals like environmental crusader Robert F. Kennedy Jr. Second, there is the old anti-fluoridation far right, as represented by the Association of American Physicians and Surgeons, Inc (AAPS). Third are parents of autistic children. Strange bedfellows, indeed!"

Here the author attempts to attach political tags ("*far left*," "*far right*") and another issue ("*fluoridation*") to the various groups that he mentions apparently in order to reduce the "worth" of the views these groups.

Moreover, this author ignores the reality that most of the members of the "*Environmental Working Group*" and "*the Association of American Physicians and Surgeons, Inc (AAPS)*" and "*Robert F. Kennedy Jr.*" are also parents.

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[5] Burbacher TM, Shen DD, Liberato N, Grant KS, Cernichiari E, Clarkson T. Comparison of blood and brain mercury levels in infant monkeys exposed to methylmercury or vaccines containing thimerosal. ***Environ Health Perspect***. 2005 April 21; **113**(4). 36-page draft "pdf" file. [Final article at doi: 10.1289/ehp.7712 (available online at http://dx.doi.org).]

Given the reality that today "*child developmental disorders*" affect more than one child in six (1 in 6), this reviewer finds it appropriate that parents from all across the spectrum of views would be uniting to demand that an unnecessary[6] compound, Thimerosal, which is also highly toxic, a proven teratogen, carcinogen, mutagen and an immune system disruptor at levels below 1 ppm in developing humans, be removed from all vaccines.

Thus, *in contrast to the author's rhetoric*, there are no strange bedfellows in the specific movement to get Thimerosal banned from medicine or the general movement to stop all uses of and exposures to mercury.

"In this latest study, Centers for Disease Control and Prevention researchers evaluated more than 1,000 children between the ages of seven and 10 who were exposed to various levels of thimerosal at various early stages in life. They made almost 400 different statistical comparisons."

While the author's statements are correct, they are misleading because the study:

1. Deliberately excluded all children with a diagnosed neurodevelopmental disorder and
2. Did not directly assess the actual children in the study but only reviewed their medical records and others' assessments.

Thus, no children were evaluated by the researchers doing this study and the medical records, which were evaluated, were only for those *without* a diagnosed neurodevelopmental disorder – obviously an apparent effort to: **a)** bias the population and **b)** ensure minimum risk of finding any association between apparent Thimerosal exposure and neurodevelopmental disorders.

To further limit the risk of finding an association, mercury exposures from Thimerosal in vaccines given beyond seven months of age were excluded from the assessment of each child's cumulative mercury exposure.

Finally, no follow-ups were done on the children with the highest recorded Thimerosal exposures to assess, by a non-invasive valid urine porphyrin profile analysis (UPPA) test[7], whether or not any of these children were mercury poisoned.

Thus, the CDC study is designed to look in the wrong place (the "healthy" children's medical records) for the symptoms ("*neuropsychological functioning*")

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[6] The use of Thimerosal in the manufacture of biological products is unnecessary because a preservative, the only approved use for Thimerosal, is only required (**21 C.F.R. Sec. 610.15(a)**) when some vaccines or other biological drug products are packaged in multiple-dose containers and, today, all vaccines can be packaged in single-dose containers and there are other non-bioaccumulative compounds that have been and are being used as preservatives in vaccines.

[7] For detailed information on the UPPA test and the clinical laboratories that are recognized to provide valid tests that can be relied upon to establish whether or not a child is mercury poisoned, the reader can consult the "Urine Prophyrin Profile Analysis (UPPA)" web page on the CoMeD web site, http://www.mercury-freedrugs.org. The "Published Studies" section of the UPPA web page contains the articles that establish the validity of the test for determining mercury poisoning as well as currently three (3) published studies verifying this tests ability to detect children who are mercury poisoned.

rather than an underlying disease (mercury poisoning).

"'We assessed children on 42 neuropsychological outcomes and found few significant associations with exposure to mercury from vaccines and immune globulins administered prenatally or during the first 7 months of life... The associations that we detected were small, almost equally divided between positive and negative effects, and mostly sex-specific.'"

This reviewer concedes that this author has accurately quoted from the opening paragraph of the "**Summary**" section of a CDC paper (Thompson WW, Price C, Goodson B, et al. Early Thimerosal Exposure and Neuropsychological Outcomes at 7 to 10 Years. ***NELJM*** 2007 September 27; **357**(13): 1281-1292).

However, after reviewing the data provided, this reviewer notes that, as the paper's "*and found few significant associations*" language indicates, in this group of "healthy" children, the records evaluated indicated an obvious association between Thimerosal exposure and "*tics*" and, to a smaller degree, "*stuttering*" (**see tables 2** and **3** in the cited ***NEJM*** article).

Thus, even though the children that had the most significant diminishment in "*neuropsychological functioning*" had been excluded, the CDC's study found clear evidence of a link between the CDC's estimate of Thimerosal exposure and the risk of "*tics*" and "*stuttering*" in the children whose records were assessed in the published ***NEJM*** paper referenced by this author.

Therefore, even though the most damaged children were excluded, this study still found evidence of a link between Thimerosal exposure up to seven months of age and "*tics*" and "*stuttering*."

"It was not a study of autism, but a multitude of earlier studies have specifically looked for a thimerosal-autism link and found none."

