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Monday, 4 June 2012

Introduction

Following this page is this reviewer's assessment of a 10 May 2012 opinion piece by Dr. Michael E. Pichichero, which is titled "**Report to WHO: No New Concerns About Thimerosal**" that was accessed on 1 June 2012 from the link posted as: http://www.familypracticenews.com/views/commentaries/single-article/report-to-who-no-new-concerns-about-thimerosal/50f640f350b36ddf1ea2650be4ab8a09.html.

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This assessment, "A Review of 'Report to WHO: No New Concerns About Thimerosal' begins on the next page.

Introductory Remarks

First, to "simplify" this review, when portions of the article, *which are quoted in the original "***Verdana***" font*, are: **a)** being evaluated and **b)** specifically addressed in this review, those portions are quoted in an *italicized "Times New Roman"* font.

Second, this reviewer's assessments are: **a)** written in a "Franklin Gothic Book" font, **b)** follow each quoted portion of the article, and **c)** except for one multiple-part table, indented on both margins to clearly separate the review remarks from the preceding portion of the document that is being addressed.

Third, when other sources are quoted, the text used is in an "Arial Narrow" font.

Finally, should anyone find any significant factual error in this review for which they have independent[a], scientifically sound, peer-reviewed published substantiating documents, this reviewer asks that he or she submit that information to this reviewer so that he can improve his understanding of factual reality and, where appropriate, revise his views and this review.

Respectfully,

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Tel. 1-973-997-1321, after 21:00 Eastern Time
[To whom all responses should be directed]

[a] To qualify, the study should be published by researchers who have no conflicts of interest from their ties to either those commercial entities who profit from the sale of vaccines or those entities, academic, commercial or governmental, who actively promote inoculation programs using vaccines.

Review of "Report to WHO: No New Concerns About Thimerosal"

"Opinion

Report to WHO: No New Concerns About Thimerosal

May 10, 2012

Opinion leaders and fellow physicians weigh in regarding key issues that affect your practice."

First, this reviewer must congratulate Dr. Pichichero, the author of this "***Opinion***" piece, for his adroit use of the English language to create a title that conceals the reality of the on-going concerns about the safety of Thimerosal by stating (emphasis added), "***No New Concerns About Thimerosal***", because the concerns about Thimerosal that the he proceeds to discuss have not only existed since the 1930s but also have been misaddressed by studies that did not or cannot prove the "safety" of Thimerosal to those injected with vaccines containing it at the nominal 0.01% (100 parts-per-million [ppm]) level in a formulation of a vaccine or any other drug product.

Further, since Thimerosal is a component of a drug, by statutory definition[1], it is also a "drug".

Since Thimerosal is a highly toxic compound and a human carcinogen, mutagen, teratogen, reproductive toxin and immune disruptor at tissue levels below 1 ppm (< 1 µg of Thimerosal/g of tissue), before it can be used as a component in any vaccine formulation (a "drug"), its "safe" level must be established in appropriate injected-solution toxicity studies for each population segment (e.g., pregnant woman, developing child, young adult, adult and elderly) to which the vaccine may be given.

To provide some margin of safety, these injected-solution toxicity studies should be conducted with Thimerosal at the equivalent of a level at least 10 times higher than the nominal human-equivalent level in the vaccine formulation in some animal species that has some known relative neurotoxicity to human neurotoxicity (e.g., in the rat, where the known relative toxicity factor is "10" and the human mercury dose in pregnant women is about 0.5 µg Hg/kg, a reproductive toxicity study for Thimerosal in pregnant rats should inject a dose of Thimerosal that nominally injects 50 µg Hg/kg of rat weight [where the specific dose (dose per weight) in the rats is 100 times the specific dose in the humans to account for Thimerosal's known 10-fold lesser susceptibility to neurotoxic effects and to provide the required 10-fold safety margin required to provide ensure that the dose provided properly addresses those individuals who are most mercury-poisoning susceptible]).

Such studies are required to ensure some margin of safety for those groups of

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[1] As set forth in 21 USC Sec. 321 (TITLE 21 - FOOD AND DRUGS of the U.S. CODE, CHAPTER 9 - FEDERAL FOOD, DRUG, AND COSMETIC ACT, SUBCHAPTER II – DEFINITIONS, Sec. 321. Definitions; generally) at "(g)(1)(D)" (emphasis added):

"(g)(1) The term "drug" means (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C)."

humans who are more susceptible to the neurotoxic effects of Thimerosal, its initial breakdown products (e.g., ethylmercury chloride, ethylmercury hydroxide, and thiosalicylate), any intermediate mercury-containing breakdown products (e.g., methylmercury chloride and methylmercury hydroxide) and its Thimerosal-related final long-term bioaccumulative tissue-bound "inorganic mercury" species and/or who, for whatever reason, retain a higher percentage of the preceding mercury-containing species to which they are exposed than the "typical" human.

However, through 2011, there was only one published chronic toxicity study[2] in rats that, in any manner, addressed the issue of the general chronic toxicity for injected Thimerosal.

In that study, bi-weekly injections of various chronic levels of Thimerosal were administered for the rat's span of life equivalent to the span of life for humans from adolescence through middle age (about 1 year from the study's start) with a follow-up that extended from the rats' middle age though their old age (until the surviving elderly rats were about 2 years of age).

Further, as far as this reviewer can ascertain, only this reviewer's published analysis of that study[3] and his recent projected safe-levels analysis[4] have attempted to assess the safe (nontoxic) level) or, as required by the applicable U.S. Food and Drug Administration (FDA) regulation[5], the "sufficiently nontoxic" level for Thimerosal in a Thimerosal-preserved vaccine approved for use in pregnant women, developing children and adults of all ages.

A few studies in isolated snail neurons, in vitro cell culture, and single-dose, short-term near-acute dosings, along with studies-mimicking the vaccination dosing of animals (fertile eggs, rats, pheasants, pigs, golden hamsters, and Macaque monkeys) with ethylmercury compounds or Thimerosal have also assessed and/or presented clinical evidence of Thimerosal's lack of safety.

Finally, some post-vaccination blood-mercury-level assessments have been performed on infants given Thimerosal-preserved vaccines where the results of those studies indirectly bear on the "safety" issue.

Unfortunately, the other published studies have attempted to substitute retrospective and comparative statistics-based population studies of one type or another for what is required – toxicological studies that establish the "safe" ("nontoxic" or, better, the "sufficiently nontoxic") level for the Thimerosal in the maximum approved dose of a Thimerosal-preserved vaccine.

"There is no new rigorous and scientifically valid evidence in the published literature

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2 Mason MM, Cate CC, Baker. Toxicology and Carcinogenesis of Various Chemicals Used in the Preparation of Vaccines. ***J. Clin Toxicol*** 1971; **4**(2): 185-204.

3 **See:** http://dr-king.com/docs/090812_fnldrft_TheTruthAboutTheToxicityOfThimerosalr5b.pdf

4 **See:** http://dr-king.com/docs/20120514_The_AnythingButMercury_Realities_b.pdf

5 **See: 21 C.F.R. § 610.15(a)**, "…Any preservative used shall be sufficiently nontoxic so that the amount present in the recommended dose of the product will not be toxic to the recipient, …". Since the toxicity of requirement is "sufficiently nontoxic" so that the "amount present in the recommended dose of the product will not be toxic to the" the most toxicologically sensitive recipient.

that calls into question the 2008 decision by the World Health Organization" [WHO] "to endorse the continued use of thimerosal as a safe preservative in multidose vaccines for children in the developing world."

Here, the author begins by making an unsubstantiated assertion that implicitly recognizes the discontinuation of the use of Thimerosal-preserved vaccines in much of the developed world while supporting the WHO's 2008 decision to "*endorse the continued use of thimerosal as a safe preservative in multidose vaccines for children in the developing world*".

Clearly, the preceding indicates that the continued use of Thimerosal is not safe for children in the developed world, where its use has been banned or stopped.

Moreover, this author's remarks clearly indicate that he has no problem with this obvious WHO double standard:

- Thimerosal-preserved vaccines are implicitly not "safe enough" for children in the developed world, where the Thimerosal-preserved early childhood vaccines have been replaced with no-Thimerosal formulations in many countries or, in a few instances, with vaccines containing significantly reduced Thimerosal levels, but
- Thimerosal-preserved vaccine formulations are explicitly "safe enough" for the developing world's children.

However, this reviewer must reject this double standard because it clearly values the lives of the children in the developed world more than the lives of the children in the developing world.

Second, the author is simply wrong.

Going back to 2007 and continuing into June of 2012, there are ever-increasing numbers of "*rigorous and scientifically valid*" toxicological studies that call into question "*the 2008 decision by the World Health Organization*", including, but most certainly not limited to, the twenty-one (21) toxicological studies that are briefly discussed in the following multiple-part table.

Table I. Twenty-one Thimerosal-Safety-Relevant Toxicological Studies – Part 1

Item	Key Findings	Article	Authors
1	Giving vaccine levels of Thimerosal to mice did not significantly elevate mercury levels in their cerebrums, but giving Thimerosal with lipopolysaccaharide did significantly elevate the mercury levels in their cerebrums. Increased mercury levels were reduced by chelating with dimercaprol.	Effects of lipopolysaccharide and chelator on mercury content in the cerebrum of thimerosal administered mice. ***Environ Toxicol Pharmacol*** 2007 Nov; **24**(3): 316-320	Minami T, et al.
2	Cell expression study showed the deleterious effects of Thimerosal and a related ethylmercury compound on metallothein expression systems.	Expression of metallothionein mRNAs on mouse cerebellum microglia cells by thimerosal and its metabolites. ***Toxicol*** 2009 Jun; **261**(1-2): 25-32	
3	Metallothionein expression on the cerebellum following low-dose exposure to injected Thimerosal supported the biological plausibility for how low-dose exposure to the mercury from Thimerosal-containing vaccines may be associated with neurodevelopmental delay.	Induction of metallothionein in mouse cerebellum and cerebrum with low-dose Thimerosal injection. ***Cell Biol Toxicol*** 2010; **26**(2): 143-152	

Table I. Twenty-one Thimerosal-Safety-Relevant Toxicological Studies – Part 2

Item	Key Findings	Article	Authors
4	Three, timing- and dose-size-appropriate injections of Thimerosal mimicking the vaccination of young developing golden hamsters with a Thimerosal-preserved vaccine resulted in significant negative neurodevelopmental effects, reduced animal growth, and gene expression effects in the treated hamsters as compared to the effects corresponding outcomes observed in the two (2) normally developing control groups (one injected with sterile pH-balanced isotonic saline and one injected with a sterile ph-balanced saline containing a concentration of sugar that was equal to the amount of Thimerosal injected).	Efectos neurotóxicos del timerosal, a dosis de vacuna, sobre el encéfalo y el desarrollo en hámsteres de 7 días de nacidos [Neurotoxic effects of thimerosal at vaccines doses on the encephalon and development in 7 days–old hamster]. ***An Fac Med Lima*** 2007 Sep; **68**(3): 222-237	Laurente J, et al.
5	Mercury (Hg) levels in the infants' blood exceeded the putative "safe" levels for "mercury in blood" in some instances. Study design precluded the trending of the Hg level in blood for any individual. No data was provided for the clearance of mercury from the body (in urine and feces). Hg speciation testing not only found the expected ethyl and inorganic Hg species but also found unaccounted-for methyl-Hg species.	Mercury Levels in newborns and infants after receipt of Thimerosal-containing vaccines. ***Pediatrics*** 2008 Feb; 121(2): e208-e214	Pichichero ME, et al.
6	Hg levels in the infants' blood exceeded the putative safe levels for mercury in blood in many instances. Study design precluded trending of the Hg level in blood for any individual. No test data was provided for the clearance of mercury from the body (in urine and feces).	Mercury Levels in Premature and Low Birth Weight Newborn Infants after Receipt of Thimerosal-Containing Vaccines. ***J Pediatrics*** 2009 Oct; **155**(4): 495-499	
7	Single vaccine-level Thimerosal dose delayed development of neonatal reflexes in infant monkeys. Some of the delays were more than sufficient to compromise the affected infants' survival in a natural environment.	Delayed acquisition of neonatal reflexes in newborn primates receiving a thimerosal containing hepatitis B vaccine: Influence of gestational age and birth weight. ***J Toxicol Environ Health, A*** 2010; **73**(19): 1298-1313	Hewitson L, et al.
8	Significant deleterious brain-altering effects were seen in developing infant macaque monkeys vaccinated according to the 1990-1994 U.S. CDC-recommended infant vaccination program. Effects were observed in the growth of the infants' amygdalas and on the development of their opioid ligand binding sites (see item **10** where the abnormal development of the opioid bindings sites in this study may have translated into the impaired sensing of pain was observed as an outcome of Thimerosal exposure.)	Influence of pediatric vaccines on amygdala growth and opioid ligand binding sites in rhesus macaque infants: A pilot study. ***Acta Neurobiol Exp*** 2010; **70**: 147-164	
9	Study in rats showed that, following administration of a vaccine-level dose of Thimerosal, the metabolism products (the expected ethylmercury species and "inorganic" mercury species and, the unexpected methylmercury species) persisted in the tissues at significant levels although the only detectable species remaining in blood were inorganic mercury species – this study provided direct evidence that some of the ethylmercury species are degraded into methylmercury species apparently by demethylation.	Identification and distribution of mercury species in rat tissues following the administration of thimerosal or methyl mercury. ***Arch Toxicol*** 2010; **84**(11): 891-896	Rodrigues JL, et al.
10	The results of multiple-level, 4-dose, vaccination-programming-imitating injections of Thimerosal into suckling rats produced persistent impairments in treated rats' nociception (sensing of pain).	Neonatal administration of a vaccine preservative, thimerosal produces lasting impairments of nociception and apparent activation of opioid systems in rats. ***Brain Res*** 2009 Nov; **1301**: 143-151	Olczak M, et al.

