

Friday, 28 September 2012 [Rev. 7 Nov 2012^b]

Introduction

Following this introduction page is this reviewer's partial analysis of a World Health Organization (WHO) report titled, "**Global Advisory Committee on Vaccine Safety, June 2012**". This reviewer downloaded this article on August 31, 2012 as a part of a "pdf" file containing the *Weekly Epidemiological Record (WER)*, *WER* 2012 July 27; 87(30): 281-287, from: <http://www.who.int/wer/2012/wer8730/en/index.html>.

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This analysis, titled "**Draft Review of Thimerosal Issues in: A report by WHO's 'Global Advisory Committee on Vaccine Safety, June 2012 [Eng]'**", begins on the next page.

Introductory Remarks

First, to simplify this analysis, each portion of the article being reviewed is first quoted in its original fonts.

Further, when some specific sentence, clause, phrase, or word is being addressed within the review, it is quoted in an *italicized "Times New Roman"* font.

Second, this reviewer's assessments are written in a "Franklin Gothic" font, follow each quoted portion of the article, and are indented to clearly separate the review remarks from the preceding portion of the document that is being addressed.

Third, when other sources are quoted or referenced, the text 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, please submit that information to this reviewer so that he can improve his understanding of factual reality and, where appropriate, revise his views and this analysis.

Respectfully,

<s>

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[a] To qualify as an independent document, the study should be published by researchers who have no direct or indirect 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 directly or indirectly, actively promote vaccines, the development of vaccines, and/or inoculation programs using vaccines.

[b] Footnote "27" contains revisions in red to correct two typographical errors.

Draft Review of Thimerosal Issues in: A report by WHO's 'Global Advisory Committee on Vaccine Safety, June 2012'

[Review is based on the English text]

Review Topics

Topic Addressed	Page
The WHO GACVS Committee	1
Reviewer's Initial Commentary on Safety of Thimerosal (Thiomersal)	1
<u>No</u> Proof of Safety for Thiomersal (Thimerosal) in Vaccines Preserved with It	2
Reviewer's Concluding Remarks	15
Acknowledgements	16
About the Reviewer, Paul G. King, PhD	16

Draft Review of Thimerosal Issues in: A report by WHO's 'Global Advisory Committee on Vaccine Safety, June 2012'

[Review is based on the English text]

The WHO GACVS Committee

"Global Advisory Committee on Vaccine Safety, June 2012

The Global Advisory Committee on Vaccine Safety (GACVS), an expert clinical and scientific advisory body, was established by WHO to provide independent, scientifically rigorous advice on vaccine safety issues of potential global importance.¹

¹ See No. 41, 1999, pp. 337–338."

"GACVS held its 26th meeting in Geneva, Switzerland, on 6–7 June 2012.² The committee reviewed the following specific topics:

² GACVS invited additional experts to present and discuss evidence related to particular topics. These experts included persons affiliated with: Bambino Gesù Hospital, Rome, Italy; Center for Biologics Evaluation and Research (U.S. F.D.A), Rockville MD, USA; John Hopkins Bloomberg School of Public Health, Baltimore MD, USA; Program for Applied Technologies in Health, Seattle, USA; Rochester General Hospital Research Institute, Rochester NY, USA; Shantha Biotechnics Limited, Hyderabad, India; University of California, Los Angeles CA, USA; University of Washington, Seattle WA, USA; Uppsala Monitoring Centre, Uppsala, Sweden."

Given the make up of this committee, GACVS, is neither 'independent' nor is the advice that it is currently providing scientifically sound much less "*scientifically rigorous advice on vaccine safety issues ...*", as this article clearly proves.

Reviewer's Initial Commentary on Safety of Thimerosal (Thiomersal)

"□ the safety of thiomersal;"

Only scientifically sound and appropriate toxicity studies can establish the "safety" of any drug and, as per **Title 21 of the United States Code (U.S.C.) at Section 321(g)(1)** [21 U.S.C. Sec. 321(g)(1)] (emphasis added),

" 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). A food or dietary supplement for which a claim, subject to sections 343(r)(1)(B) and 343(r)(3) of this title or sections 343(r)(1)(B) and 343(r)(5)(D) of this title, is made in accordance with the requirements of section 343(r) of this title is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 343(r)(6) of this title is not a drug under clause (C) solely because the label or the labeling contains such a statement",

a component of a drug is a drug and prophylactic (preventive) vaccines, which are "intended for use in the ... prevention of disease in man or other animals" are regulated as biological drugs products.