At least this author admits that this study was "*not a study of autism*."

However, his "*a multitude of earlier studies have specifically looked for a thimerosal-autism link and found none*" statement is at odds with reality because, though one other vaccine study besides the five studies included in the IOM review reported[8] not finding a "*thimerosal-autism link*," the following peer-reviewed published epidemiological, review, and case papers have found evidence of a Thimerosal-autism or a mercury poisoning-ASD link:

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[8] Fombonne E, Zakarian R, Bennett A, Meng L, McLean-Heywood D. Pervasive developmental disorders in Montreal, Quebec, Canada: Prevalence and links with immunizations. Pediatrics 2006 July; 118(1): e139-e150. [**Note:** An independent analysis of the valid data set points for the children in grades 1 through 10 actually found that this data supported a drop in PDDs (pervasive developmental disorders) when the recommended Thimerosal-preserved vaccines were replaced by a combination vaccine that contained no Thimerosal. In addition, these researchers apparently knowingly misrepresented MMR data for childhood uptake in Quebec City as if it were MMR uptake data for all of Quebec, and the lead author Dr. Fombonne has refused repeated requests to provide the raw PPD and class size data for each year. Finally, these researchers were, at best, misleading, when they titled their paper "Prevasive developmental disorders in Montreal, Quebec, Canada: ..." when they only surveyed one English-speaking school district in Montreal and not the majority French-speaking schools in that city.]

1. Geier DA, Geier MR. A Prospective Study of Mercury Toxicity Biomarkers in Autistic Spectrum Disorders. ***Journal of Toxicology and Environmental Health, Part A***. 2007; **70**: 1723-1730.
2. Geier DA, Geier MR. A case series of children with apparent mercury toxic encephalopathies manifesting with clinical symptoms of regressive autistic disorders. ***J Toxicol Environ Health A*** 2007; **70**: 837-851.
3. Geier DA, Geier MR. A prospective study of thimerosal-containing Rho(D)-immune globulin administration as a risk factor for autistic disorders. ***J Matern Fetal Neonatal Med.*** 2007 May; **20**(5): 385-390**.**
4. Geier DA, Geier MR. A meta-analysis epidemiological assessment of neurodevelopmental disorders following vaccines administered from 1994 through 2000 in the United States. ***Neuro Endocrinol Lett*** 2006; **27**: 401-413.
5. Geier DA, Geier MR. An evaluation of the effects of thimerosal on neurodevelopmental disorders reported following DTP and Hib vaccines in comparison to DTPH vaccine in the United States. ***J Toxicol Environ Health*** A 2006; **69**: 1481-1495.
6. Geier DA, Geier MR. An assessment of downward trends in neurodevelopmental disorders in the United States following removal of Thimerosal from childhood vaccines. ***Med Sci Monit*** 2006; **12**: CR231-CR239.
7. Geier DA, Geier MR. Early downward trends in neurodevelopmental disorders following removal of Thimerosal-containing vaccines. ***J Am Phys Surg*** 2006; **11**: 8-13.
8. Geier DA, Geier MR. A Prospective Assessment of Porphyrins in Autistic Disorders: A Potential Marker for Heavy Metal Exposure. ***Neurotoxicity Research***, 2006; **10**(1): 57-64.
9. Nataf R, Skorupka C, Amet L, Lam A, Springbett A, Lathe R. Porphyrinuria in childhood autistic disorder: Implications for environmental toxicity. ***Toxicology and Applied Pharmacology*** 2006; **214**: 99-108.
10. Mutter J, Naumann J, Schneider R, Walach H, Haley B. Mercury and autism: accelerating evidence? ***Neuro Endocrinol Lett.*** 2005 Oct; **26**(5): 439-446. Review.
11. Geier DA, Geier MR. A two-phased population epidemiological study of the safety of thimerosal-containing vaccines: a follow-up analysis. ***Med Sci Monit*** 2005; **11**: CR160-CR170.
12. Geier D, Geier MR. Neurodevelopmental disorders following thimerosal-containing childhood immunizations: a follow-up analysis. ***Int J Toxicol*** 2004; **23**: 369-376.
13. Geier DA, Geier MR. A comparative evaluation of the effects of MMR immunization and mercury doses from thimerosal-containing childhood vaccines on the population prevalence of autism. ***Med Sci Monit*** 2004; **10**: PI33-PI39.
14. Geier DA, Geier MR. An assessment of the impact of thimerosal on childhood neurodevelopmental disorders. ***Pediatr Rehabil*** 2003; **6**: 97-102.
15. Geier MR, Geier DA. Neurodevelopmental disorders after thimerosal-containing vaccines: a brief communication. ***Exp Biol Med (Maywood)*** 2003; **228**: 660-664.
16. Geier MR, Geier DA. Thimerosal in childhood vaccines, neurodevelopment disorders, and heart disease in the United States. ***J Am Phys Surg 2003***; **8**: 6-11.

"In a 2004 214-page summary of them, the Institute of Medicine concluded:

'The evidence favors rejection of a causal relationship between thimerosal-containing vaccines and autism.'"

Factually, the report from the IOM does contain the statement quoted by this author.