Table I. Twenty-one Thimerosal-Safety-Relevant Toxicological Studies – Part 3

Item	Key Findings	Article	Authors
11	Exposure to thimerosal during early postnatal life produced lasting alterations in the densities of brain opioid receptors along with other neuropathological changes that may disturb brain development.	Neonatal Administration of Thimerosal Causes Persistent Changes in Mu Opioid Receptors in the Rat Brain. ***Neurochem Res*** 2010 Nov; **35**(11): 1840–1847	Olczak M, et al.
12	The adverse neuropathological changes from the early postnatal administration of Thimerosal (four i.m. injections, 12 or 240 µg Thimerosal-Hg/kg, on postnatal days 7, 9, 11 and 15) on the brain pathology in Wistar rats were: ischaemic degeneration of neurons and "dark" neurons in the prefrontal and temporal cortex, the hippocampus and the cerebellum; pathological changes of the blood vessels in the temporal cortex; diminished synaptophysin reaction in the hippocampus; atrophy of astroglia in the hippocampus and cerebellum; and positive caspase-3 reaction in the Bergmann astroglia.	Lasting neuropathological changes in rat brain after intermittent neonatal administration of thimerosal. ***Folia Neuropathol***. 2010; **48**(4): 258-269	
13	Early postnatal administration of a vaccine preservative, Thimerosal, produced persistent neurobehavioral alteration in rats and changes in brain dopamine system; in general, the locomotor, emotional and social behaviors were affected but, in rats, spatial memory was not affected; the changes observed were sex dependent; and the lower-dose results appeared to be relevant to the clinically significant neurodevelopmental deficits that are observed in some vaccinated children.	Persistent behavioral impairments and alterations of brain dopamine system after early postnatal administration of thimerosal in rats. ***Behav Brain Res*** 2011 Sep; **223**(1): 107-118	
14	When exposed to 0.37 ppm solutions of Thimerosal (0.185 ppm solutions of mercury, the nlg-1 mutants were statistically ($p < 0.0001$) more sensitive than wild-type animals to poisoning by organic [Thimerosal (sodium ethylmercurithiosalicylate)] form of mercury – indicating that certain subpopulations of humans may similarly be more sensitive to Thimerosal intoxication following some exposure than the general population.	Neuroligin-deficient mutants of *C. elegants* have sensory processing deficits and hypersensitive[ity] to oxidative stress and mercury toxicity. ***Dis. Model. Mech.*** 2010 May/June; **3**(5): 366-376	Hunter JW, et al.
15	Results suggest that exposure to mercury and/or cadmium may contribute to development of autism in humans, possibly by interacting with central dopamine function. The interesting findings are that the observed deficits in social behavior are sex-specific.	Chronic metals ingestion by prairie voles produces sex-specific deficits in social behavior: An animal model of autism. ***Behav Brain Res***. 2010 Nov. 12; **213**(1): 42–49	Curtis JT, et al.
16	In prairie voles, 10 week mercury exposure (60 ppm $HgCl_2$ in drinking water) resulted in a male-specific increase in TNFα protein expression in the cerebellum and hippocampus. Again the study's importance is that the observed significant increase in TNFα protein expression only occurs in the males – more evidence that all forms of mercury poisoning disproportionately affect the males.	Chronic inorganic mercury exposure induces sex-specific changes in central TNFα expression: Importance in autism? ***Neurosci Let*** 2011 Oct; **504**(1): 40-44	
17	Thimerosal (1 µg Hg/g (1 ppm Hg)) {**note:** as compared to nominally about 0.0005 µg Hg/g of a pregnant woman's weight from a Thimerosal-preserved flu-shot that she receives} was intramuscularly administered to pregnant rats on gestational day 9 (susceptible time window for development of fetal serotonergic system), and fetal serotonergic neurons were assessed at embryonic day 15 using anti-serotonin antibodies. A statistically significant increase in the number of serotonergic neurons localized to the lateral portion of the caudal raphe was observed in thimerosal-treated group (a 1.9-fold increase [$p < 0.01$] compared to the control group). The results indicate that embryonic exposure to thimerosal affects early development of the serotonergic neurons.	Embryonic exposure to thimerosal, an organo-mercury compound, causes abnormal early development of serotonergic neurons. ***Neurosci Let*** 2011 Nov; **505**(2): 62-64	Ida-Eto M, et al.

Table I. Twenty-one Thimerosal-Safety-Relevant Toxicological Studies – Part 4

Item	Key Findings	Article	Authors
18	Study clearly established persistent harm from single-dose Thimerosal exposures at more than one dose level during the rats' fetal development, where the lowest dose administered was a dose that, *for neurodevelopmental effects*, is close to the human-equivalent dose. These results indicate that a single embryonic exposure to Thimerosal on gestational day 9 produced lasting impairment of the rat-brain's monoaminergic system.	Prenatal exposure to organomercury, thimerosal, persistently impairs the serotonergic and dopaminergic systems in the rat brain: Implications for association with developmental disorders. ***Brain Develop*** 2012, http://dx.doi.org/10.1016/j.braindev.2012.05.004	Ida-Eto M, et al.
19	The data demonstrated significant negative neurodevelopmental impacts of perinatal exposure to Thimerosal and its metabolites on the developing rat pups. The abnormal effects observed were both sex- and strain-dependent.	Maternal Thimerosal Exposure Results in Aberrant Cerebellar Oxidative Stress, Thyroid Hormone Metabolism, and Motor Behavior in Rat Pups; Sex- and Strain-Dependent Effects. ***Cerebellum*** 2012; **11**(2): 575-586	Sulkowski ZL, et al.
20	Carriers of the inositol 1,4,5-triphosphate kinase C (ITPKC) single nucleotide polymorphism (SNP) were found to be genetically more susceptible to Thimerosal-induced autoimmunity and coronary arterial lesions observed in Kawasaki's Syndrome (KS). This would explain why only a susceptible subset of inoculated children develops KS even though pediatric Thimerosal exposure is nearly universal due to vaccination with Thimerosal-containing vaccines. This article verifies another genetic susceptibility effect related to Thimerosal.	ITPKC susceptibility in Kawasaki syndrome as a sensitizing factor for autoimmunity and coronary arterial wall relaxation induced by thimerosal's effects on calcium signaling via IP3. ***Autoimmunity Rev*** 2012 March 31; online, http://dx.doi.org/10.1016/j.autrev.2012.03.006	Yeter D, Deth R.
21	Since excessive accumulation of extracellular glutamate is linked with excitotoxicity, the study's findings imply that neonatal exposure to Thimerosal-preserved vaccines may induce excitotoxic brain injuries. In humans, such excitotoxic brain injuries have been identified in the brains of developing humans diagnosed with a neurodevelopmental disorder.	Administration of Thimerosal to Infant Rats Increases Overflow of Glutamate and Aspartate in the Prefrontal Cortex: Protective Role of Dehydroepiandrosterone Sulfate. ***Neurochem Res*** 2012; **37**(2): 436-447	Duszczyk-Budhathoki M, et al.

Hopefully, after reviewing these toxicological studies, Dr. Pichichero will also find some that are not only scientifically sound and appropriate but also clearly establish that preservative levels of Thimerosal are unequivocally toxic to the developing fetus and to some developing children.

"In preparation for a treaty on environmental protection, the United Nations asked the World Health Organization for a consultation regarding the safety of mercury in vaccines in the overall context of mercury in the environment. My contribution was to summarize the literature on the safety of the mercury in vaccines from 2008 to the present, in order to learn whether there was anything new that might cause WHO to revise its 2008 decision that informed the previous UN treaty."

While not privy to the inner workings of the United Nations, in general, after its last meeting in Africa (INC3) in late 2011, the United Nations Environmental Programme (UNEP) Intergovernmental Negotiating Committee (INC) for a global legally binding mercury instrument asked all interested non-governmental organizations and other interested quasi-governmental agencies, including the WHO, for their input and the WHO, not the UNEP, set up a consultation regarding the safety of mercury in vaccines that was held on 3-4 April 2012 in Geneva Switzerland.

Further, the key issue regarding mercury in vaccines is the risk to human health

in those individuals who are being given those vaccines that are still preserved using Thimerosal (49.55% mercury by weight) notwithstanding the global context of the level of mercury in the overall environment.

Moreover, since, this reviewer is not aware of any existing UN "treaty on mercury", it would seem that, had this author been more focused on the future health of the public and *dispassionately* reviewed the scientific toxicological literature on the safety of Thimerosal from 2007 to the "present" (early 2012), he might have had information of more health value to contribute to the April meeting.

However, such information, including the recent toxicity and toxicological studies on Thimerosal, might have caused the WHO to change its 2008 position on the use of Thimerosal as a preservative in vaccine formulations.

Not surprisingly then, as the author's narrative will reveal, this author apparently chose to focus on the epidemiological and other related statistical population studies that, *by their very nature*, cannot validly be used to determine whether the use of Thimerosal as a preservative in vaccines is truly "safe" or not.

"Mercury is everywhere in the environment, including the air and in the fish we eat. Mercury in the air is called 'inorganic' mercury, mercury in fish is methylmercury, and mercury in vaccines is ethylmercury (thimerosal). Between 1989 and 1998, as more vaccines with earlier administration times were added to the recommended childhood immunization schedule, average cumulative exposure to ethylmercury from vaccines containing thimerosal subsequently rose. Calculations showed that some infants could receive, during their first year of life, doses of ethylmercury from childhood vaccines that exceeded limits set for methylmercury exposure established by some public health and environmental agencies. However, no evidence for harm from thimerosal was found."

Here, this reviewer must respectfully point out that the "*[m]ercury*" in the air is called "elemental" mercury; "elemental" mercury is not "*called 'inorganic' mercury*".

Mercuric chloride [$Hg(Cl)_2$] is an example of an "inorganic" mercury compound and, when discussing biological systems where the exact nature of the substituent groups associated with the "inorganic mercury" cation, typically Hg^{++}, are unknown, this type of mercury is best characterized by using the phrase, "'inorganic' mercury species" or "'inorganic mercury' species".

Similarly, the principal organic mercury compound stored in the fish's fat is probably methylmercury cysteine [$(CH_3)Hg(S\text{-}CH_2\text{-}CH(NH_2)\text{-}C(O)OH)$]; it is not "*methyl-mercury*", which is the common chemical name for the compound dimethylmercury [$(CH_3)_2Hg$].

Finally, the mercury compound that is added to some vaccines is commonly called "sodium ethylmercury thiosalicylate" [$Na+ (C_2H_5)Hg(o\text{-}S\text{-}C_6H_4\text{-}COO^-$], which commonly has the trade name Thimerosal in the USA; it is not "*ethylmercury*", which is a common chemical name for the compound diethylmercury [$(C_2H_5)_2Hg$].

While the published literature is dominated by those who inappropriately use the terms, "methylmercury" and "ethylmercury" as stand-ins for the actually mercury compound that is being addressed (e.g., methylmercury chloride, methylmercury

hydroxide or, for "ethylmercury", Thimerosal [a trade name for sodium ethylmercurithiosalicylate], ethylmercury chloride and ethylmercury hydroxide); or as labels for "methylmercury species" and "ethylmercury species" when the exact nature of the other groups that are attached to the mercury is not known, this reviewer hopes that this narrative may cause those who report on studies using organic and/or inorganic mercury compounds to be more accurate in describing the mercury species administered or found in their experiments.

Moreover, between "*1989 and 1998*" more than simply increasing, the typical maximum early childhood exposure to children under the age of 1 year increased from nominally 150 micrograms (µg) of Thimerosal (nominally 75 µg of mercury [Hg]), with the earliest dose at 2 months of age, to nominally 375 µg of Thimerosal (nominally 187.5 µg of Hg), with the earliest dose at birth – a 150 % increase.

Since the doses for mercury from fish consumption are exposure by ingestion, where a variety of factors limit the absorption of the organic mercury compounds in the fish by the person consuming the fish[6], the levels set based on fish consumption are not appropriate for injected mercury where, unlike ingestion, the total dose enters the body's blood stream and tissues.

Further, the statutory requirement for a drug (and a component of a drug, including a vaccine, is a drug) is for proof of safety to the standards required before that component, Thimerosal in this instance, may be used in a drug or, when the "safety" requirement has been established after the component has been being used, continue to be used in that drug.

In addition, though they try hard to ignore their duty to prove that the components they use in their drugs are safe, as required by the law, the manufacturers of drugs, including vaccines, have an absolute, nondischargeable legal duty to meet all of the applicable safety standards before a toxic component, like Thimerosal, can continue to be used in the manufacture of a vaccine in the USA.

Thus, the author's non-relevant and misleading statements concerning "standards", "calculations" and "*no evidence for harm*" should be ignored because they do not address or provide any manufacturers' toxicological proofs that the use of Thimerosal at a preservative level in the manufacturers' Thimerosal-preserved vaccines is "safe" or that, *from 1968*, it has met all of the applicable safety requirements for a compound used as a preservative in vaccines including the "sufficiently nontoxic …" FDA requirement set forth in 21 C.F.R. § 610.15(a).

"The 1999 decision by the U.S. Food and Drug Administration and the American Academy of Pediatrics calling for the removal of thimerosal in vaccines sold in the United States was made in haste, based on the inaccurate presumption of identical pharmacokinetics of ethylmercury and methylmercury. In the United States and elsewhere in the developed world, multidose vials have been replaced with single-dose vials, which do not require a preservative. Doing this in poorer parts of the world

[6] Ouédraogo O, Amyot M. Effects of various cooking methods and food components on bioaccessibility of mercury from fish. Environ Res 2011Nov; 111(8):1064-1069. http://www.sciencedirect.com/science/article/pii/S001393511100243X

would represent a very significant cost barrier to providing needed vaccines to the most vulnerable children."