If there were the requisite scientifically sound and appropriate toxicity studies for "*thiomersal*", then there would be a set of population appropriate "no observed adverse effect level" (NOAEL¹) values for injected "*thiomersal*" (Thimerosal)² in each vaccine matrix.

¹ <http://medical-dictionary.thefreedictionary.com/NOAEL> — NOAEL, n, 'no-observed-adverse-effect-level,' the maximum concentration of a substance that is found to have no adverse effects upon the test subject. Jonas: Mosby's Dictionary of Complementary and Alternative Medicine. (c) 2005, Elsevier.

² In the USA, trade names for chemical compounds are capitalized; in much of the rest of the English-speaking nations, trademarks need not be capitalized unless they are the first word in a sentence. Thus, whenever the US trade name of

Since there are no such published NOEL values for Thimerosal used as a preservative in vaccines, clearly the scientifically sound and appropriate safety studies for “thiomersal” (Thimerosal) used as a preservative in a vaccine formulation have not been conducted and published.

In the United States of America (USA), the manufacturer of a drug product, including a vaccine, has an absolute, non-dischargeable duty to prove the “safety” of each of their vaccines and other drug products to all of the applicable safety standards in^{3,4}.

Until the vaccine makers or other researchers conduct and publish all of the requisite toxicity studies, there can be and is no proof that the use of “thiomersal” as a preservative in vaccines is “safe”, much less, what is required in **Title 21 of the United States Code of Federal Regulations (C.F.R.)** at Section 610.15(a) [21 C.F.R. Sec. 610.15(a)] for compounds used as a preservative, “sufficiently nontoxic ...”, where “nontoxic” is the regulatory equivalent of “safe” (a level below the applicable NOEL values for the population segment(s) to which the vaccine may be administered); and “sufficiently nontoxic ...” requires that there be an appropriate “safety margin” for the level of the preservative in the biological drug product that is some factor less than the “nontoxic” level.

For bioaccumulative toxicants, like the end-point metabolites for mercury, which accumulate in the brain and have half-lives of on the order of 18-20 years in the brain’s tissues, the appropriate “safety margin” should be a factor of at least 10 and, preferably, a factor of 100 or more.

Finally, two very recent studies, which have been published electronically, have confirmed that giving Thimerosal-preserved inactivated-influenza vaccines to pregnant women is not safe⁵ and, confirming the exposure estimates reported in this paper, revealed the approximate degree of intoxication in the fetus after a pregnant woman is injected with a vaccine preserved with Thimerosal (“thiomersal”)⁶.

No Proof of Safety for Thiomersal (Thimerosal) in Vaccines Preserved with It

“Thiomersal in vaccines

In 1999, concerns were raised in the United States of America (USA) regarding exposure to mercury following immunization with thiomersal-containing vaccines.

This was based on the calculation that the cumulative amount of mercury in primary infant immunization schedules in the USA potentially exceeded the recommended threshold set by its Environmental Protection Agency for methyl mercury.”

Factually, the EPA did not set a “*recommended threshold ... for methyl mercury*”. The EPA estimated a reference dose (RfD) for ingested mercury from the methylmercury species in fish, where it was and is known, that only some fraction of these mercury species in eaten fish are absorbed into the human body⁷.

Based on that 2006 RfD estimate, the EPA reported that a safe level of ingested mercury for developing children might be 0.1 microgram of mercury exposure from dietary fish consumption per

Thimerosal or Merthiolate are used, this reviewer will always capitalize these terms and, to recognize the European view, this reviewer will not generally capitalize the European trade name for Thimerosal but rather will put it in quotes as “thiomersal”, whenever it is not capitalized.

³ For all drugs, see 21 U.S.C. § 351(a)(2)(b).

⁴ For biological drug products, including vaccines, see 42 U.S.C. § 262(a)(2)(C)(i)(I).

⁵ Goldman GS. Comparison of VAERS fetal-loss reports during three consecutive influenza seasons: Was there a synergistic fetal toxicity associated with the two-vaccine 2009/2010 season? [Hum Exp Toxicol 2012 Sep 27 0960327112455067](#).

⁶ Brown IA, Austin DW. Maternal transfer of mercury to the developing embryo/fetus: is there a safe level?. [Toxicol Environ Chem. 2012, DOI:10.1080/02772248.2012.724574](#).