However, since the "*evidence*" to which this statement alludes was "*evidence*" from the five epidemiological studies the IOM deemed to be credible by non-transparent processes (a hallmark of the pseudoscientific subjective approach to study evaluation that the IOM committee used[9]), this reviewer notes that, *since the actual studies upon which the IOM based its findings were statistically based epidemiological inference studies assessing the possibility of a link*, no scientifically valid assessment of a causal nature can be made.

Thus, the IOM's "*The evidence favors rejection of a causal relationship between thimerosal-containing vaccines and autism*" is neither scientifically nor logically sound.

"Unfortunately, back in 1999 federal health officials caved into activist demands."

Here, Mr. Fumento is shamelessly attempting to rewrite history.

Factually, *based on internal FDA, CDC, and vaccine maker documents*,

- after "realizing" that the dose of Thimerosal in vaccines exceeded government's guidelines for mercury exposure from food and had not been proven to be safe, as well as
- in response to the actions being taken by other governments in many of the Western European nations in the early 1990s,

the U.S. governmental regulatory agencies (CDC and FDA), the medical establishment (American Academy of Pediatrics) and the vaccine makers jointly agreed in 1999 that Thimerosal should be ***removed*** from all vaccines as soon as possible.

However, this reviewer must note that, *on balance*, this 1999 commitment to "remove Thimerosal from vaccines as soon as possible" has not been honored.

This is the case because the parties have acted to offset any Thimerosal removal in "childhood vaccines" by "recommending," since April 2002, that women who were in their second and third trimesters of pregnancy during the flu season and young children (initially, limited to children 6 months to 23 months of age) be given a flu shot when all of the available flu shots, up until late 2003, were Thimerosal-preserved flu shots.

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[9] Oxymoronically, this subjective review process has been named the "evidence-based medicine (EBM)" approach to the review of scientific publications where factors (like the authors, the "stature" of the journal, the agreement with consensus views) other than the validity of the published findings are used to assess whether or not a given paper should be considered in any review evaluation of medical epidemiological, case and research studies.

Furthermore, the FDA has also continued to approve reduced-Thimerosal and Thimerosal-preserved vaccines, actions that are clearly inconsistent with a commitment to remove Thimerosal from vaccines.

Moreover, to increase the population exposure risk to Thimerosal from influenza vaccine shots, by 2004, the trimester limitations on pregnant women had been removed, an initial 2-shot regimen was recommended for the first time a child was given a flu shot, and the upper limit on the age range was increased to 35 months.

To additionally increase the population exposure risk, the age range was further increased to 59 months in 2006 and extended to those who care for young children, including nursing mothers.

In 2007, the CDC added a general up-to-9-years recommendation for any child with any risk factor and a stronger suggestion that all parents with young children including nursing mothers and caregivers should get a flu shot.

Partially offsetting the increasing risk from additional Thimerosal-preserved flu shots, *in 2003*, limited supplies of reduced-Thimerosal flu shots became available for children 3 and under with a larger supply, on paper, of reduced-Thimerosal flu shots for all children.

In 2006, the first no-Thimerosal flu shots, though the supply was limited, became available for the 3 year-old and under set and, in 2007, slightly more "no Thimerosal" doses should be available for the youngest children.

On balance, the risk of mercury poisoning from Thimerosal-containing vaccines has significantly declined only for those who demanded and obtained reduced- and no- Thimerosal vaccines for their children and themselves.

For the majority of children, the cumulative risk of mercury poisoning from Thimerosal-containing vaccines has continued to rise as the age range for inoculation has continued to be widened.

Moreover, since recent peer-reviewed published studies and the applicable references[10] have shown that the influenza vaccines are not effective in preventing those inoculated from getting influenza, it appears that the recommended influenza vaccination program for pregnant women and children is really a national program to maintain and/or increase the risk that any susceptible child will be mercury poisoned by the Thimerosal-containing vaccines he or she receives.

"While reaffirming that evidence indicated thimerosal was safe, they nonetheless 'urged' the removal of anything but trace amounts of the preservative from childhood vaccines."

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[10] **a.** Jefferson T. Influenza vaccination: Policy versus evidence. ***BMJ*** (***British Medical Journal***) 2006 October 28; **333**: 912-915

b. Geier DA, King PG, Geier MR. Influenza Vaccine: Review of effectiveness of the U.S. immunization program, and policy considerations. ***JAPS*** (***Journal of American Physicians and Surgeons***) 2006 Fall; **11**(3): 69-74

Ever the vaccine apologist, here the author twists what was asserted, "lack of evidence of harm," into "*evidence indicated thimerosal was safe*" when the required proof of safety to the standard minimum "**sufficiently nontoxic** …" (**21 C.F.R. Sec. 610.15(a)**) had not, and has not, been met.

Additionally, Mr. Fumento has changed the 1999 promise to the public to remove Thimerosal from vaccines into his "*they nonetheless 'urged' the removal of anything but trace amounts of the preservative from childhood vaccines*."

"This was accomplished in 2001, although the last of the stocks weren't used up until January 2003. (Flu shots still contain the ingredient.)"

Since certain non-influenza vaccines (e.g., multi-dose Menomune and JE-Vax) that are given to children are still Thimerosal-preserved and there are reports of patient records showing that Thimerosal-preserved lots of other Thimerosal-preserved vaccines were being administered after January 2003, this reviewer must reject Mr. Fumento's assertions here.