Here, the author starts by making unsupported statements about the removal of Thimerosal from vaccines

Factually, these statements are at odds with the realities concerning the FDA's awareness of not only the toxicity of Thimerosal at preservative levels in vaccine formulations but also its awareness of the actions taken by the former Union of the Soviet Socialist Republics (USSR) in the 1980s[7] and the Scandinavian countries (Denmark, Finland, and Sweden) in the early 1990s to remove Thimerosal because of its proven toxicity (based on studies in the USSR, including a seminal multiple-generation reproductive toxicity study conducted in the USSR that showed adverse effects to the second-generation offspring of the first-generation female rats whose mothers had been given "vaccine" levels of an ethylmercury compound before these mother rats were impregnated by an untreated fertile male rat[8]).

When this author states,

> *"In the United States and elsewhere in the developed world, multidose vials have been replaced with single-dose vials, which do not require a preservative"*,

he is obscuring the reality that during the replacement of Thimerosal-preserved vaccines, both reduced-Thimerosal vaccines and a multidose DTaP vaccine formulation that was preserved with 2-phenoxyethanol instead of Thimerosal were approved and then marketed in the USA before being subsequently replaced by single-dose no-Thimerosal and reduced-Thimerosal vaccine formulations — the final single-dose formulations that are being marketed today in the USA.

In addition, when each switch was made, the remaining within-expiration-date vials of the vaccines containing a higher level of Thimerosal or other preservative were not recalled when the vaccines containing a lower level of Thimerosal or other preservative or, later, the vaccines with no added Thimerosal or other compound that was previously used as a preservative were approved.

Thus, the existing stocks of Thimerosal-preserved vaccines continued to be used until the last batches produced expired in the 2004 to 2005 timeframe.

Moreover, as the FDA's web site continues to acknowledge[9], 2-phenoxyethanol (2-PE) and phenol are still used as preservatives in US-FDA-licensed vaccines as the table on the next page clearly shows.

Thus, as the manufacturer of one formerly Thimerosal-preserved DTaP vaccine

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7 Kravchenko AT, Dzaqurov SG, Chervonskaia GP. Evaluation of the toxic action of prophylatic and therapeutic preparations on cell cultures. III. The detection of toxic properties in medical biological preparations by the degree of cell damage in the L132 continous cell line. ***Zh Mikrobiol Epidemiol Immunobiol***. 1983; **(3)**: 87-92.
"Thus Thimerosal, commonly used as preservative, has been found not only to render its primary toxic effect, but also capable of changing the properties of cells. This fact suggests that the use of Thimerosal for the preservation of medical biological preparations, especially those intended for children, is inadmissible."

8 Goncharuk GA. Experimental investigation of the effect of organomercury pesticides on generative functions and on progeny. ***Hyg Sanit***. 1971; **36**: 40-43

9 http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/VaccineSafety/UCM096228, last visited on 2 June 2012.

did, switching to 2-phenoxyethanol as the preservative in multi-dose vaccines that are currently preserved with Thimerosal should be relatively easy and relatively inexpensive[10] for the vaccine makers, given the preceding facts.

"Table 2: Preservatives Used in U.S. Licensed Vaccines

Preservative	Vaccine Examples (Trade name; Manufacturer)
Thimerosal	TT (one) Influenza multi-dose presentations (several)
Phenol	Typhoid Vi Polysaccharide (Typhim Vi; Sanofi Pasteur, SA) Pneumococcal Polysaccharide (Pneumovax 23; Merck & Co, Inc)
Benzethonium chloride (Phemerol)	Anthrax (Biothrax; Emergent BioDefense Operations Lansing Inc.)
2-phenoxyethanol	IPV (IPOL; Sanofi Pasteur, SA)

"

Moreover, the single-use disposable micro-needle-attached vaccine packet that is being developed in the USA could be used instead of the current syringe and needle technologies, which could reduce the per-dose packaging costs for single-dose vaccine units to less than 1-tenth the cost of the current single-dose vial or single-dose needleless syringe.

Therefore, the author's single-dose-vaccine's packaging cost issue is, at best, a misstatement apparently knowingly designed to mislead the uneducated reader since the author appears to be speaking as a knowledgeable expert concerning this aspect of vaccine production.

"I presented remotely at the United Nations Environmental Programme (UNEP)–convened Intergovernmental Negotiating Committee Meeting 4 (INC4), held April 3-4, 2012, at WHO headquarters in Geneva. The presentation will be made again on June 7 to WHO's Global Advisory Committee on Vaccine Safety for their consideration and vote."

First, this reviewer recognizes that the author, Dr. Pichichero, did make a presentation, in a meeting, advertised by the WHO as a "WHO informal consultation on vaccines in preparation for a UNEP-convened Intergovernmental Negotiating Committee Meeting on a global legally-binding treaty on mercury", which was held by the WHO on 3-4 April 2012 at WHO headquarters in Geneva, Switzerland.

Further, this reviewer also contributed to and remotely attended the 3 April 2012 open information session for the WHO consultation and pointed out that at least one of the population-study papers, on which the WHO's 2008 position on the use of

10 http://mercury-freedrugs.org/docs/20110105_CoMeD_onepager_Preservatives_rb.pdf, last visited on 2 June 2012. [**Note:** This entry documents the use of 2-phenoxyethanol and phenol in the manufacture of various FDA-approved vaccines and establishes a per-dose cost differential of less than U.S. $ 0.0018 (0.18 US cent).]

Thimerosal in vaccines was based, contains falsified data and conclusions (and the results of several other similar population-study papers could not be confirmed)[11].

This is the case because the holders of the original data claimed the datasets had been "lost" or refused to share the critical data with qualified independent scientists so that the validities of each such study and its findings could be confirmed or, *as in the case of the Ip P, et al study*[12], found to have a significant error, which, *when identified and properly corrected by Desoto and Hitlan*[13,14], clearly indicated a possible link between Thimerosal exposure and the risk of subsequent neurodevelopmental harm.

Hopefully, before the author, Dr. Pichichero, again makes his presentation on "*on June 7 to WHO's Global Advisory Committee on Vaccine Safety for their consideration and vote*", he will have read the latest studies, including one by M Ida-Eto, A Oyabu, T Ohkawara, Y Tashiro, N Narita and M Narita, entitled "Prenatal exposure to organomercury, thimerosal, persistently impairs the serotonergic and dopaminergic systems in the rat brain: Implications for association with developmental disorders", which can be read online at http://dx.doi.org/10.1016/j.braindev.2012.05.004, because this article clearly establishes persistent harm from single-dose Thimerosal exposures (at near the human-equivalent mercury levels for a single Thimerosal-preserved vaccine dose) administered to their mothers at a precise time during the rats' fetal development.

Finally, this reviewer hopes that the author will correct the distortions and misstatements he has made in this article and, *based on his slides*, apparently in his previous presentation to the WHO consultation.

"A total of five studies of blood and hair mercury in children have now been published, and all show that the foundational presumption of similar pharmacokinetics between methylmercury and ethylmercury was incorrect. The blood half-life of ethylmercury from thimerosal in vaccines in both full-term and premature infants is 10 times shorter than that of oral methylmercury in adults (Pediatrics 2008;121:e208-14; J. Pediatr. 2009;155:495-9). The worry that ethylmercury might accumulate between vaccination visits at 2, 4, and 6 months of age was unfounded and now disproven. The ethylmercury has a half-life of 4-5 days, not 45 days as with methylmercury in fish. Because of the differing pharmacokinetics, exposure guidelines based on oral methylmercury in adults were not accurate for children who received thimerosal-containing vaccines. Moreover, by 1 year of age the contribution of thimerosal ethyl-

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11 http://dr-king.com/docs/20120331_FalsusInUnoFalsusInOmnibusAThimerosalpreservedVaccineConundrum_b.pdf, that has also been appended to this review. Appending this document has offset the footnote numbers by +29 from the original paper. In addition, the pages of this appended document have had their page numbers changed so that page numbers are prefixed with "*Appended-Document-1-*".

12 Ip P, Wong V, Ho M, Lee J, Wong, W. Mercury Exposure in Children With Autistic Spectrum Disorder: Case-Control Study. ***J Child Neurol*** June 2004; **19**(6): 431-434.

13 DeSoto MC, Hitlan RT. Blood levels of mercury are related to diagnosis of Autism: A reanalysis of an important data set. ***J Child Neurol*** 2007; **22**: 1308-1312.

14 DeSoto MC, Hitlan RT. Sorting out the spinning of autism: Heavy metals and the question of incidence. ***Acta Neurobiol Exp (Wars)*** 2010; **70**: 1565-1576.

mercury to total mercury exposure in infants and children is multifold lower than the contribution from methylmercury in fish (Clin. Chim. Acta 2011; 412: 1563-1566)."

Here, the author begins by misrepresenting the clearance of the various mercury species, both inorganic mercury and organic mercury compounds, from the blood as if that clearance from the blood somehow establishes clearance from the body as a whole.

However, a 1968 study[15] using radiolabeled inorganic, ethylmercury, and other aryl mercury and alkyl mercury compounds injected into adult 7-week-old rats clearly established that less than 15 % of the total dose of the ethylmercury chloride that was given cleared these "adult" rats via their feces and urine within the 8 days after an injection at the 10 mg of ^{203}Hg-radiolabeled ethylmercury chloride (EtHgCl) per kg (10 µg of ^{203}Hg-radiolabeled EtHgCl per gram) of rat weight.

Moreover, a 1971 time-dependent distribution study[16] using 200-220-gram male and 15th-day pregnant Wistar rats and 900-1200-gram male Cynomolgus monkeys (also known as the Crab-eating Macaque (Macaca fascicularis) monkey) and injected (intravenous or intraperitoneal) ^{203}Hg-radiolabeled mercuric chloride and ethylmercury chloride demonstrated that the mercury species from ethylmercury chloride bioaccumulated in both study animals' kidneys and brains over the eight-day period that the study was conducted, as shown in the tables on the next page.

Both the rat data and the monkey data clearly indicate that radiolabeled mercury was accumulating, *over the 8-day period that these test animals were evaluated*, in the kidneys and the brains of the animals dosed with ethylmercury chloride.

Most recently, as cited above, a 2012 reproductive rat toxicity study by Ida-Eto M, et al[17], a study that was partially supported by the "Ministry of Health, Labor and Welfare of the Japanese Government", has clearly demonstrated that a single dose of Thimerosal administered to the pregnant rat has deleterious effects on her offspring that persist into the adulthood of her offspring.

Moreover, in this 2012 article's abstract, the study's researchers stated (emphasis added),

> "...These results indicate that embryonic exposure to thimerosal produces lasting impairment of brain monoaminergic system, and thus every effort should be made to avoid the use of thimerosal".

Based on the preceding realities, the recent 2012 Ida-Eto, M et al study alone has established that the use of Thimerosal as a preservative in vaccines is not safe for use in pregnant women and developing children and that this use of Thimerosal as a preservative in vaccines and other drugs should be immediately abandoned.

Additionally, as a recent 2010 Rodriques JL, et al[18] study of the speciation of the

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15 Takeda Y, Kunugi T, Hoshino O, Ukita T. Distribution of Inorganic, Aryl, and Alkyl ^{203}Hg-labeled Mercury Compounds In Rats. Toxicol Appl Pharmacol 1968; 13: 156-164.

16 Takahashi T, Kimura T, Sato Y, Shiraki H, Ukita T. Time-dependent Distribution of [203]Hg-Mercury Compounds in Rat and Monkey as Studied by Whole Body Autoradiography. J Hygenic Chem (Japan) 1971; 17(2): 93-107.

17 http://dx.doi.org/10.1016/j.braindev.2012.05.004, last visited on 3 June 2012.

18 Rodriques JL, Serpeloni JM, Batista BL, Souza S, Barbarosa Jr F. Identification and distribution of mercury

mercury compounds in rats given Thimerosal has clearly shown, the breakdown of Thimerosal in the body not only produced significant levels of "ethylmercury" and "inorganic mercury" species in the rats' tissues (brain, kidney and liver) when only low levels of "inorganic" mercury species were found in the rats' blood but also unexpectedly produced "methylmercury" species in the brain, heart, kidney and liver, where, *in the heart tissue*, all of the "ethylmercury" species initially present had been converted into "methylmercury" and "inorganic mercury" species (data not shown).

"Table I. Distribution of Radioactive Mercury in Tissues of Rats" [that] "received ^{203}Hg—EtHgCl (950 µgHg/kg)" **[0.95 µg Hg/g]** "by Intraperitoneal injection"

Tissues	µgHg/g after[*]						
	60 min	3 hr	6 hr	24 hr	2 day	4 day	8 day
Liver	3.05	4.04	4.43	4.70	5.05	3.70	3.30
Kidney	4.90	5.10	5.90	6.80	10.40	11.80	17.90
Brain	0.07	0.13	0.14	0.14	0.23	0.27	0.31

[*] **Bolding** added for emphasis by this reviewer for those values that exceeded the initial dosing level of **0.950 µg Hg/g** when the initial dose was "^{203}Hg—EtHgCl (950 µgHg/kg)"

"Table II. Distribution of Radioactive Mercury in Monkey Tissues 60 Minutes after Intravenous Injection and 8 days after Intraperitoneal Injection of ^{203}Hg—EtHgCl (800 µgHg/kg)" **[0.800 µg of Hg/g of subject weight]**

General Tissues	µgHg/g after[*]	
	60 min	8 day
Kidney	**6.73**	**8.60**
Liver	**6.50**	**3.04**
Lung	**5.10**	0.44
Myocardium	**4.62**	0.81
Arteries	**3.36**	0.28
Intestinal wall	**1.28**	0.77
Muscle	**1.05**	0.41
Tongue	**0.94**	0.62
Testis	0.37	0.07

Portion of brain		µgHg/g after[*]	
		60 min	8 day
Cerebellum		0.214	**1.22**
Cerebral Cortex	frontal lobe	0.170	**1.39**
	parietal lobe	0.176	**1.47**
	occipital lobe	0.213	**1.68**
Cerebral white matter	frontal lobe	0.064	**1.16**
	parietal lobe	0.067	**1.14**
	occipital lobe	0.068	**1.10**
Midbrain		0.188	**1.24**
Corpus callosum		0.047	**0.96**

[*] **Bolding** added for emphasis for those values that significantly exceeded the initial dosing level of **0.800 µg Hg/g** when the initial dose was "^{203}Hg—EtHgCl (800 µgHg/kg)"

Moreover, if the apparent demethylation degradation pathway observed in the rats by Rodriques JL, et al also occurs, *as would be predicted*, in humans, the majority of the "methylmercury" species also observed in the blood samples from certain infants (where such were also found in a study in which the author, Dr. Pichichero, was the lead researcher[19]) may have come from the breakdown of the initial ethylmercury species.