⁷ EPA’s Roadmap for Mercury, Chapter “[I. Addressing Mercury Releases](#)”, EPA 2006 July – page “26” (emphasis added),

“**Clean Water Act requirements.** Under the Clean Water Act, states and authorized tribes must have water quality standards in place that define the designated uses and acceptable levels of pollutants for each water body under their jurisdiction. For mercury, EPA has published a national methylmercury ambient water quality criterion for protection of human health. This is a fish tissue concentration of 0.3 parts per million of methylmercury, based on EPA’s 2001 Reference Dose (RfD) for methylmercury and consumption rates.¹⁷ EPA’s RfD is an estimate, with uncertainty spanning perhaps an order of magnitude, of a daily oral exposure to the human population (including sensitive groups) that is likely to be without an appreciable risk of deleterious effects during a lifetime.¹⁸”

¹⁷ EPA, 2001b. Water Quality Criterion for the Protection of Human Health: Methylmercury. EPA-823-R01-001. Accessible at: www.epa.gov/waterscience/criteria/methylmercury/.

¹⁸ EPA, 2001a.”

kilogram of body weight per day with a built-in “uncertainty spanning perhaps an order of magnitude”.

Moreover, a recent study has clearly shown that the percentage absorbed from a fish meal depends upon how the fish is cooked and what foods and beverages are consumed with it – to the point that, *for fried fish eaten while drinking green tea or black tea*, virtually none of the mercury species in the fish were released into the gastric contents from whence, *after neutralization in the duodenum*, they could then be absorbed into the body⁸.

This finding not only makes the EPA value more uncertain but also, because the dose was based on extrapolations from estimated fish consumption and non-speciated total-hair-mercury levels, probably makes it an order of magnitude higher than it should be.

Ignoring the fact that the endpoint metabolites from organic mercury exposures bioaccumulate in the brain, based on the EPA’s 2006 position (see footnote “7”), the EPA’s uncertainty in the values proposed, and the recently published variable release effects of the temperature of cooking and the foods and beverages consumed while eating fish (see footnote “8”), *at a minimum*, the EPA estimate for American children’s tolerable level for the daily ingestion (consumption) of dietary organic mercury should be revised to “< 0.01 µg of organic mercury per kilogram of body mass per day”.

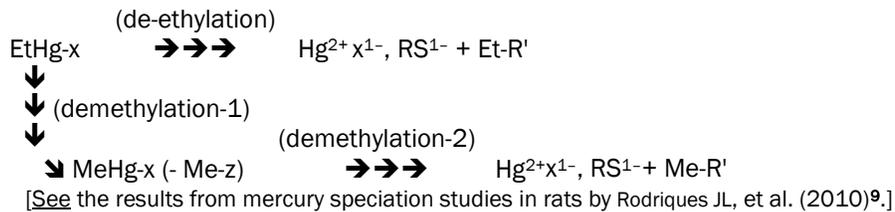
However, because the gastrointestinal system also has heavy-metal sequestering capabilities, the ingestion value set by the U.S. EPA is not an appropriate limit for the Thimerosal in an injected Thimerosal-preserved vaccine, which obviously bypasses the gastrointestinal system.

“ Hence, the policy decision in the USA to use only vaccines without thiomersal was based on a precautionary principle founded on the presumption of equal pharmacokinetics of ethyl mercury and methyl mercury, despite the fact that thiomersal contains only ethyl mercury.”

First, it is not what “*thiomersal contains*” but rather the metabolites into which “*thiomersal*” is converted and the pathways that generate these metabolites which matter.

Based on these recent speciation studies, it is clear that, after initial solvolytic breakdown in the body into ethylmercury chloride and ethylmercury hydroxide and sodium thiosalicylate, the resultant mercury compounds are dealkylated in the tissues into “tissue-retained” inorganic mercury by pathways that include partial conversion into the corresponding methylmercury compounds (methylmercury chloride and methylmercury hydroxide) that are then further demethylated into the “tissue retained” inorganic mercury” species found to be retained in the brains and kidneys of Macaque monkeys injected with Thimerosal (“thiomersal”) – though the precise pathways and mechanisms have not been completely delineated.

A generalized depiction of the preceding degradation realities is shown below



Second, GACVS is providing misleading information because comparative toxicity studies conducted in the former Union of Soviet Socialist Republics (USSR) in conjunction with occupational exposures to simple ethylmercury ‘salts’ (e.g., chloride, hydroxide, and phosphate) clearly showed, *at levels below those which produced acute mercury-poisoning effects* (at chronic-exposure levels) that the ethylmercury compounds comparatively were slightly more toxic than the comparable methylmercury compounds studied¹⁰.

⁸ Ouédraogo O, Amyot M. [Effects of various cooking methods and food components on bioaccessibility of mercury from fish](#). *Environ Res* 2011 Nov; 111(8):1064-1069.