In addition, the FDA's October 6, 2003 Table 3 list of Thimerosal-containing vaccines lists the following Thimerosal-preserved vaccines licensed for use in the U.S. (obviously, still being manufactured at the end of 2003), where most can be administered to older children:

Thimerosal Content in Currently Manufactured U.S. Thimerosal-Preserved Licensed Vaccines				
Vaccine	**Trade Name**	**Manufacturer**	**Thimerosal Concentration**	**Mercury**
DT	No Trade Name	Aventis Pasteur, Inc.	< 0.00012% (single dose) 0.01% (multi-dose)	< 0.3 µg/0.5mL dose 25 µg/0.5mL dose
		Aventis Pasteur, Ltd.	0.01%	25 µg/0.5 mL dose
Td	No Trade Name	Mass Public Health	0.0033%	8.3 µg/0.5 mL dose
		Aventis Pasteur Inc.	0.01%	25 µg/0.5 mL dose
TT	No Trade Name	Aventis Pasteur Inc.	0.01%	25 µg/0.5 mL dose
Hepatitis B	Recombivax HB Adult (adolescent) Dialysis	Merck	0.005% 0.005%	25 µg/1.0 mL dose 25 µg/1.0 mL dose
Influenza	Fluzone	Aventis Pasteur, Inc.	0.01%	25 µg/0.5 mL dose
	Fluvirin	Evans	0.01%	25 µg/0.5 ml dose
Japanese Encephalitis	JE-VAX	BIKEN	0.007%	35 µg/1.0mL dose 17.5 µg/0.5 mL dose
Meningococcal	Menomune A, C, AC and A/C/Y/W-135	Aventis Pasteur, Inc.	0.01% (multidose) 0 (single dose)	25 µg/0.5 dose 0

Thus, *given the reality that all Thimerosal-preserved vaccine formulations* <u>*except*</u> *some influenza vaccines were being marketed in October of 2003*, as the preceding FDA information clearly proves, it is clear that Mr. Fumento's remarks are, *at best*, inaccurate.

Factually, though the level of exposure to Thimerosal has been reduced for some children, with the addition of the flu shot for pregnant women at any stage in pregnancy and the addition of the flu shot for children in risk groups up to the age of 18, the specific level (weight-corrected level) of exposure for most children has <u>not</u> been reduced significantly and, in some cases, has actually increased.

"Nevertheless, this has allowed an interesting way of assessing the thimerosal-autism connection, in that ending use of such vaccines should be followed by a drop in cases."

<u>When</u>

- The use of all vaccines and other drugs containing any level of Thimerosal or other mercury compound is actually stopped,
- All remaining doses of Thimerosal-preserved vaccines and other mercury-containing drug products are recalled and destroyed, and, since there is a typical "3 – 5 year" delay between exposure and symptom onset, and
- Five full years have elapsed,

then, *as has been the case in Canada and Denmark*, there should be a significant drop in all cases of mercury poisoning from Thimerosal in vaccines <u>including</u> those cases exhibiting the symptom set diagnosed as autism and other autism spectrum disorders (ASDs).

"California has become a statistical battleground, presumably because of data collected from the state's Department of Development Services and provided online in its FactStats quarterly reports. Blogged David Kirby at the Huffington Post in 2005, 'If the numbers [of autism cases] in California and elsewhere continue to drop - and that still is a big if - the implication of thimerosal in the autism epidemic will be practically undeniable.'"

Mr. Fumento's "*California has become a statistical battleground*" is an attempt to focus the reader on the uncorrected[11] data being reported by California for people ages 2 and up who have a confirmed, included diagnosis of autism.

[11] All that the State of California is reporting is "autism" cases by age group and quarter. Since the population of California is growing at developing-country rates and the population of children is growing at rates estimated at not less than 4 % annually (because of the influx of illegal aliens and the illegal migration of their children to the households their illegal-immigrant parents establish as well as the magnet effect that California's higher standard of care has on those in neighboring states), the number of cases in a given age group cannot be validly interpreted as a growth in the incidence rate for autism or in its prevalence rate. That this population-growth factor is a strong bias can be seen in the increases in the number of new cases in the older groups of children. If the estimated population growth rates are used to adjust the case rates, the data seem to indicate that the case rates have plateaued or are slightly decreasing. Moreover, in the rest of the U.S. where the population growth for children has been much less rapid, raw cases data seems to indicate that the rates for autism cases are dropping.

Moreover, David Kirby's statement was based on data from those born after the 1999 pledge and before 2002 (when the flu shot started being recommended for administration to pregnant women and young children).

When all drug products containing Thimerosal or other mercury compound have *actually* been withdrawn and appropriately destroyed, and five years have passed, then this reviewer is confident that the mercury-poisoning-related cases of "autism/autistic spectrum disorders (ASDs)" will fall.

However, until all such usages stop, this reviewer expects to see no significant drop in cases in states like California where the population is rapidly growing, and only plateaus or small drops in other states.

"Problem is, they weren't dropping."

Mr. Fumento, the real problem, which you have conveniently ignored, is all use of Thimerosal in vaccines has not been stopped.