Since the baby's mothers were neither fish eaters nor had mercury-amalgam dental fillings, the "methylmercury" species found in some of the human infants' blood samples did not come from some "unknown" alternate source, as Pichichero ME, et al speculated in 2008, but rather probably came from the metabolism of the Thimerosal in the Thimerosal-preserved vaccines those infants had been given.

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species in rat tissues following administration of Thimerosal or methyl mercury {chloride}. ***Arch Toxicol*** 2010; **84**: 891-896.

19 Pichichero ME, Gentile A, Giglio N, Umido V, Clarkson T, Cernichiari E, Zareba G, Gotelli C, Gotelli M, Yan L, and Treanor J. Mercury Levels in Newborns and Infants After Receipt of Thimerosal-Containing Vaccines. ***Pediatrics 2008***; **121**(2): e208-e214.

Thus, the Dr. Pichichero's final statement here:

"*Moreover, by 1 year of age the contribution of thimerosal ethylmercury to total mercury exposure in infants and children is multifold lower than the contribution from methylmercury in fish (Clin. Chim. Acta 2011; 412: 1563-1566)*",

again confuses the time-remote excretion of alkyl-mercury species in hair as if it were a measure of the infants and children's "mercury" exposure or body burden when there are no established linkages between the level of methylmercury species and/or ethylmercury species found in hair and the body burden of all mercury species in the brains of the children being tested.

This is especially because studies in Macaque monkeys have shown that the principal long-term mercury species in the brain are "inorganic mercury" species, which had estimated half-lives of greater than 180 days in the monkeys' brains.

In addition, the average level of these brain-retained "inorganic mercury" species in the brains of the monkeys given Thimerosal was roughly 2 to 3 times the average "inorganic mercury"-species level in the monkeys force-fed vaccine-level solutions of methylmercury hydroxide, *where the "inorganic mercury" species level was below the test method's limit of detection in brain samples from 9 of the 17 methylmercury-hydroxide-force-fed monkeys sacrificed*,[20].

Finally, none of the preceding studies has even addressed, much less overcome the findings in the seminal 1978 publication by M. Sugita, which established that the half-life for the "inorganic mercury" species lodged in the human brain is on the order of 18 to 20 years[21].

"Of the 11 epidemiologic studies reviewed, the large, well-conducted ones show no association between thimerosal and increases in autism. The largest, from the California Department of Developmental Services, showed no recent decrease in autism in California despite the exclusion of more than trace levels of thimerosal from nearly all childhood vaccines. Following the removal of thimerosal from most vaccines used in the United States (except injectable multidose influenza vaccines), rates of diagnosed and reported autism have continued to escalate, strongly arguing against a causal association (Arch. Gen. Psychiatry 2008; 65: 19-24)."

First, this reviewer again notes that the findings of epidemiological studies cannot find "*no association between*" any putative causal factor and any subsequent outcome.

All that a valid epidemiological study can do is estimate what the statistical population probability of such associations at a given level of confidence or, *in this instance*, *where the putative causal factor is Thimerosal exposure and the suspected outcome is the overall risk of an "autism" diagnosis*, the statistical population probability that a given level of exposure to Thimerosal produces some subsequent increased risk of diagnoses of "autism", at some level of confidence.

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20 Burbacher TM, et al. Comparison of blood and brain mercury levels in infant monkeys exposed to methylmercury or vaccines containing Thimerosal. ***Environ Health Persp*** 2005; **113**(8): 1015-1021.

21 Sugita M. The biological half-time of heavy metals. The existence of a third, "slowest" component. ***Int Arch Occup Environ Health*** 1978; **41**(1): 25-40.

Secondly, it is not the number of vaccines that are Thimerosal-preserved that is critical but rather the cumulative exposure to Thimerosal-preserved vaccine doses (because the doses are clearly toxicological "bolus" doses of Thimerosal that is then metabolized into bioaccumulative bolus doses of long-term-retained "inorganic mercury" species), the exposures' timings, and the time-specific ability of the individual being exposed to rapidly excrete some significant portion of each bolus dose, which are the important exposure factors.

Thus, the author's statements here are, *at best*, misleading, and, *at worst*, intentionally deceptive.

Factually, the total maximum lifetime dose of mercury from the vaccination schedule recommended by the U.S. Centers for Disease Control and Prevention (CDC) from Thimerosal-preserved vaccines that children born from the 1990s until the present may have received has not decreased.

Rather, *with the CDC's 2002 recommendation to annually vaccinate pregnant women and developing infants with inactivated-influenza vaccines that may be Thimerosal-preserved flu vaccines and the subsequent increases in the dosing age range for children and the removal of the prohibition against vaccinating pregnant women in the 1st trimester (starting in 2004)*, the actual maximum total dose of Thimerosal to which a normal healthy child born in 2004 may have been exposed has, *including the 2009 pandemic flu shot*, only been slightly reduced to nominally 175 µg of mercury from Thimerosal by the time that he or she is 4 years of age – a dose which is still 2.3 times the dose an early 1980s child would have received.

However, with an ongoing annual additional maximum exposure to nominally 25 µg of mercury from Thimerosal each year thereafter, the maximum total is now 525 µg of mercury from Thimerosal by the time the child turns 18 years of age even if the child receives the no-Thimerosal Tdap vaccine instead of the Thimerosal-preserved TT vaccine that was previously recommended in late adolescence.

Under the 1999 vaccination schedule with the individual Thimerosal-preserved vaccines (Hepatitis B, DTaP and Hib), where the nominal maximum exposure from childhood vaccines and RhoGAM® for healthy children with Rh-negative mothers by 4 years of age was 230 µg of mercury from Thimerosal with only two additional doses (from a DTaP shot at 4-6 years of age and a TT shot at 14-16 years of age) during the rest of their "childhood", the compliant child's nominal maximum exposure would have been about 280 µg of mercury from Thimerosal in total from his or her conception to 18 years of age.

Thus, while the maximum nominal exposure to mercury from the Thimerosal-preserved vaccines for healthy children in the USA has been slightly reduced at the age-4-years time point (by up to 24%), the maximum nominal "childhood" dose of Thimerosal (received by a vaccination-schedule-compliant healthy child born in the USA in 2004 and vaccinated with Thimerosal-preserved flu shots up to 18 years of age) will have significantly increased (by 87.5%) unless Thimerosal-preserved flu shots are completely banned.

Coincidently, *after this vaccination-program mercury-exposure redistribution*,

even with the medical push for "early diagnosis", the average age at which children in the USA have a confirmed "autism" diagnosis has apparently increased.

Finally, the results of the last CDC-sponsored estimates for the "autism spectrum disorder" rates in the USA were for the 8-year-old children born in late 1999 through 2000 who not only received the full early childhood vaccination with Thimerosal-preserved vaccines in most instances but also, beginning in 2002, could have received annual Thimerosal-preserved flu shots so that their total maximum mercury exposure from Thimerosal by age 8 was greater than that of those healthy 8-year-olds born in the mid-1990s who were not recommended to receive an annual flu shot until the 2008 to 2010 timeframe.

"In another well-designed and executed study of managed care organization members, prenatal and early-life exposure to ethylmercury from thimerosal-containing vaccines and immunoglobulin preparations was not related to the increased risk of autism spectrum disorders (Pediatrics 2010; 126: 656-64)."

Contrary to the author's unsupported views, this reviewer finds that this study is not well-designed and it inappropriately introduces a variable, the specific managed care organization at which the individual's records resides, that only serves to dilute the probability of finding any linkage.

Moreover, because this is a case-control study of outcomes that are neither common nor defined by measurable clinical abnormalities and there is no evidence that the cases selected are an unbiased representation of the population or span the entire population, the number of cases selected (256) is too small to make any valid population estimates.

Further, since the design details and datasets used are not open to independent review and confirmation, this epidemiological study should be classified as a "non confirmable" study because the validity of its datasets, study design, exclusion criteria, calculations and results cannot be independently reviewed.

In addition, because this is a study overseen by the CDC, an organization that has been shown to be complicit in the falsification of at least one study in which it had participatory oversight (see footnote "**11**"), until the original datasets and design and execution details are available for independent review, the results of all such closed-to-data-review studies published or overseen by the CDC should not be accepted as being valid.

After all, without the ability to review the study designs and the datasets and to check and confirm the validity of epidemiological or other statistical population study's calculations and findings, any such journal-published statistics-based paper is no more than a "scientific" anecdotal story published in a journal.

Thus, *given the preceding scientific realities*, this reviewer and any other scientist who is aware of others' inability to independently confirm the validity of the datasets and the calculations should: **a)** question the author's scientific objectivity and **b)** respectfully, decline to give this study any scientific credence.

"The handful of studies I did find that reported a link between thimerosal and autism were, to quote the term I use in my report, "specious." One lacked information about how subjects or controls were selected for inclusion in the study, with retrospective analysis in which a potentially false conclusion is reached based on an association (Neuro. Endocrinol. Lett. 2008;29: 272-80)."

In general, *absent evidence of fraud, lack of access to the raw data after the paper is published, or obvious epidemiological study errors based on a lack on the part of the researchers or the paper's reviewers of an understanding of the differences between the number of individuals needed for a valid population causal-linkage determination and the number for a valid sample causal-linkage assessment*, this reviewer understands that findings in all published papers in reputable journals that "*reported a link between thimerosal and autism*" should be accepted as valid unless and until, *as it was for the 2004 Ip P, et al study (see footnote "**12**")*, an independent review (see footnote "**13**") finds that the published paper is materially flawed.

Thus, given Dr. Pichichero's apparent 'biased' acceptance of certain studies that clearly are not only flawed but also, *because they are not toxicological studies*, cannot prove that the use of Thimerosal is safe when the fundamental issue in question is whether the use of Thimerosal as a preservative in vaccines is safe, this reviewer must question this author's finding that the "*... studies … that reported a link between thimerosal and autism were, to quote the term I use in my report, 'specious'*".

Turning to the cited study, after reading the article's abstract, reading the article, and conferring with the contact researcher, this reviewer finds that, because the two clinics reviewed are small medical practices, adequate information was provided as to how the two subject groups (Caucasian women who visited the clinics ("A" and "B") between 1987 and 2001 and whose children had a diagnosed neurodevelopmental disorder [ND]) and the three control groups (the two groups of Caucasian women who visited the two clinics between 1987 and 2001 and whose children did not have an ND, and the third control group was Caucasian women who visited the clinics between 2002 and 2004, when none of the Rho(D) products marketed in the USA contained any Thimerosal) were selected – therefore, the exclusion criteria were: **a)** all non-Caucasian women who visited these two clinics during the relevant time periods and **b)** all women who visited these two clinics outside of the study's inclusion time periods.

Moreover, because all such retrospective analyses are statistical in nature, all such statistical studies are limited to finding the probability of an association, at some level of confidence (95% in this study), and, from a legal and scientific point of view, associations with a probability value (*p-value*) for the association that is "< *0.05*" are *probably causally connected* provided the mean odds ratio is greater than 2 and the lower-bound on the 95% confidence interval is not less than 1.0.

In other words, provided the mean odds ratios exceed 2.0 and the lower-bound on the 95% confidence intervals for the odds ratios are greater than 1, whenever the *p*-value is "< *0.01*", the associations are *highly probably causally connected* and

when the *p*-value is "*<0.001*", the associations are *very highly probably causally connected*.

Since all of the associations had: **a)** a mean odds ratio that was greater than "2.0", **b)** an odds-ratio that was greater than "1.0" for the lower bound at the 95% confidence level and **c)** *p*-values that ranged from "*<0.05*" in one instance to "*<0.01*" in five instances and to "*<0.001*" in two instances, the causal probability for all of the calculated associations ranged from probable in one instance, to highly probable in five instances, and to very highly probable in two instances.

Thus, at best, the author's assertion, "*with retrospective analysis in which a potentially false conclusion is reached based on an association*" should be ignored.

Finally, given the mean odds ratios, and the probabilities values and the calculated lower bounds for the 95% confidence interval values from the data, absent any further investigation of the data, at a minimum, the causal inferences generated from the association values generated should be accepted as probable to very highly probable for the population studied.

"Another was a retrospective ecological study of a possible association between thimerosal exposure from vaccines and neurodevelopmental disorders. The control disorders selected (pneumonia, congenital anomalies, and failure to thrive) have not shown secular trends similar to those seen for neurodevelopmental disorders and an increase in use of vaccines containing thimerosal in the United States (J. Neurol. Sci. 2008;271:110-8)."

Here, this reviewer finds that the author, Dr Pichichero, is attempting to make up some apparently nonexistent requirements for the "*control disorders selected*" – that they should have "*secular trends that are similar to those seen for neurodevelopmental disorders and an increase in use of vaccines containing thimerosal in the United States*".

Moreover, although all such statistical studies in the Vaccine Safety Datalink Database should include an evaluation of several appropriate control disorders for which there is no biologically plausible link, this reviewer notes that, *when it comes to studies involving Thimerosal*, only the statistical epidemiological database studies designed by or with David A. Geier and Mark R. Geier actually incorporate such control disorders.