⁹ Rodriques JL, Serpeloni JM, Batista BL, Souza S, Barbarosa Jr F. Identification and distribution of mercury species in rat tissues following administration of Thimerosal or methyl mercury [chloride]. *Arch Toxicol* 2010; 84: 891-896.

¹⁰ See translation of monograph, **Chronic Effects of Mercury on Organisms** by IM Trakhtenberg (1969) available in 1974 as National Institutes of Health (NIH) publication number 74-473, 206 pages – updated publication ID (2002): 101-562-749. For example, CHAPTER XIII MORPHOLOGICAL CHANGES IN ORGANS AND TISSUES AFFECTED BY MERCURY, pages 136-

Further, other studies have established how toxic the ethylmercury compounds are¹¹, 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 rat¹²

In addition, case studies followed subjects who were the victims of ‘accidental’ human ingestion of both methylmercury compounds and ethylmercury compounds from eating bread made from wheat seeds treated with fungicidal coatings containing these organic mercury compounds.

Initially, those who consumed these alkyl-mercury-salt-contaminated breads experienced no harm.

This was the case because: **a)** the level of the organic mercury fungicides was relatively low in the bread; **b)** the methyl- and ethyl- mercury compounds released when the bread was eaten had to accumulate in the tissues for some time before any mercury-poisoning symptoms were observed; and **c)** the effects observed were, as would be expected, highly variable¹³.

“ Between 2002 and 2008, GACVS reviewed several pharmacokinetic and epidemiological studies concerning thiomersal. Pharmacokinetic data in human infants, including premature and low birth-weight infants, established that the half-life of ethyl mercury” [in the blood] “is 3–7 days, and that ethyl mercury is efficiently excreted in the stools and does not accumulate over the long-term in blood, since” [blood] “levels returned to baseline within 30 days of vaccination.”

Here, the statements made about the disposition of the mercury from the “ethyl mercury” species generated initially after Thimerosal (“*thiomersal*”) is injected into humans matches the experience seen in radiolabeled (²⁰³Hg) ethyl mercury compounds in Macaque monkeys conducted by Takahashi T, et al. (1971)¹⁴.

Moreover, if the apparent demethylation degradation pathway observed in the rats by Rodriques JL, et al. (2010) also occurs, *as would be predicted*, in humans, the majority of the “methylmercury” species also observed in the blood samples from certain infants¹⁵ probably came from the degradation of the initial ethylmercury species.

Since the babies’ mothers were reported to neither be fish eaters nor have mercury-amalgam dental fillings, the “methylmercury” species found in some of the human infants’ blood samples probably did not come from some “unknown” alternate source, as Pichichero ME, et al. (2008)¹⁶ speculated in 2008, but rather came from the body’s metabolism of the Thimerosal in the Thimerosal-preserved vaccines those infants had been given.

However, not one of the studies of which this reviewer is aware in the period from 2002 through 2012 provides any quantitative mass-balance data to establish that the injected ‘mercury’ is rapidly eliminated in the feces of babies administered the “*thiomersal*”-preserved vaccines.

In addition, the studies by Takeda Y, et al. (1968)¹⁷ in rats do not support either rapid or complete

146 especially, Figures 55-57 (pages 144-145) showing poisoning effects of inhaled ethylmercury chloride and ethylmercury phosphate in guinea pigs and rabbits, respectively.

- 11 Kravchenko AT, Dzaqurov SG, Chervonskaia GP. [Evaluation of the toxic action of prophylactic 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 continuous cell line.] *Zh Mikrobiol Epidemiol Immunobiol*. 1983; (3): 87-92. [Article in Russian] – from English abstract, "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".
- 12 Goncharuk GA. Experimental investigation of the effect of organomercury pesticides on generative functions and on progeny. *Hyg Sanit*. 1971; **36**: 40-43.
- 13 Jalili MA, Abbasi AH. [Poisoning by Ethyl Mercury Toluene Sulphonamide](#). *Brit J Industr Med*. 1961; **18**(4): 303-308.
- 14 Takahashi T, Kimura T, Sato Y, Shiraki H, Ukita T. Time-dependent Distribution of [²⁰³Hg]-Mercury Compounds in Rat and Monkey as Studied by Whole Body Autoradiography. *J Hygenic Chem (Japan)* 1971; **17**(2): 93-107.
- 15 Such methylmercury species were found in a study of the blood drawn from infants shortly after they were inoculated with Thimerosal-preserved vaccines. Dr. Pichichero was the lead researcher and lead author in this study (see footnote “16”).
- 16 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.
- 17 Takeda Y, Kunugi T, Hoshino O, et al. Distribution of inorganic, aryl, and alkyl mercury compounds in rats. [Toxicol Appl Pharmacol](#) 1968; **13**: 156-164.

elimination via the fecal route of radiolabeled [²⁰³Hg] mercury species from the ²⁰³Hg-labeled ethylmercury compounds administered to the rats.