Until you recognize and address this problem, the reader should ignore your myopic rhetoric that obviously does not look beyond the pro-vaccine propaganda that permeates the media.

"The alleged decline is an urban legend, apparently based primarily on a 2006 'study' by the father-son team of Dr. Mark and David Geier."

Here the author begins by denigrating an unidentified "*2006 'study' by the father-son team of Dr. Mark and David Geier*" by casting it as the basis for the author's "*The alleged decline is an urban legend*."

Factually, the Geiers published two peer-reviewed papers in 2006 that assessed the early downward trends in autism cases following the 1999 commitment to remove Thimerosal from vaccines and, more importantly, to omit the birth dose of Thimerosal-preserved hepatitis B until the trace-Thimerosal vaccines became available:

1. Geier DA, Geier MR. An assessment of downward trends in neurodevelopmental disorders in the United States following removal of Thimerosal from childhood vaccines. ***Med Sci Monit*** 2006; **12**: CR231-CR239.
2. Geier DA, Geier MR. Early downward trends in neurodevelopmental disorders following removal of Thimerosal-containing vaccines. ***J Am Phys Surg*** 2006; **11**: 8-13.

Thus, two independent peer-reviewed journals found the epidemiological studies, submitted by the Geiers and reporting a decline in autism rates, were scientifically sound and elected to publish them – · not just the one to which the author alludes.

"The Geiers make their living as expert witnesses and consultants for lawyers."

Here the author appears to be *knowingly* misrepresenting the Geiers' main source of income as the facts clearly indicate that the majority of their current income comes from the medical practices in which they work, and not from the moneys they receive from occasionally being "*expert witnesses and consultants for lawyers*."

"The Geier paper appeared in the AAPS journal."

Here, the author identifies the particular paper he is addressing as the one published "*in the AAPS journal*," but he does not mention, much less challenge, the validity of the data the Geiers used or the findings they reported.

"Health professionals (and often federal courts) have harshly dismissed the Geiers' work, with the American Academy of Pediatrics condemning them for 'numerous conceptual and scientific flaws, omissions of fact, inaccuracies, and misstatements.'"

This reviewer must discount these unsupported allegations about the "*Geiers' work*" by unnamed "*(h)ealth professionals*" and "*(and often federal courts)*" as the carping of one who, *unable to attack the validity of the published studies*, chooses to attack the character and reputation of the authors of the research.

Moreover, this reviewer notes that the quotation included here is taken from an unsigned AAP letter[12] that was published online by unnamed persons and only "condemned" the paper and not, as this author's "*condemning them*" does, the Geiers.

Were the accusations cited here supported by scientific fact, then why is it that no one signed this online letter?

Also, why is it that the AAP, electing to post this letter, did not also seek out and would not post the Geiers' response[13] to this letter as any reputable truth-seeking journal would do?

Given all of the preceding realities, this reviewer is compelled to dismiss the preceding as, at best, "sour grapes" and, at worst, "unwarranted slanders on the Geiers' good names."

"Further, California isn't our only test case. Published studies have also shown a continued increase in autism after thimerosal's removal from vaccines during the 1990s in Sweden, Denmark, and Canada."

Several independent reviews[14] of the available data from the published studies alluded to in Sweden and Denmark[15] have established that the researchers knowingly confounded cases reported with an increased incidence in order to

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[12] http://www.aap.org/profed/thimaut-may03.htm (last accessed 29 October 2007)

[13] Geier MD, Geier DA. Response to Critics on the Adverse Effects of Thimerosal in Childhood Vaccines. ***J Am Phys Surg*** 2003 Summer; **8**(3): 68 – 70.

[14] **a.** Trelka JA, Hooker BS. More on Madsen's analysis. ***J Am Phys Surg*** 2004; **9**: 101.
b. Bernard S. Association between thimerosal-containing vaccine and autism. ***JAMA*** 2004; **291**: 180.
c. Blaxill MF. Concerns continue over mercury and autism. ***Am J Prev Med*** 2004; **26**: 91.

[15] **a.** Stehr-Green P, Tull P, Stellfeld M, et al. Autism and thimerosal-containing vaccines: lack of consistent evidence for an association. Am J Prev Med 2003; 25: 101-106.

mislead the reader into thinking that the prevalence rate for "autism" in those born after Thimerosal was removed from the DPT vaccine was not lower than the prevalence rate for autism in those who received the DPT series of vaccinations.

In the case of the Canadian study alluded to here[16], this reviewer has clearly established that the apparently valid data points for both the time period where Thimerosal was used in several vaccines and the time period after it was withdrawn from all but the Hepatitis B and influenza vaccines clearly shows a decrease in the total PDD cases reported[17].

Moreover, *as alluded to above*, numerous attempts by this reviewer and other independent scientists to get the lead and contact author, Dr. Fombonne, to provide the actual data for independent review have been unanswered by Dr. Fombonne.

Thus, this reviewer finds that the researchers who published these studies "*after thimerosal's removal from vaccines during the 1990s in Sweden, Denmark, and Canada*" and the author who relies on them in this article are mistaken when it comes to the change in incidence of autism cases whenever there truly is a significant reduction in the maximum exposure level to Thimerosal in the majority of a population.

"But the general public is essentially ignorant of all this."