Since the author's criticism is an invalid criticism, this reviewer must conclude that the associations reported in this paper are valid and probably causal in nature.

Finally, the observed outcomes for the control disorders used serve to strengthen the causal nature of the associations observed between the Thimerosal exposures and subsequent risk of neurodevelopmental disorders in the population studied.

"Importantly, I found two studies regarding the use of the preservative 2-phenoxyethanol (2-PE) that call into question whether it is an acceptable alternative to thimerosal. One found that thimerosal is a superior preservative at 50 mcg/dose compared with 2-PE at 5 mg/dose in hepatitis B vaccines (Southeast Asian J. Trop. Med. Public Health 2010;41:876-82). The other found that while 2-PE was superior to thimerosal in inhibiting bacterial growth in the Prevnar 13 vaccine, it was less effective

than thimerosal for controlling growth of *Candida albicans* or *Aspergillus niger* (Vaccine 2011;29:7144-53)."

First, contrary to this author's views, both of these studies found that 2-phenoxyethanol was acceptable for use as a preservative in the vaccines studied.

Second, *though Dr. Pichichero ignored this finding*, the second study found that Thimerosal "did not meet EP antimicrobial effectiveness acceptance criteria" when used in a Pfizer Prev(e)nar 13® vaccine formulation, while, *over a 30-month storage period*, the 2-phenoxyethanol-preserved Prev(e)nar 13 formulation met the EP criteria.

Furthermore, the first study's abstract only reported that the GlaxoSmithKline Thimerosal-preserved Energix B® vaccine was superior to the formulation preserved with 2-phenoxyethanol from the standpoint of efficacy,

> "The results showed protective levels in 86.8% (2PE New), 89% (2PE Old) and 95.3% [HBV(Thio)]. … However, both 2PE groups had significantly lower seroprotection rates than the HBV(Thio) group and the number of non-responders was higher in the 2PE groups than in the Thio group."

and not that Thiomersal (another trade name for Thimerosal) was superior from a preservative effectiveness point of view.

Importantly, the findings in the first study were recently confirmed in a recent 2012 study by Mahboubi A, et al.[22]

Thus, on balance, the articles that the author, Dr. Pichichero, cited only serve to suggest that 2-phenoxy-ethanol is an effective preservative that should be used as a replacement for Thimerosal, which, *for the Thimerosal-preserved Prev(e)nar 13 vaccine studied*, "did not meet EP antimicrobial effectiveness acceptance criteria".

"Alternative preservatives such as 2-PE have not been field tested, and therefore have not been proven to equal or surpass the proven preservative effectiveness of thimerosal. The potential risks of endorsing alternative preservatives such as 2-PE are unknown. Switching to single-dose vaccine vials adds about $1 per dose of each vaccine. That $1 is currently the cost of vaccinating a child with *all* of the current vaccines given in those countries, including pertussis, diphtheria/tetanus, hepatitis B, polio, measles, and *Haemophilus influenzae* B conjugate. It simply isn't affordable or practical to do that. Not to mention unwise and unnecessary."

Obviously, the author's first statement is patently false.

As shown n the FDA's "Table 2: Preservatives Used in U.S. Licensed Vaccines"[23] that is reproduced on page "11" of this review, 2-phenoxyethanol (2-PE) continues to be used as a preservative in Sanofi Pasteur, SA's IPOL® Inactivated-polio vaccine, and has, *at various times*, previously been used as a preservative in other approved, mar-

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22 Mahboubi A, et al. Evaluation of Thimerosal Removal on the Immunogenicity of Aluminum Salts Adjuvanted Recombinant Hepatitis B Vaccine. Iran J Prarma Res 2012; 11(1): 39-46. [**Note:** This study again confirms that, *for polymeric aluminum-salt adjuvanted Hepatitis B vaccine*, Thimerosal affects both such vaccines' general immunogenicity in a manner that reduces it and the seroconversion in a manner that increases it. In addition, this paper noted that vaccine levels of Thimerosal are highly toxic to the recipient's T-cells.]

23 http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/VaccineSafety/UCM096228, last visited on 2 June 2012.

keted vaccines, including GlaxoSmithKline's Infanrix® DTaP vaccine, Havrix® Hepatitis A vaccine, and Twinrix® Hepatitis A/Hepatitis B vaccine[24].

Since the FDA has licensed 2-phenoxyethanol preserved vaccines produced by Sanofi Pasteur and by GlaxoSmithKline, and Pfizer's studies on its Prev(e)nar 13 vaccine formulations have clearly established that Thimerosal-preserved Prev(e)nar 13 formulation fails to meet the European Pharmacopeia (EP) "antimicrobial effectiveness acceptance criteria" but, *even after storage for 30 months*, the 2-PE-preserved Prev(e)nar 13 formulation continues to meet the "EP antimicrobial effectiveness acceptance criteria", it is clear that 2-PE has been proven to: **a)** be an acceptable alternate preservative to Thimerosal and **b)** clearly surpass Thimerosal, which failed the "EP antimicrobial effectiveness acceptance criteria", as an acceptable preservative in Pfizer's Prev(e)nar 13 formulation.

Furthermore, the author's rant about the cost of switching

- From: multi-dose vials (including the unaddressed costs of the syringes, needles, manual dose withdrawal and delivery as well as the need to discard vials before all doses have been dispensed because of the time limits on the use of a once-pierced multi-dose vial)
- To: pre-filled syringes with integral capped needles (where the costs associated with manual withdrawal and dispensing, the contamination of the syringe and/or needle if either is reused, and the required discarding of the multi-dose vial before all of the doses are dispensed disappear)

is a disingenuous discussion, given the proven viability for using 2-PE as a preservative for the DTP, Hepatitis B, Hepatitis A, and IPOL vaccines and the rapid approval that the switch from a Thimerosal-preserved DTaP vaccine formulation to the corresponding 2-PE-preserved formulation received from the FDA,.

In addition, there alternative single-dose technologies such as the pouch-with-micro-needle approach that, if implemented, could possibly reduce the overall cost of the single-dose dispenser to below one-tenth the cost of the safe use of the 10-dose vial that, *to be safe to administer*, also requires some multiple of 10 sterile syringes and 10 sterile needles for at least some number of such 10-dose vials.

Thus, this reviewer must conclude that Dr. Pichichero's arguments here about alternative preservatives and the single-dose-vaccine costs lack validity.

"The United Nations is expected to vote on the environmental treaty this summer. The evidence suggests the 2008 endorsement of the use of thimerosal as a safe and effective preservative in vaccines for children worldwide should remain."

First, Dr. Pichichero is apparently again mistaken because the next meeting of the UNEP, scheduled this summer (from 27 June to 2 July 2012 in Punta del Este, Uruguay) is to be the fourth session (INC4) of the Intergovernmental Negotiating

[24] http://mercury-freedrugs.org/docs/20110105_CoMeD_onepager_Preservatives_rb.pdf, last visited on 2 June 2012.

Committee to prepare a global legally binding instrument on Mercury[25], where there will again be discussions and negotiations on the key issues.

Second, with respect to Thimerosal, the body of toxicological evidence continues to lower the level at which any exposure in the fetus or developing child is safe for all children.

Currently, this reviewer's estimate for the no observed adverse-effect level (NOAEL), a "nontoxic" level, or general "safe" level for the mercury in Thimerosal-containing vaccines injected into developing children is 0.002 microgram (µg) of mercury (Hg) per kilogram (kg) of body weight at any one time[26] with Thimerosal's "sufficiently nontoxic …"[27] level in developing children at 0.0002 µg Hg/kg of body weight at any one time for infrequently injected Thimerosal-containing vaccines and at 0.00002 µg Hg/kg of body weight at any one time for Thimerosal-containing flu shots given any time during pregnancy, at 6 months and 7 months of age, and then at least annually thereafter.

Hence, based on the "safe"/"nontoxic" and "sufficiently nontoxic" values derived by this reviewer from the applicable long-term injected-Thimerosal chronic toxicity study in rats recognized by the FDA, there is no preservative level of Thimerosal (nominally from 33 to 100 µg of Thimerosal [17.5 to 50 µg of mercury] per milliliter [mL] of vaccine) that is safe to inject into the developing fetus who weighs from much less than a milligram at conception to generally no more than 5 kg (ca. 11 pounds) at full-term birth.

This is the case because even using the "safe" level for injected mercury from Thimerosal (0.002 µg Hg/Kg) and a 5 kg baby weight, the maximum safe injected dose of Thimerosal-derived Hg is about 0.01 µg Hg and the fetal exposure from a Thimerosal-preserved flu shot is nominally some significant percentage (estimated from rabbit studies as no less than 50% of the injected dose) of the 25 µg of Hg injected into the pregnant woman given a Thimerosal-preserved flu shot or ≥ 1250 times the "safe" exposure level.

For the newborn being given a Thimerosal-preserved Hepatitis B vaccine at birth, when the Hepatitis B vaccine dose nominally delivers 12.5 µg of Hg injected, that amount of Thimerosal-derived mercury is also ≥ 1250 times the "safe" exposure level.

Thus, the preceding evidence and the evidence in the recent study by Ida-Eto M, et al (see footnote "**17**") and many other toxicological studies clearly indicates that Thimerosal-preserved vaccines are not safe to give to pregnant women, developing children, or, *for that matter*, adults and the elderly.

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25 http://www.unep.org/hazardoussubstances/Mercury/Negotiations/INC4/tabid/3470/Default.aspx that was last visited on 3 June 2012.

26 http://mercury-freedrugs.org/docs/20120514_The_AnythingButMercury_Realities_b.pdf, from the bottom of page 3 through the top of page 5 – A Copy of this document has also been appended to this review. Appending this document has offset the footnote numbers by +36 from the original paper. In addition, the pages of this appended document have had their page numbers changed so that page numbers are prefixed with "*Appended-Document-2-*".

27 See 21 C.F.R. § 610.15(a), "… Any preservative used shall be sufficiently nontoxic so that the amount present in the recommended dose of the product will not be toxic to the recipient, …".

Furthermore, the recent antimicrobial effectiveness studies conducted by Pfizer (see http://www.ncbi.nlm.nih.gov/pubmed/21651942) have clearly established that vaccine formulations using Thimerosal as a preservative do not always meet the "EP antimicrobial effectiveness acceptance criteria".

In addition, there have been prior failures of a Thimerosal-preserved vaccine to suppress bacterial growth[28] or to maintain sterility [e.g., the 2004 failure of Thimerosal-preserved Fluvirin® vials produced by Chiron, which is now a division of Novartis, to meet their sterility requirements because of vial-contamination with culturable levels of the bacterium *Serratia marcescens*[29]].

Based on all of the preceding realities, the use of Thimerosal clearly does not make it "*a safe and effective preservative in vaccines for children*".

Factually, the FDA has determined that over-the-counter (O-T-C) products containing a 0.1% level of Thimerosal are not safe for even occasional topical use in antiseptics and, in 1998, banned Thimerosal's use in all O-T-C antiseptic drug products.

Given: **a)** the preceding reality and **b)** the fact that: **1)** Thimerosal is highly toxic and a carcinogen, mutagen, teratogen, reproductive toxin, and immune-system disruptor at levels below 1 ppm and **2)** some significant portion of each dose is converted into bioaccumulative tissue-bound "inorganic mercury" species that, *in the human brain*, have half-lives of 18-20 years (see footnote "**21**"), how can this author expect this reviewer or anyone with any education to believe that vaccines with nominal Thimerosal levels at 0.01 % (only ten times lower than the concentration in the banned "unsafe" O-T-C drug products) are "safe", much less safe to the required "sufficiently nontoxic …" level?

Hopefully, after reading this review and checking the references in this review, even Dr. Pichichero will realize that the main reason that the vaccine manufacturers have avoided establishing the toxicological safety level for Thimerosal to the level "sufficiently nontoxic …" (as they were required to do by law since 1968) is that, long ago, they realized that the safe level for injected Thimerosal was orders of magnitude below the level of Thimerosal they were using in their Thimerosal-preserved vaccines.

"Dr. Pichichero, a specialist in pediatric infectious diseases, is director of the Rochester (N.Y.) General Research Institute. He is also a pediatrician at Legacy Pediatrics in Rochester. Dr. Pichichero said he received an honorarium to prepare this report from WHO and donated it to charity. All of his work on thimerosal in vaccines was supported by the National Institute of Allergy and Infectious Diseases. He said he has never received any payment from any vaccine or pharmaceutical company relating to thimerosal in vaccines or any product. He said he has received honoraria/consultant fees and his institution has received research grants from GlaxoSmithKline, Sanofi Pasteur, Pfizer, Novartis, and Crucell for new vaccine and product development, but none of these payments had any direct or indirect relationship to the evaluation of thimerosal in vaccines."

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28 Stetler HC, Garbe PL, Dwyer DM, et al. Outbreaks of group A streptococcal abscesses following diphtheria-tetanus toxoid-pertussis vaccination. ***Pediatrics*** 1985; **75**: 299-303

29 http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2004/ucm146700.htm that was last visited on 3 June 2012.

About the Reviewer

In addition to the general information available on his web site, http://www.dr-king.com/, Paul G. King is the Science Advisor and the current Secretary for the Coalition for Mercury-Free Drugs (CoMeD, Inc., a 501(3)(c) corporation) which has an Internet web site at, http://www.Mercury-freeDrugs.org/.

As a scientist and student of the federal regulations and statutes that govern drugs, including vaccines, Dr. King has led CoMeD, on two (2) separate occasions, in the drafting and submission of a "Citizen Petition" seeking to have the federal government comply with the law, and, based on the improper denial of the Citizen Petition submitted, a federal lawsuit seeking to have the Federal District Court for the District of Columbia compel the Secretary of the Department of Health and Human Services and the Commissioner of the FDA to comply with the statutes and regulations regulating their lawful conduct. The second civil suit, 1:2009-cv-00015, is still being litigated at the present time.