Further, GACVS assertion that “*that ethyl mercury is efficiently excreted in the stools*” is at odds with the Japanese radiolabeled (²⁰³Hg) mercury studies by Takahashi T, et al. (1971) [see footnote “14”], which show that, after a single ethylmercury chloride dose,

- ◆ Most of the mercury in the dose administered was not rapidly excreted in either the feces or the urine of the monkeys studied though it rapidly left the blood and
- ◆ The mercury was accumulating in the brain and the kidneys of the monkeys studied to the point that even the concentration in the monkey brain tissues was higher on the eighth day after dosing than the initial specific dose (0.8 micrograms of mercury per gram of animal body weight) administered to the monkeys (see reconstructed Table I below).

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

General Tissues	µgHg/g after ^[1]		Portion of brain	µgHg/g after ^[1]		
	60 min	8 day		60 min	8 day	
Kidney	6.73	8.60	Cerebellum	0.214	1.22	
Liver	6.50	3.04	frontal lobe	0.170	1.39	
Lung	5.10	0.44	Cerebral Cortex	parietal lobe	0.176	1.47
Myocardium	4.62	0.81	occipital lobe	0.213	1.68	
Arteries	3.36	0.28	frontal lobe	0.064	1.16	
Intestinal wall	1.28	0.77	Cerebral white matter	parietal lobe	0.067	1.14
Muscle	1.05	0.41	occipital lobe	0.068	1.10	
Tongue	0.94	0.62	Midbrain	0.188	1.24	
Testis	0.37	0.07	Corpus callosum	0.047	0.96	

^[1] **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 ²⁰³Hg—EtHgCl (800 µgHg/kg)”

Since the level of mercury in the monkey brain areas was accumulating from near zero “0” initially to “0.047 – 0.214” µg of Hg/gram of various brain tissues at 60 minutes (0.04167 day) and to “0.96 – 1.68” µg of Hg/gram of various brain tissues at 8 days, clearly the half-life of “inorganic” mercury in the brains of the monkey was certainly much greater than the apparently still accumulating mercury values found in the monkey’s brain at 8 days after dosing and probably greater than 4 months, as Burbacher TM, et al. (2005)¹⁸ reported.

Given the results for the radiolabeled mercury found in the brain and other tissues from single-dosed monkeys at 60 minutes and 8 days, radiolabeled mercury rapidly accumulated in the monkey’s kidneys and more slowly accumulated in the monkey’s brain.

However, because the level in the brain at 8 days exceeded the dosing level by 20% (“Corpus callosum”) to 110% (“occipital lobe” of the “Cerebral Cortex”), it is obvious that the half-life for clearance of the mercury from the brain exceeds 8 days, which invalidates GACVS’ reliance on the blood data to establish clearance of the injected mercury from the bodies of those inoculated with Thimerosal-preserved vaccines (containing nominally 12.5 or 25 µg of mercury from Thimerosal [“*thiomersal*”] per dose)

Based on the results reported for adults by Sugita M (1978)¹⁹, the half-life for the “inorganic mercury” retained in the brain cells of developing humans is probably greater than the 18 – 20 years estimated for the developed (adult) human brain.

Since the information on the bioaccumulation of mercury in the brains of the monkeys and the recent speciation of the mercury compounds in the blood and various tissues of rats was provided on 6 June 2012 to GACVS (gacvs@who.int), the World Health Organization (WHO) designated contact person, “ANNOVI Vera Christiane” (annovic@who.int), for issues dealing with Thimerosal in vaccines,

¹⁸ Burbacher TM, Shen DD, Liberato N, Grant KS, Cernichiari E, Clarkson T. [Comparison of blood and brain mercury levels in infant monkeys exposed to methylmercury or vaccines containing Thimerosal](#). *Environ Health Persp* 2005; **113**(8): 1015-1021.

¹⁹ 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 Dr. Michael E. Pichichero (Michael.pichichero@urmc.rochester.edu), a key presenter at this GACVS meeting, as a formal submission titled, "Review of 'Report to WHO: No New Concerns About Thimerosal'", before its meeting on 6–7 June 2012 ended, GACVS has no valid excuse for failing to consider this substantiated information that, at a minimum, invalidates the claim that mercury "*clears the body*" for the mercury from injected Thimerosal ("*thiomersal*").