Here, this reviewer must agree with Mr. Fumento – the public is "*ignorant of all this*":

- All the distortions of the epidemiological data that have been used to justify the continued presence of Thimerosal in vaccines
- All of the toxicology data that clearly establishes no level of Thimerosal above 0.01 ppm (0.00001%) is safe to be used in any medicine, and
- The fact that the public is routinely lied to by federal government officials, vaccine apologists, healthcare officials, and the media when it comes to:
  - The ***proof of safety*** required to legally continue to use Thimerosal as a preservative in any vaccine as well as
  - The reality that, in the U.S., all Thimerosal-preserved vaccine formulations that lack ***proof of safety*** to the standard "**sufficiently nontoxic** …" being marketed today are adulterated drugs that are being illegally marketed.

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b. Madsen KM, Lauritsen MB, Pedersen CB, et al. Thimerosal and the occurrence of autism: negative ecological evidence from Danish population-based data. Pediatrics 2003; 112: 604-606.

c. Hviid A, Stellfeld M, Wohlfahrt J, et al. Association between thimerosal-containing vaccine and autism. JAMA 2003; 290: 1763-1766.

[16] Fombonne E, Zakarian R, Bennett A, et al. Pervasive developmental disorders in Montreal, Quebec, Canada: prevalence and links with immunizations. Pediatrics 2006; 118: e139-e150.

[17] King PG (e-mail) to Fombonne E [27 August 2006]: http://www.mercury-freedrugs.org/docs/060827_PGKsCmmnts_CanadianEpidemioStudy_Pediatrics-Full-b.pdf

"'It doesn't seem to matter what the studies and the data show,' Kristen Ehresmann, a Minnesota Department of Health official told The New York Times. 'And that's really scary for us because if science doesn't count, how do we make decisions? How do we communicate with parents?'"

Here, ironically, this reviewer must partially agree with Kristen Ehresmann.

This is the case because this reviewer, apparently unlike Ehresmann, has studied the toxicological and case data for Thimerosal in animal studies and human toxicity exposures and found that there is no "ppm level" of Thimerosal that has been proven to be "**sufficiently nontoxic so that the amount present in the recommended dose of the product will not be toxic to the recipient**" (as required by **21 C.F.R. Sec. 610.15(a)**, a CGMP safety requirement *minimum*) for Thimerosal used at a preservative (100 ppm to 10 ppm) or, *under* ***21 U.S.C. Sec. 351(a)(2)(B)*** *and* ***42 U.S.C. Sec. 262(a)(2)(C)(i)(I)***, lower levels in any drug product or other biological drug formulation.

Moreover, this reviewer must also take exception to the comments Mr. Fumento quoted whenever that is a precedent legal requirement *minimum* that must be met and that *minimum* has *knowingly* not been met.

Thus, this reviewer would ask Michael Fumento, Kristen Ehresmann, and all who read this review: "Why is it that federal government officials are *knowingly* colluding with vaccine makers to permit adulterated Thimerosal-preserved vaccines to continue to be illegally marketed?"

Thus, before trying to communicate with parents about studies and data that do not ***prove safety***, Kristen Ehresmann and Michael Fumento should first question federal government officials and vaccine makers as to why adulterated vaccines are continuing to be sold and administered to our children.

"One reason for the public ignorance, unfortunately, is that precautionary 'ban.' Many health professionals now regret it. 'The removal of thimerosal created the impression of risk, where none existed,' Dr. Paul Krogstad professor in the departments of pediatrics and medical pharmacology at the David Geffen School of Medicine at UCLA, told ABC News Online."

Given:

- The ongoing willful and knowing failure of the vaccine makers to comply with **21 C.F.R. Sec. 610.15(a)** and conduct the scientifically sound and appropriate toxicity studies required to prove, *with at least a 10-fold safety margin*, that Thimerosal is "**sufficiently nontoxic** …,"
- The 1971 report that Eli Lilly and Company found Thimerosal toxicity at the 1 ppm level, and
- *By the mid-1970s*, Lilly had exited the vaccines business (because all of their vaccine formulations contained a 100-ppm level of Thimerosal as a preservative),

this "*'ban'*" was, and is, *obviously* not merely a "*precautionary 'ban.'*"

In addition, the healthcare establishment's continuing misrepresentations that the 1999 promise, expressed as "*removal of thimerosal*" here, has been kept or is being kept continues to undermine the credibility of this establishment as it also undermines the credibility of Mr. Fumento in this article and Dr. Paul Krogstad's quoted comments.

"But a much more important reason is deliberate disinformation."

It never ceases to amaze this reviewer that those whose remarks are intended to misinform, invariably claim that "*deliberate disinformation*" is the reason the public is rejecting their message.

"There are over 150 anti-vaccine web sites. And who cares what a multitude of studies say when former Playboy Playmate Jenny McCarthy claims on Oprah and in the new book she's hawking that her son got autism from a vaccine?"

Mr. Fumento, it is <u>not</u>

- the number of web sites vaccine (pro or anti), or
- the number (100s) of toxicity studies, *which you did <u>not</u> even mention*, that prove Thimerosal or one of its solvolysis products or metabolites is highly toxic, teratogenic, carcinogenic, mutagenic and an immune-system disruptor in humans and crosses all "barriers" to transmission within the human body (e.g., blood-brain, dermal, intestinal, and placental), or
- any claim of any author hawking a book on any talk show

that matters.