Furthermore, Dr. King has, on several occasions, drafted legislation for submission to the Congress of the USA as well as to the legislatures of various States, submitted cogent comments in opposition to proposed changes to federal regulations that are not in the public interest or appear to be at odds with the law, reviewed numerous documents, and written several articles on a variety of vaccine-related and other issues – including a formal request for correction of false and misleading statements by the FDA in a previous posted document under the applicable Data /Information Quality regulations.

Finally, Dr. King has: ***a)*** *provided various groups with his analysis of various other Congressional bills, resolutions and treaty documents, and* ***b)*** *been an author of several papers bearing on issues related to the toxicity of Thimerosal and other compounds and, if any, their connection to various chronic neurodevelopmental, other developmental and behavioral abnormalities that appear to be well-above (> 1 in 10 children; asthma), above (> 1 in 100 children; the autism spectrum disorders), at (~ 1 in 1000 children; childhood type 1 diabetes), or approaching (life-threatening peanut allergy) epidemic levels in U.S. children.*

With respect to Thimerosal, Dr. King's conflicts of interest are that he is a strong advocate for a ban on its use in the manufacturer of any finished pharmaceutical product, including all biological drug products unless scientifically sound and appropriate toxicity studies can establish that the level in the vaccine dose is at least ten times, and preferably 100 times, lower than the safe level as determined by the NOAEL for the most Thimerosal-sensitive group to which that vaccine or other drug product has been legally approved to be given by the FDA.

Moreover, as is the case for most all of the reviews he writes, Dr. King is neither paid for nor financially compensated for his efforts.

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"Falsus in Uno, Falsus in Omnibus" —
A Thimerosal-preserved Vaccine Conundrum

By Paul G. King, PHD, CoMeD Science Advisor and Secretary; http://dr-king.com

Introduction

The "safety" of using Thimerosal as a preservative in vaccines is a proverbial "house of cards" that lacks a scientifically sound toxicological foundation.

As with any such unstable structure, if one of the key "cards" that are propping up this foundationless claim of Thimerosal's "safety" is proven false, the entire structure is doomed to collapse.

This is the case because proof that the findings are false in any one of the key statistical population studies overseen by the U.S. Centers for Disease Control and Prevention (CDC) and/ or those studies or reports produced by those who the CDC hires (the Institute of Medicine), works with (the consultants and academics), regulates (the vaccine makers), influences (the public health officials) or funds taints all such studies and reports.

Further, it unhinges all of the administrative proceedings (e.g., the 'vaccine court hearings') that relied upon such "falsified" studies to justify their decisions.

A recent paper[30], reiterated this thought by stating, "*… the very efforts designed to produce legitimacy in this type of lopsided dispute will be counter-mobilized as evidence of injustice, helping us understand why settling a scientific controversy in court does not necessarily mean changing anyone's mind*" based on: **a)** confusing the administrative vaccine-injury hearings by "special masters" with "courts" and **b)** the perception that the key scientific papers upon which this "*scientific controversy*" is based are "proven science".

The key to this concluding remark becomes the validity of the "science" upon which the World Health Organization (WHO) is relying.

Key Denmark Study's 'Findings' Proven to Differ from the Facts

One of the key studies that has been repeatedly used to "disprove" evidence of a causal connection between the developing child's exposure to Thimerosal in Thimerosal-preserved vaccines and "autism" is, "*Thimerosal and the Occurrence of Autism: Negative Ecological Evidence From Danish Population-Based Data*", which was: **a)** authored by Kreesten M. Madsen, Marlene B. Lauritsen, Carsten B. Pedersen, Poul Thorsen, Anne-Marie Plesner, Peter H. Andersen and Preben B. Mortensen; **b)** published in the journal ***Pediatrics*** (2003; **112**: 604-606), and **c)** in its abstract, stated, "*The discontinuation of thimerosal-containing vaccines in Denmark in 1992 was followed by an increase in the incidence of autism*".

If the true incidence and prevalence rates for autism in Denmark actually had significantly increased after all of the Thimerosal-preserved vaccines were removed from the Danish vaccination schedule in 1992, then, this finding would be powerful evidence that:

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30 Kirkland A. Credibility battles in the autism litigation. ***Social Studies of Science*** 2012Apr; **42**(2): 237-261.

- There was no causal linkage between Thimerosal exposure and the risk of autism, and
- Denmark should have re-introduced the Thimerosal-preserved vaccines because the study's published findings clearly indicated that Thimerosal-preserved vaccines "suppressed" the risk of autism.

However, the Danes did not reintroduce the Thimerosal-preserved vaccines and the 2004 estimate (made more than a decade after Thimerosal's removal) for the incidence of autism in Denmark children aged 5 to 9 years in 1995-2000 had, for several reasons, changed to the point that it was about 1 child in "1400"[31].

In contrast, in the USA, where no effort was made to "remove" Thimerosal-preserved vaccines from the market until after 2000, the latest estimate for the raw incidence[32] of "autism" as "autism spectrum disorders" (ASDs) in 8-year-old-children born in 1999-2000[33] and appraised in 2008 is, *on average*, "1 in 88" in the disjoint districts in the surveillance areas where, *in some states (e.g., in New Jersey and in Utah)*, the raw incidence rates were *greater than* 2% (1 in < 50).

How can anyone fail to understand that the action taken by Denmark, and the outcomes reported in Denmark and the USA are not consistent with the hypothesis that Thimerosal-preserved vaccines have no causal effect on the risk for, and incidence of, "autism"?

The answer is simple: Recently revealed documents obtained from the CDC using the U.S. Freedom of Information Act (FOIA) process have uncovered proof that, on, or after, "*Wed 13-11-2002*", some, *if not all*, of the authors in the key Danish study cited in this discussion and the CDC's liaison person knew that "*the incidence and prevalence*" [of "autism"] "*are still decreasing in 2001*"[34].

Thus, "autism" rates decreased after the Thimerosal-preserved vaccines were removed.

Therefore, the abstract's statement, "*The discontinuation of thimerosal-containing vaccines in Denmark in 1992 was followed by an increase in the incidence of autism*", was, and is, an obviously problematic declaration at best.

Now, the 2008 survey "autism" rate for 8-year olds in the USA ("1 in 88") and the 2004 "autism" rate for Danish children 5-9 years of age in 1995-2000 (1 in "1400") make perfect

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31 From **Table 1**, 5-9 Age Group, 1995-2000, Prevalence in 2000 ("71.44" per 100,000) in Goldman GS. Yazbak FE. An Investigation of the Association Between MMR Vaccination and Autism in Denmark ***Journal of American Physicians and Surgeons*** 2004 Fall; 9(3): 70-75.

32 Since these data are survey based, the reported "raw counts" values underestimate the true number of affected individuals in the survey population by some amount. Moreover, the disparity in incidence rates in the various survey districts clearly indicates that some districts had a significantly higher level of undercounting than other districts. Had the CDC used another survey source that was independent of the primary survey source(s), identified the cases that were common to both surveys and then appropriately applied capture-recapture statistics, not only should the wide disparity between certain districts have been reduced but the ascertainment-corrected incidence values, though they would have been higher, would have more accurately estimated the probable true population of 8-year-old children having an ASD diagnosis.

33 In this period, all of the vaccine formulations for the Diphtheria, Tetanus and Pertussis (DPT), Diphtheria and Tetanus (DT and Td), Tetanus toxoid (TT), Haemophilis influenzae type b (Hib), Hepatitis B (Hep B), Influenza, Japanese encephalitis and Meningococcal meningitis vaccines that were licensed by the U.S. Food and Drug Administration (FDA) were Thimerosal-preserved formulations.

34 See a copy of the included redacted e-mail that reveals this truth. This copy follows the statement provided.

sense – when the Thimerosal-preserved vaccines were removed in 1992 from the vaccines in the Danish vaccination schedule, the autism rate started to decline and, *in 2004's Denmark vaccination program*, appeared to contribute to *not more than* 1 "autism" diagnosis in every "1400" Danish children (since the Danes have medical records for all their residents and the data in the cited paper was from a major Danish medical treatment center, this number is a population estimate [see footnote "**29+7" = "36"**], and not a sampled-areas estimate).

Thus, to a first approximation[35], the level of Thimerosal exposure from the Thimerosal-preserved vaccines given to 8-year-old children who were vaccinated under the 1999-2008 vaccination programs in the USA and evaluated in 2008 has *probably* increased the rate for "autism" in the USA by *more than* 25 times the level that would have been observed in those 8-year olds if they had not received any Thimerosal-preserved vaccine doses.

Since the Danes still give the Measles, Mumps and Rubella (MMR) vaccine and still use vaccines that contain aluminum adjuvants at levels similar to those in the U.S. vaccination program in 1999 and 2000, clearly Thimerosal-preserved vaccines are a major causal factor for the large disparity between the 2008 "autism" survey rates in the USA and the tracked, but not openly reported, "autism" incidence and prevalence rates in Denmark, where the latest in estimate, calculated *from data published in October 2010 for Danish children born between 1994 and 2004*[36], was 1 in 1272 (< 7% of the CDC's reported raw incidence rate for "autism").

WHO – "Choose You This Day Who Ye Will Serve"

Given the preceding realities, it seems clear that the WHO has two (2) paths that it can take from this day forward.

Either the WHO can "suddenly" see the light and support the "immediate" banning of the use of Thimerosal and any other mercury compound in the manufacture of any vaccine or other drug product, or the WHO can continue to be a part of the "lie" that Thimerosal is "safe" and risk having the countries of the world discover the "lie" and not only stop the use of Thimerosal but also stop the use of any vaccine – on the basis that, if the WHO/CDC/vaccine makers/public health officials are "lying" about the harm from Thimerosal in vaccines, then they are probably "lying" about the safety of all vaccines – falsus in uno, falsus in omnibus – indicating that any person who willfully falsifies one matter is not credible on any matter.

This commenter does not know the choice the WHO will make but he does understand what the logical outcomes of either choice will probably be.

Thus, the WHO needs to choose its path; but, it should choose carefully since the "lie" that was hidden has been revealed and the truth about this "lie" is spreading rapidly across the world!

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35 This approximation presumes that: **a)** the districts with the highest case levels more accurately represent the true population number than those with the lower number and **b)** the residual undercounting makes up for any definitional differences in the general usage of the term "autism" to encompass the ASD spectrum between Denmark and the USA.

36 In 2010, Pia Olsen Dhyr, a Danish Parliament member, asked then Danish Health Minister Bertel Haarder to provide official autism rates for Denmark. In November 2010, that member was told that the health officials did not track this data. From data in a US Associated Press (AP) release on jaundice and autism in Danish children that were born between 1994 and 2004, the "autism" rate was about 1 in 1272 [577/733,826] (http://lubbockonline.com/health/2010-10-11/danish-study-jaundice-autism-newborns-raises-unanswered-questions, last visited on 31 March 2011).

Included Redacted Email

10-05-2005 02:55pm From-

Schendel, Diana

ORIGINAL EDITED
FILE COPY
DO NOT RELEASE

From: Kreesten Meldgaard Madsen [KMM@SOCI.AU.DK]
Sent: Wednesday, November 13, 2002 5:33 AM
To: Marlene Briciet Lauritsen; Poul Thorsen; Schendel, Diana
Subject: RE: Manuscript about Thimerosal and autism

Hi Marlene,

[redacted] I am not currently at the university but I will contact you and Poul tomorrow to make up our minds. Best regards, Kreesten

-----Original Message-----
From: Marlene Briciet Lauritsen [mailto:mbl@dadlnet.dk]
Sent: Wed 13-11-2002 09:24
To: Poul Thorsen; Kreesten Meldgaard Madsen; dcs6@cdc.gov
Cc:
Subject: Manuscript about Thimerosal and autism

Dear Poul, Kreesten and Diane Schendel
Attached I send you the short and long manuscript about Thimerosal and autism in Denmark. [redacted]

I need to tell you that the figures in the manuscripts do not include the latest data from 2001. I only have these figures as a paper version and they are at work [redacted] But the incidence and prevalence are still decreasing in 2001. [redacted]

I look forward to hear from you again.
Best regards
Marlene

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The 'Anything but Mercury' Realities

By Paul G. King, PhD, CoMeD Science Advisor

Introduction

On 15 April 2012, this researcher read an interesting Internet article posted on 13 April 2012 on ***The Daily Bell's*** web site, http://thedailybell.com/3790/Latest-Elite-Meme-Autism-Caused-by-High-Fructose-Corn-Syrup.

While many agree that the Establishment has repeatedly tried to place the as-yet-'unknown'-cause(s) of "*autism*" on the doorstep of 'genetics' and/or a wide variety of 'suspect' products (e.g., pesticides and, in the cited article, high-fructose corn syrup) or activities (e.g., 'cold parenting' and 'too much television'), the only 'causal' suspects that the Establishment claims that it has exonerated are Thimerosal (in preserved vaccines) and the measles-mumps-rubella (MMR) vaccine.

However, before proceeding, this researcher would be remiss if he did not point out that the "Staff" of ***The Daily Bell*** has accepted the Establishment's misdirection when it comes to "autism".

This misdirection is a reality because "autism" is only one of the lesser, harder-to-prove epidemics that have contributed to today's reality that less than 50% of American children are healthy (do not have some chronic adverse medical condition) and more than 25% will have at least one lifetime chronic adverse medical condition, with asthma and obesity leading the list and childhood diabetes probably increasing at the fastest rate.

However, *before the 1980s*, these medical conditions in children were either rare (e.g., asthma and obesity) or unknown (e.g., childhood type 2 diabetes[37] and childhood Kawasaki's syndrome[38]).