“ At the June 2012 meeting, GACVS reviewed the most recently available information concerning the safety of thiomersal since it last reviewed this topic in 2008. A comprehensive review identified 28 publications that addressed mercury blood levels in the short and long term following vaccine administration, and epidemiological studies that examined the relation between thiomersal receipt and several health outcomes.”

First, research studies have shown retention of mercury species in the brain of adult [Takahashi T, et al. (1971)] and developing monkeys [Burbacher TM, et al. (2005)]; in rats [Takeda Y, et al. (1968), Takahashi T, et al. (1971), and Rodriques JL, et al. (2010)]; and in adult humans [Sugita M (1978)] for times significantly longer than the half-lives of the mercury species in the blood.

How, then, how can any scientific review:

- ◆ Only consider the half-life of the mercury species in human blood with no proof that the dose administered clears the developing human body as rapidly as it clears the blood and
- ◆ Ignore the body of evidence in monkey and rat studies that show bioaccumulating brain and kidney levels of mercury species after an injected dose of an ethylmercury compound?

Further, since only toxicity studies, and not epidemiological studies or, *for that matter*, clinical trials, can prove the "*safety of thiomersal*" (see, for example, a 1998 point paper addressing the need for reproductive toxicity studies for vaccines intended for pregnant women²⁰), why did GACVS waste

²⁰ Dr. Marion F. Gruber, DVRPA/OVRR, CBER, FDA, DHHS. MEMORANDUM: POINT PAPER "PRECLINICAL REPRODUCTIVE TOXICITY STUDIES FOR VACCINES", dated September 17, 1998, , text from the bottom of Point Paper's "page 2" through Point Paper's "page 4" (emphasis added):

"Preclinical versus clinical experience with vaccines:

Clinical data that may have been obtained from a small number of pregnant women enrolled in non-IND studies immunized with an investigational vaccine do not replace the need for comprehensive reproductive toxicity studies.

However, clinical experience derived from immunization of pregnant women may be helpful in the evaluation of the potential for any adverse outcome on the viability and development of offspring. Such information may also aid in the design/monitoring of appropriate preclinical studies.

Design of reproductive toxicity studies

Males

The potential adverse effects on male fertility should be assessed if the vaccine indication includes the male population. This is particularly important for products that are given to military forces, e.g., the Anthrax and Botulinum toxoid vaccine. However, additional discussion will be required regarding the details of the types of studies needed for these products. The ICH S5B document may serve as guidance in the design of these studies (Reproductive Toxicology: Male fertility studies, April 5, 1996, FR 15360, Vol.61, No. 67)

Females

While the type of study performed depends on the clinical indication and the product, in general, relevant information can be obtained by conducting Segment II teratology studies and/or studies designed following stages C - E of the ICH guidance document entitled "Detection of Toxicity to Reproduction for Medicinal Products" (September 22, 1994, FR 48746, Vol. 59, No. 183)

It is important that a postpartum follow-up period be included in the design of the study, in order to evaluate the active immune response in the offspring following vaccination of pregnant females.

The reproductive toxicity study should be designed to include:

- 1) the detection of antibody production in the pregnant animal;
- 2) the feasibility of antibody transfer from the pregnant female to the fetus through antibody measurements in the newborn.

General Considerations

All available clinical experiences in pregnant females should be considered for any potential application to the design of reproductive toxicity studies in animals.

All data generated from prior acute or repeat dose preclinical toxicity studies should be reviewed for their possible contribution to the interpretation of any adverse developmental effects that appear in the reproductive toxicology studies.

Reproductive toxicity studies should include a dose response component in order to assess 1) the ability of a certain dose of vaccine to elicit an antibody response and 2) the effect(s) that a particular dose has on the dam and on the conceptus.

The immunization interval and frequency of immunization(s) in a reproductive toxicity study should be based on the clinically proposed immunization interval and its timing, i.e., use of the vaccine at pre-conception or during the 1st, 2nd and/or 3rd trimester.

Reproductive toxicity studies for vaccines similar in structure and/or activity to other compounds:

Although the reproductive toxicity potential of a "prototype" vaccine may have been assessed and the similarity between the "prototype" vaccine and a new investigational vaccine(s) may have been established in terms of the manufacturing process, product characterization and clinical safety, additional reproductive toxicity studies using the final clinical vaccine formulation may be necessary (e.g., 9 versus 11-valent pneumococcal conjugate vaccine;

time reviewing studies that cannot prove safety, unless GACVS wanted to continue misleading the public about the studies needed to prove safety?