What really matters, and what Mr. Fumento keep dodging, is the on-going knowing failure of the vaccine makers to prove the safety of Thimerosal, *with a 10-fold or higher safety margin*, to the standard "**sufficiently nontoxic** …" that condemns: **a)** any use of Thimerosal in medicine and **b)** all those who promote, facilitate, or defend its use, including writers like Mr. Fumento.

"Activists also fiercely target the MMR vaccine (measles-mumps-rubella), insisting it, too, causes autism - though MMR never contained thimerosal. (This is the vaccine Jenny McCarthy blamed.)"

Based on the increase in "autism" incidence rates when the MMR vaccine was introduced in Denmark[18], it appears that when MMR was "universally" administered in a population where the children born after 1992 received <u>no</u> childhood vaccine that contained Thimerosal, the cohort- and reporting-criteria- corrected data (**see footnote 18**, **Figure 4**) indicate that the prevalence of "autism" increased from about "2." cases per 10,000 in 1990 to "14.5" cases per 10,000 in the 2000 – 2002 time period.

Considering that the MMR vaccine delivers three live viral diseases that can

[18] Goldman GS, Yazbak FE. An Investigation of the Association Between MMR Vaccination and Autism in Denmark. ***J Am Physicians and Surgeons*** 2002 Fall; **9**(3): 70-75.

cause neurological damage and that prevalence rate in a vaccine-saturated population is only about 14.5 cases per 10,000 (0.145 %) as compared to the guesstimated[19] U.S. prevalence rates of 75 to 150 cases of "autism" per 10,000 (0.75% to 1.5%) in the same timeframe, it would seem that MMR could be a factor in 10 % to 20 % of the U.S. "autism" cases.

Thus, Mr. Fumento, the data in Denmark, a country where Thimerosal has not been present in routine childhood vaccines since 1992, indicate that MMR is indeed linked to the prevalence of "autism" observed in Denmark in the early 2000s.

"Like fluoridated water, there's a segment of our society that sees childhood vaccines as some sort of black magic."

Since "*fluoridated water*" is another case of the mass drugging of large segments of the population with toxic fluoride-releasing substances (typically, fluorosilicates in the U.S.) without:

- proof of safety for the maximum water consumption with at least a 10-fold safety margin, and
- proof of effectiveness since only the reduction of dental caries has only been proven for topical application to the teeth,

this reviewer understands both the realities of water fluoridation and the reasons behind Mr. Fumento's desire to tie it to the issue of Thimerosal in vaccines.

As a scientist, this researcher finds there is no "*black magic*" in "*fluoridated water*" just as there is no real proof of safety or effectiveness and mounting evidence of harm to the very young and other segments of the population where the drinking water is fluoridated.

Similarly, this reviewer finds there is no magic, black or otherwise, in vaccines in spite of this author's attempts to tie vaccines to "*magic*."

However, this reviewer finds that the healthcare establishment continues to conceal and misrepresent the risks associated with vaccines and to over sell the theoretical benefits of childhood vaccines to the point it has become increasingly obvious that their actions are clearly other than medically or health care motivated.

"Any vaccine will cause some side effects if given to tens of millions of people."

Here, this author glibly speaks of "*some side effects*" as if they are nothing in the context of "*tens of millions of people*."

However, the reality is that, if, *as internal FDA/CDC studies indicate*, only 10 % of all adverse events from vaccines are reported to VAERS, the U.S. vaccine adverse events reporting system, then these annual side effects

[19] This guesstimate is based on the reported survey "autism" rates for U.S. children in the early 2000s, the underascertainment inherent in such surveys, and the California data, which has uncertain population denominators.

include hundreds of potentially avoidable deaths and thousands of serious injuries that increasingly appear to exceed the deaths and serious injuries that would have occurred if there were none of the vaccines that were approved after 1987 for diseases that are, *in spite of the hype*, increasingly less severe, *like chickenpox*, and more rare, *like HPV infection*, which may cause cervical cancer 30 or more years later or, *equally likely*, may only be associated with the cervical cancers that occur in older women.

Thus, this reviewer has no problems with the rabies vaccine, given to humans after there has been a disease exposure, because it is clear that the risks associated not getting the rabies vaccine in such cases are clearly less than the almost certain death that comes with not treating the rabies exposure.

However, having carefully studied the risks and outcomes from the "universal" chickenpox program, this reviewer can unequivocally state that this program is wrongheaded and should be stopped because the experience-based costs and risks far outweigh the unrealized theoretical benefits projected by the vaccine manufacturer, Merck, to get the vaccine licensed and approved for "universal" use in the first place.

Thus, unless government, healthcare officials and the vaccine makers start telling the public the truth about the very real risks and the less than certain benefits of each vaccine, the public should become increasingly disenchanted with the recommended vaccination programs that increase direct and indirect healthcare costs (monetary and health) beyond the treatment costs (monetary and health) so that the only true beneficiaries are the vaccine makers and the healthcare system who charges both for the costs of vaccination and the costs needed to treat all those damaged by any component in those vaccines while, through the National Vaccine Injury Compensation Program, transferring the costs of the harm done to the taxpayer, the persons who are harmed, and the parents of the children damaged.