As with the Establishment's focus on "lung cancer" in a previous attempt to control the message in order to protect the tobacco-products Industry, the Establishment continually strives to keep the focus on "autism" (severely affecting more than 1% of our children) and away from asthma, where more than 10% of our vaccinated children currently have, or will develop, this lifetime chronic medical disease – while, *in breastfed, never vaccinated children*, asthma has been anecdotally reported as '*not observed*' (< 1 in 15,000; Dan Olmsted's reporting on the Pennsylvania Amish who do not vaccinate) or '*rare*' (about 1 in 30,000-plus children; Dan Olmsted's and Dr. Eisenstein's reporting on Home First's children patients who were not vaccinated).

Accordingly, to prove that the use of Thimerosal as a preservative in a vaccine is "safe", safety must be proven for all possible averse conditions starting with the most frequent and proceeding through all of the others, where the use of Thimerosal-preserved vaccines has been followed by an appropriate temporally offset increase in the adverse medical outcomes in the population subgroup(s) given Thimerosal-preserved vaccines.

Proving Safety

When the studies used by the Establishment to prove the 'safety' of Thimerosal-preserved

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37 http://www.nytimes.com/2012/05/07/opinion/no-longer-just-adult-onset.html?_r=1, last visited on 9 May 2012.

38 Yeter D, Deth R. ITPKC susceptibility in Kawasaki syndrome as a sensitizing factor for autoimmunity and coronary arterial wall relaxation induced by thimerosal's effects on calcium signaling via IP3, ***Autoimmun Rev*** 2012, doi: 10.1016/j.autrev.2012.03.006. [Available online 31 March 2012.]

vaccines are examined, the first problem is that most of these studies are based on statistical examinations of the medical records of some population – even though such studies lack the fundamental ability to prove the 'safety' of the use of anything.

Further, such statistical population studies (usually called 'epidemiological studies') suffer from the flaw that 'correlation is not proof of causation'.

This flaw was repeatedly exploited by the tobacco-products industry – to show, for example, that, because the growth in the sales of refrigerators paralleled the increase in the cases of lung cancer, 'refrigerators caused lung cancer'.

However, to prove that a given level of exposure to a defined substance[39] is safe for a given population group (e.g., developing children), scientifically sound and appropriate toxicological studies in an animal species having known differential response ratios to the corresponding human responses for the substance being tested must be used to establish the level of exposure by a given exposure pathway (e.g., ingestion, inhalation, injection) below which there is no observed adverse effect – where, the toxicologists call this level the NOAEL $_{\text{exposure pathway for substance, population segment}}$[40].

To accomplish this, appropriately designed chronic toxicity studies must be conducted at multiple exposure levels such that all possible toxic effects disappear below some low-but-above-zero level or, for live biologicals, some level of colony/plaque-forming units above the lowest level of colony/plaque-forming units in the study.

When, except for no exposure, adverse effects are observed for all levels of exposure, all that can be accurately stated is that the NOAEL is less than the lowest non-zero-exposure level at which any adverse effect was observed provided the incidences of the observed adverse effect increase in a roughly linear manner as the chronic levels of exposure increase.

Hopefully, now that this researcher has explained what must be done to prove that an injected chemical or biological substance is "safe", the public will demand that the Establishment find the appropriate animal models, conduct the appropriate, scientifically sound studies in those animal models, and then publish the valid scientifically sound NOAEL $_{\text{injected Thimerosal, population segment}}$ values that such studies support.

When these NOAEL values are published for each population segment, then the public will, *to a first approximation*, know the level of injected Thimerosal that is "nontoxic" for the recognized human population segments (fetal, neonatal, early childhood, childhood, adolescent, young adult, adult, and the elderly – or the broader categories, 'developing children', which, in the USA, currently encompasses the time from some point in gestation until the 'child' reaches 18 years of age, and 'adults', which currently starts at 18 years of age and continues until the adults die).

Meeting the Safety Standards for Preserved Biological Drug products

Under the current good manufacturing practice (CGMP) requirement minimums[41] for biologi

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[39] Such substances can be a chemical compound that is 'toxic', known as a 'toxicant' or a biological component that can be toxic, known as a toxin. For vaccines, Thimerosal and other chemical compounds used as preservatives and aluminum adjuvants are examples of toxicants and the live or inactivated viruses, modified bacterial components (e.g., the tetanus and diphtheria toxoid) or bacterial or viral fragments (e.g., Lipid A and the hepatitis B fragments) are toxins.

[40] For example, for substances that are injected into developing children, the NOAEL $_{\text{injection, developing children}}$ is the required NOAEL.

[41] Under the CGMP framework, all establishment requirements are, as stated, minimums that must be met and, below which, a drug product to which they are applicable is considered an adulterated drug product, which is illegal to be marketed.

cal drug products, the explicit safety standard for those compounds, like Thimerosal, used as a preservative are set forth in **Title 21** of the United States **Code of Federal Regulations** in **Part 610 —GENERAL BIOLOGICAL PRODUCTS STANDARDS** (**21 C.F.R. Part 610**) in **21 C.F.R. § 610.15 Constituent materials** at **21 C.F.R. § 610.15(a)**:

> "… Any preservative used shall be sufficiently nontoxic so that the amount present in the recommended dose of the product will not be toxic to the recipient, …"

Since Thimerosal is used as a preservative in certain vaccines and these Thimerosal-preserved vaccines are biological drug products, the CGMP minimum safety standard for such Thimerosal-preserved vaccines is "sufficiently nontoxic so that the amount present in the recommended dose of the product will not be toxic to the recipient".

To be "sufficiently nontoxic" the level of Thimerosal in a dose of vaccine must be below the "nontoxic" (NOAEL) level by some factor, which, for highly toxic compounds, *like Thimerosal (49.55% mercury by weight), whose mercury-containing metabolites bioaccumulate and have a half-life in human tissues that is on the order of one to two decades*, an acceptable safety factor for a Thimerosal-preserved vaccine that is given infrequently or only a few times over the person's life expectancy might be a factor of 10.

However, for Thimerosal-preserved influenza vaccines that are currently recommended to be administered annually or when multiple Thimerosal-preserved vaccines are even given infrequently, the "sufficiently nontoxic ..." safety factor would need to be a factor of 100.

Injected Thimerosal's Estimated NOAEL and Its Derived "Safe" ("Nontoxic" and "Sufficiently Nontoxic") Levels

Based on an FDA-recognized chronic rat study that injected low-level doses of Thimerosal, administered twice weekly, over an extended period of time, this author has estimated[42] that the NOAEL (for injected Thimerosal in developing children) is less than (<) 0.0086 microgram (µg) of Thimerosal [< 0.0042 µg of organic mercury] per kilogram (kg) of body weight (per day) and, *from the imputed incidence and the calculated "0" exposure residual effects*, the probable $NOAEL_{\text{injected Thimerosal, developing children}}$ is about 0.004 µg of Thimerosal per kg of body mass (per day) or, in terms of the injected organic mercury, about 0.002 µg of organic mercury per kg of body mass (per day)[43,44].

Therefore, for the Thimerosal-preserved vaccines (other than the influenza vaccine) that are injected infrequently in the USA, the "sufficiently nontoxic ..." Thimerosal injection level for these other vaccines probably is about 0.0004 µg of Thimerosal (0.0002 µg of mercury) per kg of body weight (per day) [or about 0.4 nanogram of Thimerosal {0.2 nanogram of organic mercury} per kg of body weight (per day)].

For Thimerosal-preserved flu shots that can be administered to a mother during her pregnancy

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[42] http://dr-king.com/docs/090812_fnldrft_TheTruthAboutTheToxicityOfThimerosalr5b.pdf, last revisited on Monday, 30 April 2012

[43] The estimated NOAEL was imputed from the apparent small difference in computed percentage of animals affected for the lowest level Thimerosal that was administered and the computed zero "0" exposure level.

[44] Since the half-lives for the final organic mercury metabolite, tissue-retained inorganic mercury is on the order of one to two decades, averaging the amount injected per kilogram over the number of days between injections to reduce the peak amount injected is not appropriate because the toxicant's terminal 'metabolites' are bioaccumulative toxicants with half-lives in humans of from 10 to 20 years (from 3652.5 to 7305 days), depending upon the tissue [see, Sugita M. The biological half-time of heavy metals. The existence of a third, "slowest" component. ***Int Arch Occup Environ Health*** 1978; **41**(1): 25-40].

and to the child at 6 months, 7 months and annually thereafter, the "sufficiently nontoxic" Thimerosal injection level for these Thimerosal-preserved vaccines probably is about 0.00004 µg of Thimerosal (0.00002 µg of organic mercury) per kg of body weight (per day[45]) [or about 0.04 nanogram of Thimerosal (0.02 nanogram of organic mercury) per kg of body weight (per day)].

However, even using this reviewer's projected NOAEL $_{\text{injected Thimerosal, developing children}}$ of 0.002 µg of organic mercury per kg of body weight (per day) for Thimerosal and knowing that the developing post-natal child's minimum nominal dose of organic mercury from Thimerosal is 12.5 µg of organic mercury from a flu shot, the least that the developing child can weigh for the vaccine dose to be "nontoxic" is about [12.5 / 0.002] kilograms or 6,250 kg (13,779 pounds).

Because developing children typically weigh much less than less 100 kg (ca. 220.46 pounds), all of the estimates for the NOAEL $_{\text{injected Thimerosal, developing children}}$ indicate that even an injected 0.25-milliliter (mL) dose of a Thimerosal-preserved vaccine is toxic to some degree to the developing child who is given a 0.25-mL dose of a Thimerosal-preserved vaccine.

Moreover, since the CGMP requirement minimum is "sufficiently nontoxic", the 0.25-mL dose of a Thimerosal-preserved influenza vaccine delivering 12.5 µg of mercury (Hg) exceeds the "sufficiently nontoxic" level (0.00002 µg of Thimerosal-derived mercury), which is 100 times lower than the estimated NOAEL value for injecting Thimerosal-preserved vaccines into developing children because these Thimerosal-preserved vaccines are recommended to be repeatedly injected.

Clearly even the minimum dose (0.25-mL) of a Thimerosal-preserved flu vaccine administered annually exceeds the safe level by at least a factor of:

[12.5 ~~µg of organic Hg from Thimerosal~~ divided by 0.00002 ~~µg of organic Hg from Thimerosal~~ per kg of body weight], or

[6,250,000 divided by the child's weight in kg].

Presuming that a developing child weighs between 2 kg and 50 kg, depending on his or her stage in development, the minimum dose of a Thimerosal-preserved flu shot exceeds:

a. The "sufficiently nontoxic" level (as required by **21 C.F.R. § 610.15(a)**) by a factor of 125,000 to 3,125,000 or twice these when the vaccine dose delivers 25 µg of organic mercury and

b. The "safe" ("nontoxic"; estimated NOAEL) level (as required by the statutory requirements set forth in **42 U.S.C. § 262(a)(2)(C)(i)(I)**) by a factor of 1,250 to 31, 250 or, when the dose is 25 µg organic mercury, twice these factors.

Thus, it is clear that even the minimum vaccine dose (0.25-mL) is <u>not</u> "safe" for a Thimerosal-

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[45] Because the data in animals indicates that most of the mercury dosed is retained in the tissues for long periods of time that translate into half-lives that are a significant fraction (on the order of 15% to 30%) of the animals' expected lifetimes, it is less than appropriate to average the dose over the period between doses when the period between dosings (1 month to 1 year for humans) is significantly less than the half-life in the animal in question (for humans, that half-life in the brain is on the order of 18 to 20 years – making the inter-dosing periods between 0.42% and 5.5% of the half-life of the ultimate toxicant, "tissue retained mercury". In the original rat study using rats with a life expectancy of 24 months, the dosing was 2-times a week for 50% of the rats' life expectancy. In rats, the half-life of the mercury is on the order of 6 months (180 days) and the between-dosing period was 3.5 days in the chronic dosing study or about 2 % of the retained mercury's half-life with more than 75% of any dose's being long-term retained. Thus, averaging of the dose over time is not appropriate because that model presumes that the toxic substance dosed is rapidly cleared from the body, which is not the case in this instance. [**See**: Takeda Y, Kunugi T, Hoshino O, Ukita T. Distribution of Inorganic, Aryl, and Alkyl Mercury Compounds in Rats. ***Toxicol Applied Pharmacol*** 1968; **13**: 156-164, and Takahashi T, Kimura T, Sato Y, Shiraki H, Ukita T. Time-Dependent Distribution of ^{203}Hg-Mercury Compounds in Rat and Monkey as studied by Whole Body Autoradiography. ***J Hygenic Chem*** 1971; **17**(2): 93-107.]

preserved flu shot and is most certainly not "sufficiently nontoxic" for the developing child.

For adults, where the minimum dose is 0.5-mL, the nominal level of organic mercury from Thimerosal in an injected Thimerosal-preserved flu shot (25 µg of mercury) exceeds even the "safe" ("nontoxic") level by a factor of 1,250 (25.0/ 0.02) divided by the adult's weight in kg or, *since the typical adult weighs between about 42 kg (about 92.6 lb) and 250 kg (about 551.2 lb)*, is ***unsafe*** by a factor of about 5 to about 30.

Therefore, Thimerosal-preserved vaccines are not even toxicologically "safe" as required by **42 U.S.C. § 262(a)(2)(C)(i)(I)** for administration to either developing children or adults.

The National Vaccine Injury Compensation Program (NVICP): An Unfulfilled Mandate to Make Thimerosal-containing Vaccines Safer by Reducing the Risk of Adverse Effects.

In addition to the statutory and regulatory requirement that vaccines must be safe and meet all applicable safety standards, the National Vaccine Injury Compensation Program (NVICP) [codified in **42 U.S.C. §§ 300aa-10 through 300aa-34**], enacted in 1986, established a mandate, as set forth in **§ 300aa-27. Mandate for safer childhood vaccines**, which, at **§ 300aa-27(a)(2),** states (emphasis added):

> "(a) General rule
>
> In the administration of this part and other pertinent laws under the jurisdiction of the Secretary, the Secretary shall –
>
> (1) …, and
>
> (2) make or assure improvements in, and otherwise use the authorities of the Secretary with respect to, the licensing, manufacturing, processing, testing, labeling, warning, use instructions, distribution, storage, administration, field surveillance, adverse reaction reporting, and recall of reactogenic lots or batches, of vaccines, and research on vaccines, in order to reduce the risks of adverse reactions to vaccines".