“Three ecological studies suggesting an association between thiomersal and neurodevelopmental disorders were found to be fraught with methodological flaws.”

Where is GACVS’ proof that the validity of this association is “*fraught with methodological flaws*”?

Since each of these unidentified “*ecological studies*” were apparently published in a peer-reviewed journal, what do the GACVS committee members know about the proper design of statistical population studies that the multiple peer reviewers of each of these three unidentified articles do not?

Why, except to keep the reader from reviewing them, were the studies in question not even identified in the footnotes as were the references for the two (2) aluminum-adjuvant studies with which GACVS also has a problem?

Or, is it that the unsubstantiated claim, “*fraught with methodological flaws*”, is simply GACVS’ way of dismissing those published studies that find statistically significant and plausible associations that are ‘inconvenient’?

Absent any evidence to support its claims, this reviewer must conclude that GACVS’ assessment of these three unidentified papers is simply a dismissive falsehood.

“In addition, the continuous increase in the number of cases of autism diagnosed in the USA despite removal of thiomersal from most vaccines strongly argues against a causal association (fulfilling the exposure and removal criteria).”

Here, GACVS simply presents a false argument.

First, this argument is false because, for all of the disjointed surveys of 8-year-old children on which the U.S. estimates for the rates of autism spectrum disorders are based (including the survey reported in 2012), the children were born before 2002, the first year that some small, but significant, percentage American children across the USA might have received reduced-Thimerosal early childhood vaccines, which were then slowly²¹ replacing the Thimerosal-preserved stocks as the preserved vaccines were used up.

Further, some of those Thimerosal-preserved doses were used up in the early childhood vaccinations given to the cohort of children born in 1999 and 2000 who were 8 years of age in 2008 when the last survey’s assessors were performing their surveys – even though their survey assessments were reported in 2012.

In addition, in April of 2002²², the U.S. Centers for disease Control and Prevention (U.S. CDC) began publishing a recommendation that all infants 6 months to 23 months of age should be given a flu shot, “when feasible”, at a time when all the licensed inactivated-influenza vaccines for the 2001-

multivalent versus monovalent GBS vaccine). [Note that, in CDER, reproductive toxicology studies are usually performed for every new “molecular entity”.]

Reproductive toxicity studies should be performed for all vaccines that belong to a similar class (e.g., polysaccharide vaccines), but which contain components derived from different organisms, or where different manufacture and/or purification procedures are employed.

Use of mercury containing preservatives in vaccines intended for maternal immunization:

The FDA Modernization Act (FDAMA) of 1997, Section 413 (c) (2), States that ‘... regulations shall be designed to protect the health of children and other sensitive populations from adverse effects resulting from exposure to, or ingestion or inhalation of] mercury.’

For investigational vaccines indicated for maternal immunization, the use of single dose vials should be required to avoid the need of preservative in multi dose vials as required by the Code of Federal Regulations (CFR). Of concern here is the potential neurotoxic effect of mercury especially when considering cumulative doses of this component early in infancy. All mercury-containing vaccine formulations should be evaluated in appropriate preclinical reproductive toxicology studies that include the assessment of postnatal behavioral and developmental endpoints (This topic is being addressed by the FDA-wide working group on mercury-containing drugs).

CBER/DVRPA:preparedbyMGruber(DVRPA) :8/17/98”

- 21 Within-date multi-dose vials of some of the Thimerosal-preserved early childhood vaccines were still on the market in the USA until sometime in 2005. In addition, for some of the less-frequently used vaccines, like the DT vaccine used in place of the DTP vaccine when the children were found to be ‘allergic’ to the ‘pertussis’ component, were marketed into the late 2000s.
- 22 Bridges CB, Fukuda K, Uyeki TM, Cox NJ, Singleton JA. Prevention and Control of Influenza Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 2002 Apr 12; **51**(RR03): 1-31, with underlining added for emphasis, “The 2002 recommendations include five principal changes or updates, as follows: ..., influenza vaccination of healthy children aged 6–23 months is encouraged when feasible. ...”

2002 flu season were Thimerosal- preserved – a recommendation which actually increased the maximum dose of mercury that some children born in late 2000 might have received.

Moreover, without proof of reproductive safety, in April of 2002, the U.S. CDC reiterated its proof-of-safety-less 1997 recommendation that pregnant women in the second and third trimesters should be given a flu shot (see footnote “22”) – again when all the then-licensed flu vaccines were Thimerosal-preserved.