"But there's no evidence that any vaccine has ever caused a single case of autism."

Here, this reviewer simply notes that this author is not only mistaken but also apparently living in an Orwellian world where all "inconvenient" truths are denied and all statements are lies enclosed in half truths.

As the preceding discussion of the increase in the prevalence of "autism" in Sweden that is linked to the Swedish program for universal 2-dose MMR vaccination plainly indicates, there is clear evidence that the MMR vaccine can cause neurological brain damage to a child that includes the set of neurological deficit symptoms that can result in a diagnosis of autism.

When it comes to Thimerosal used as a preservative in several vaccines, there is clear evidence that Thimerosal can mercury poison the brain and cause the set of clinical symptoms used to diagnose autism in a child.

However, this reviewer would argue that mercury poisoning by Thimerosal in a vaccine is not "autism" caused by a vaccine but rather "autism" caused by an unnecessary toxic component, Thimerosal, added to several

vaccines as a "**preservative**" <u>without</u> the required toxicological ***proof of safety*** to the standard "**sufficiently nontoxic** …" (as per **21 C.F.R. Sec. 610.15(a)**).

Moreover, there is an every-growing body of case evidence that many of the young children with an ASD diagnosis have been mercury poisoned principally by the Thimerosal in the vaccines administered to them.[20]

Thus, *contrary to Mr. Fumento's rhetoric*, there is a considerable and growing body of evidence that vaccines have caused and are causing cases where children are diagnosed with autism or another ASD.

"Scaring parents - including when it's parents scaring parents - is unconscionable."

Here, this reviewer agrees with this author.

However, this reviewer notes that the "*parents scaring parents*" are the government officials, healthcare professionals, academics and writers who continually use or publish documents that use "scare tactics" and threats to our children's access to schooling or their being able to work to coerce the public into going along with whatever vaccination program that is "recommended."

As some have said: if vaccines were the life savers they are touted to be, then there would be no need to scare the public or have any coercive laws to "influence" the public to have their children vaccinated or to be vaccinated themselves.

"'Suffer the little children' should <u>not</u> become a working principle."

Here, this reviewer finds that Mr. Fumento is too late, the healthcare establishment and the vaccine makers, *operating under the guise of healthcare while maximizing the moneys they receive*, clearly have already made "Suffer the little children" into an integral part of their programs to maximize the treatment population and their profits, with little or no regard for the health of the public.

Since vaccines makers are protected from being sued by most of those whom their products harm, by the National Vaccine Injury Compensation Program, it is no wonder that this is the area where drug companies are not only concentrating their efforts but, *by pricing each dose of their new vaccines based on what the market will bear*, also increasingly reaping their greatest profits.

Little wonder the vaccine makers, the healthcare establishment and their

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[20] **a.** Nataf R, Skorupka C, Amet L, Lam A, Springbett A, Lathe R. Porphyrinuria in childhood autistic disorder: Implications for environmental toxicity. ***Toxicology and Applied Pharmacology*** 2006; **214**: 99-108.

b. Geier DA, Geier MR. A Prospective Assessment of Porphyrins in Autistic Disorders: A Potential Marker for Heavy Metal Exposure. ***Neurotoxicity Research***, 2006; **10**(1): 57-64.

c. Geier DA, Geier MR. A case series of children with apparent mercury toxic encephalopathies manifesting with clinical symptoms of regressive autistic disorders. ***J Toxicol Environ Health A*** 2007; **70**: 837-851.

friends have been and are so vehemently opposed to an independent science-based comparative evaluation of the population of children who have been vaccinated with a similar population of children whose mothers were not vaccinated near or during pregnancy and who have not themselves been vaccinated.

If you really want to prove how wonderful vaccination programs are, then, Mr. Fumento, you and your friends should do all you can to have H.R. 2832, the "Comprehensive Comparative Study of Vaccinated and Unvaccinated Populations Act of 2007," enacted by veto-proof majorities in both houses of Congress before the 110th Congress adjourns, and then funded and, as soon as possible, conducted by independent scientists using a scientifically sound and appropriate protocol.

Should you and others of your ilk fail to support this legislation, oppose it, or seek to subvert or bias the protocols, then, it will be clear to this reviewer and the informed public that you have no interest in the suffering of our children, their parents and the American public when it comes to vaccines.

Finally, to paraphrase this reviewer's high school Latin teacher's motto: the duplicitous actions of government and healthcare officials, and academics stand above them and thunder so loudly that this reviewer cannot hear their glib factually unsupported pronouncements or those of paid vaccine apologists such as yourself, Mr. Fumento.

"Michael Fumento is a D.C.-based medical, science, and military free-lance writer. He can be reached at fumento@pobox.com."

Paul G. King, PhD is a New-Jersey-based Analytical Chemist who consults in the areas of quality and regulatory compliance and who is engaged in the study of the safety and effectiveness of vaccines and other problematic drugs in general and, in specific, the unnecessary use of Thimerosal in the manufacture of vaccines and other drugs without proof of safety to the toxicologically based standard "**sufficiently nontoxic** …"

Dr. King writes reviews, such as this, to rebut the misleading rhetoric he finds in articles published by writers like Mr. Fumento.