Because the vaccine coverage of the NVICP have been widened to include those vaccines recommended by the U.S. Centers for Disease Control and Prevention (CDC) for routine prophylactic administration to adults, the current directive is an absolute, all-authorities mandate for the Secretary and all who report to the Secretary to make all vaccines covered by the NVICP safer by reducing "the risks of adverse reactions to vaccines".

Since, *even before the NVICP was enacted*, scientifically sound and appropriate studies had proven that adding Merthiolate (another trade name for Thimerosal) to a vaccine formulation at preservative levels increased the adverse reactions to that vaccine formulation[46], the Secretary's repeated refusal to remove Thimerosal from all Thimerosal-containing vaccines and revoke the licenses for all Thimerosal-containing vaccine formulations that are covered by the NVICP in the more than 25 years that have elapsed since this mandate became effective on December 22, 1987 are actions by the Secretary that: **a)** clearly have been "unlawfully withheld", **b)** are "not in accordance with law", **c)** are "short of statutory right", and **d)** have been taken "without observance of procedure required by law"[47].

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[46] Nelson EA, Gottshall RY. Enhanced toxicity for mice of pertussis vaccines when preserved with Merthiolate. ***Appl Microbiol***. 1967; **15**: 590-593, last visited on 15 April 2012.

[47] **"**TITLE 5 - GOVERNMENT ORGANIZATION AND EMPLOYEES

Because **§ 300aa-27(a)(2)** is a statutory mandate, the Secretary of the Department of Health and Human Services (DHHS) and the officials (e.g., the Commissioner of the Food and Drug Administration [FDA]) who, and agencies that, report to said Secretary (e.g., the CDC, the FDA, National Institutes of Health [NIH], and the Public Health Service [PHS]) have no administrative discretion[48] to ignore compliance with any aspect of this absolute statutory directive and, therefore, *to the extent that their activities directly affect vaccine safety*, aforesaid officials and agencies have, with respect to Thimerosal-preserved vaccines, been knowingly[49] operating outside of the Secretary's legal mandate to make vaccines safer for more than a quarter of a century.

In addition, though, in **§ 300aa-31. Citizen's actions**, the NVICP states (emphasis added):

"(a) General rule

Except as provided in subsection (b) of this section, any person may commence in a district court of the United States a civil action on such person's own behalf against the Secretary where there is alleged a failure of the Secretary to perform any act or duty under this part.

(b) Notice

No action may be commenced under subsection (a) of this section before the date which is 60 days after the person bringing the action has given written notice of intent to commence such action to the Secretary",

the federal courts have, *so far*, refused to permit the CoMeD plaintiffs to "commence in a district court of the United States a civil action on such person's own behalf against the Secretary where there is alleged a failure of the Secretary to perform" the duty to make vaccines safer by reducing the risk of adverse reactions as mandated by **§ 300aa-27(a)(2)** even though the Administrative Practices Act at **5 U.S.C. § 701** clearly states (emphasis added):

"Sec. 702. Right of review

A person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof. An action in a court of the United States seeking relief other than money damages and stating a claim that an agency or an officer or employee thereof acted or failed to act in an official capacity or under color of legal authority shall not be dismissed nor relief therein be denied on the ground that it is against the United States or that the United States is an indispensable party. The United States may be named as a defendant in any such action, and a judgment or decree may be entered against the United States: Provided, That any

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PART I - THE AGENCIES GENERALLY
CHAPTER 7 - JUDICIAL REVIEW
Sec. 706. Scope of review [emphasis added]
To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall -
(1) compel agency action unlawfully withheld or unreasonably delayed; and
(2) hold unlawful and set aside agency action, findings, and conclusions found to be -
(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;
(B) contrary to constitutional right, power, privilege, or immunity;
(C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;
(D) without observance of procedure required by law ..."

48 See the limitations placed on administrative discretion by the U.S. Supreme Court in *Berkovitz v. United States* 486 U.S. 531 (1988): "The agency has no discretion to deviate from this mandated procedure. [10] Petitioners' claim, if interpreted as alleging that the DBS licensed Orimune in the absence of a determination that the vaccine complied with regulatory standards, therefore does not challenge a discretionary function. Rather, the claim charges a failure on the part of the agency to perform its clear duty under federal law. When a suit charges an agency with failing to act in accord with a specific mandatory directive, the discretionary function exception does not apply."

49 21 U.S. C. § 321. Definitions; generally
§ 321(bb) The term "knowingly" or "knew" means that a person, with respect to information -
(1) has actual knowledge of the information, or
(2) acts in deliberate ignorance or reckless disregard of the truth or falsity of the information.

mandatory or injunctive decree shall specify the Federal officer or officers (by name or by title), and their successors in office, personally responsible for compliance. Nothing herein (1) affects other limitations on judicial review or the power or duty of the court to dismiss any action or deny relief on any other appropriate legal or equitable ground; or (2) confers authority to grant relief if any other statute that grants consent to suit expressly or impliedly forbids the relief which is sought",

The courts have done this by redefining the future-injury bar to exclude:

a. The proven ongoing failure of flu-shot vaccine providers to provide truthful information about the nature of the level of Thimerosal in, and/or the prohibitions for the administration of, inactivated-influenza and live-virus influenza vaccines to pregnant women, where it is not possible to reliably determine the nature of the Thimerosal level (Thimerosal-preserved, reduced-Thimerosal, or no-Thimerosal) in an inactivated-influenza vaccine dose in a syringe presented for administration to an individual from the possible future adverse outcomes for those members of CoMeD seeking no-Thimerosal, inactivated-influenza vaccines as well as

b. The proven coercion of certain pregnant CoMeD members into being vaccinated with Thimerosal-preserved inactivated-influenza vaccines using the threat that their developing babies would die if that pregnant CoMeD member did not get the Thimerosal-containing flu shot being offered – even though one or more of these pregnant CoMeD members subsequently lost their fetus to fetal death shortly after they were vaccinated and suffered the on-going mental injury that such losses can engender in those who grieve for the loss of a child as well as, in one instance, prolonged loss of feeling in one arm.

Since, as CoMeD member declarations have asserted, CoMeD members have been misled, lied to, and/or coerced into getting a Thimerosal-preserved flu shot in the past, then, as long as Thimerosal-preserved flu-shots are available and there is no way to ensure that the dose of inactivated-influenza vaccine presented to them in a given syringe does not contain Thimerosal, **a)** CoMeD members, **b)** their minor children and **c)** the general public will be at risk of being: **i)** denied the "no Thimerosal" inactivated-influenza vaccines they are seeking and/or **ii)** harmed by being tricked, misled or coerced into receiving a Thimerosal-preserved inactivated-influenza vaccine in the foreseeable future.

Beyond Unsafe: Thimerosal, the Marginal Vaccine Preservative

The justification for adding Thimerosal to vaccines originally (in the early 1930s) was that it was a preservative for protecting multi-dose vials from bacterial contamination during the removal of multiple aliquots of vaccine from the vial, whenever less than aseptic technique was used for withdrawing the vaccine dose.

To a first approximation, for a compound used as a preservative, the vaccine makers rely on a preservative effectiveness test that, as outlined in the United States Pharmacopeia (USP), is based on a challenge panel for multiple objection organisms that, among other criteria, requires a significant reduction in the initial level of bacteria at 7 and 14 days after bacterial contamination.

However, if the need is to protect patients from being infected after a given withdrawal has contaminated the contents of the vial, then the substance being used as a preservative must be

bactericidal (a substance that quickly kills the contaminating bacteria) and not simply bacteriostatic (a substance that initially only stops the contaminating bacteria from growing) after a withdrawal contaminates the multi-dose vial.

Thus, although a 100-ppm Thimerosal solution may pass the requirements in the USP's **<51>** "*Antimicrobial Effectiveness Testing*" method[50], Thimerosal at this level is a less-than-effective preservative because: **a)** since 1948, *when definitive studies were conducted*, Thimerosal has been found to be bacteriostatic[51] at Thimerosal (Merthiolate) levels of 1,000 ppm and below[52], and **b)** in the presence of proteins containing sulfhydryl groups (-SH) and other sulfur-containing components, even Thimerosal's bacteriostatic action is inhibited[53] and its preservative effectiveness is diminished[54].

Therefore, Thimerosal is obviously a less-than-effective preservative in vaccine formulations that contain proteins – as all vaccine formulations do.

Thimerosal's deficiency as an effective preservative was recently reaffirmed in a direct comparative study of vaccine formulations for Pfizer's (formerly Wyeth's) Prev(e)nar 13®.

This study compared 0.01-% (100-parts-per-million [100-ppm]) levels of Thimerosal and 2.5-% levels of 2-phenoxyethanol, used as a preservative, and assessed the comparative preservative-effectiveness for both the substances by themselves and in the Prev(e)nar 13 formulation[55].

The study found that 2-phenoxyethanol was clearly a superior preservative in the Prev(e)nar formulations.

Previously, the problematic nature of the use of Thimerosal as a preservative in an inactivated-influenza vaccine formulation was revealed when post-filling sterility studies found bacterially contaminated lots of the 2005-2006 Fluvirin® formulation of Thimerosal-preserved inactivated-influenza vaccine filled in multi-dose vials that was produced by then Chiron, which is now part of Novartis.

Specifically, viable *Serratia marcescens* bacteria was found in the multi-dose vials of the finished packaged Fluvirin product[56].

Together, these findings clearly demonstrate that, *at best*, because it is a bacteriostatic chemical at the level used in a preserved vaccine, Thimerosal is a marginal bacterial preservative.

Finally, *because vaccines contain proteins*, Thimerosal is less effective in vaccine formulations at the nominal maximum 100-ppm Thimerosal level used as a preservative than a preservative level (2.5%) of 2-phenoxyethanol would be based on the study cited in footnote "**19**".

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50 http://www.microbiol.org/wp-content/uploads/2010/07/sutton.pda_.2002.6.pdf, last visited on 1 May 2012.

51 Bacteriostatic (Biology) adjective "Referring to inhibition of bacterial growth and/or reproduction" from "McGraw-Hill Concise Dictionary of Modern Medicine. © 2002 by The McGraw-Hill Companies, Inc.", in http://medical-dictionary.thefreedictionary.com/bacteriostatic, last visited 1 May 2012.

52 Morton HE, North LL, Engley FB. The bacteriostatic and bactericidal action of some mercurial compounds on hemolytic streptococci. ***JAMA*** 1948; **136**: 37-41.

53 Engley FB. Evaluation of mercurial compounds as antiseptics. ***Annals of the New York Academy of Sciences*** 1950; **53**: 197-206.

54 Stetler HC, Garbe PL, Dwyer DM, et al. Outbreaks of group A streptococcal abscesses following diphtheria-tetanus toxoid-pertussis vaccination. ***Pediatrics*** 1985; **75**: 299-303.

55 Khandke L, Yang C, Krylova K, Jansen KU, Rashidbaig A. Preservative of choice for Prev(e)nar 13™ in a multi-dose formulation. ***Vaccine*** 2011 Sep 22; **29**(41): 7144–7153.

56 http://www.in-pharmatechnologist.com/Processing/FDA-report-sheds-light-on-Chiron-s-problems, last visited on 1 May 2012.

Realities Concerning Vaccines That Nominally Contain "100"-ppm Levels of Thimerosal as a Preservative

Based on Thimerosal's established lack-of-proof-of-safety reality and Thimerosal's marginal effectiveness as a preservative at the 100-ppm level, how can anyone continue to justify using Thimerosal as a preservative in vaccine formulations?

Further, since Thimerosal (a/k/a Merthiolate) is known to increase the adverse effects caused by a vaccine formulation[57], the on-going failure of the Secretary of Health and Human Services to mandate the removal of Thimerosal from all vaccines is a violation of § 300aa-27. Mandate for safer ... vaccines[58] (at **§ 300aa-27(a)(2)**) of the "National Vaccine Injury Compensation Program" (**NVICP**; as set forth in **42 U.S.C. §§ 300aa-10** through **300aa-34**), which mandates that the Secretary must use all of the Secretary's authorities "in order to reduce the risks of adverse reactions to vaccines".

Thus, any recommendation to continue to support the use of Thimerosal as a preservative in vaccines is a recommendation that is at odds with the applicable laws of the USA that govern:

- General vaccine safety (as set forth in **42 U.S.C. § 262**),
- Preserved-vaccine safety (as set forth in **21 C.F.R. § 610.15**) and
- The mandated safening of vaccines (as set forth in **42 U.S.C. § 300aa-27**).

Note to the Reader

Should anyone find any significant factual error in this article for which they have independent[59], scientifically sound, peer-reviewed published substantiating documents, the author asks that he or she submit that information to the author so that he can improve his understanding of factual reality and, where appropriate, revise his views and this article.

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57 Nelson EA, Gottshall RY. Enhanced toxicity for mice of pertussis vaccines when preserved with Merthiolate. ***Appl Microbiol***. 1967; **15**: 590-593, last visited on 15 April 2012.

58 In the original, the word "childhood" was included because, as enacted, the **NVICP** only covered children's federally recommended prophylactic vaccines. However, the U.S. code was subsequently amended to include vaccines that the federally recommended for mass use in adults. Given the addition of the federally recommended adult vaccines, the **§ 300aa-27** mandate now extends to all of the federally recommended prophylactic vaccines.

59 To qualify, the study should be published by researchers who have no conflicts of interest from their ties to either those commercial entities who profit from the sale of vaccines or those entities, academic, commercial or governmental, who actively promote inoculation programs using vaccines.