This recommendation ensured that more children would be exposed to mercury at a time, before birth, where the adverse effects of the dose could be magnified but not seen and, *given the lag between mercury intoxication and the onset of significant symptoms (identified in non-acute human exposures to ethylmercury-based seed coatings)*, would not be observable until some time after the child was born.

Since 2002, the U.S. CDC has further increased the possible mercury exposure by:

- a. Removing the first-trimester contraindication for giving flu shots;
- b. Broadening the dosing age range for annual flu shots for humans (until it now spans the period from 6 months of age to death [cradle to grave]);
- c. Increasing the number of doses (by calling for the child to get 2 doses initially instead of 1 dose and
- d. Most recently, suggesting that any child that missed the “pandemic” 2009-A-H1N1 vaccine should get one extra dose of the 2012-2013 flu vaccines.

In 2009, the U.S. CDC also recommended the “pandemic flu shot” which added another 2 doses for the younger children and one dose for all pregnant women and children over 8 years of age.

Making things ‘all the better’, though the supply of influenza vaccine doses in the USA has expanded from less than 40 million doses in 2002 to more than 130 million doses in the 2011-2012 flu season, more than 50% of the available doses are still Thimerosal-preserved doses.

Thus, the supply of Thimerosal-preserved doses is more than 60% higher in the 2011-2012 flu season than it was in the 2002-2003 flu season – so much for the empty promise to remove Thimerosal from vaccines given to children as soon as possible.

For American children who only get the recommended Thimerosal-preserved vaccine doses, the total maximum dose of mercury from the Thimerosal-preserved flu shots to which children under 19 years of age can now be exposed from the flu shot alone is currently about twice the level of exposure that children born in 1999/2000 timeframe would have received under the 1999/2000 vaccination recommendations²³.

Thus, not only has “thiomersal” not been removed from all of the vaccines recommended for children but also the CDC, the FDA, and the flu-vaccine manufacturers have colluded to ensure that the maximum total exposure to Thimerosal from vaccines has not dropped.

Consequently, GACVS’ assertion, “*despite removal of thiomersal from most vaccines*”, is a duplicitous claim, which implies that it is only the number of vaccines that contained “*thiomersal*” which determines the overall mercury exposure that a developing child receives.

However, the truth is that the degree of vaccine-mercury poisoning in a given child depends on:

- The child’s susceptibility to mercury intoxication at the time each injected dose of a vaccine containing a preservative level of sodium ethylmercurithiosalicylate or other mercury compound is given;
- The specific toxicities of the form of mercury administered and its breakdown products;
- The magnitude of the dose over the safe level for that child;
- The timing of the “toxic” doses administered;
- The child’s existing mercury body burden;
- Background mercury exposures from air, water and food; and
- The number and frequency of the “toxic” doses that are given.

All that the CDC, the FDA, and the vaccine makers have done is colluded to fold the preservative-

²³ [The ‘No Thimerosal-Preserved Vaccines’ Lie, 12 August 2009, 9 pages.](#)

level doses (formerly contained in the DTaP, DT, TT, Td, Hib, and Hep B vaccines given to children from birth to, with decreasing frequency, age 18 years) into the Thimerosal-preserved flu shot, now given from before birth, at 6 and 7 months of age, and annually thereafter with one or two doses annually plus, an additional one or two “pandemic” doses from time to time.

Thus, “*thiomersal*” has not been removed from all of the vaccines routinely given to “children” in the USA from before birth to 18 years of age.

Currently, by the time they are adults, the maximum total doses of nominally “25 µg” of mercury from Thimerosal that children born in late 2000 could receive from the Thimerosal-preserved flu shots alone is 19 – 21 such doses of mercury.

Presuming the individual DTaP or DT, Hib and Hep B vaccines given to these children were also Thimerosal preserved, healthy children born in 1999/2000 who followed the 1999/2000-CDC-recommended early childhood vaccination schedule would have also received about 8.5 more nominal “25 µg” doses of mercury (4 from DTaP, 3 from Hib and 1.5 mercury from 3 doses of the hepatitis B vaccines) from their early childhood vaccinations.

As a result, by the time they reach adulthood, these healthy children following the 1999/2000 dosing schedule from birth to 2 years of age and then being given Thimerosal-preserved flu shots from 2002 onwards could receive a total maximum of 27.5-29.5, nominal “25 µg”-mercury doses²⁴.

Thus, by the time they reach adulthood in 2018/2019, the maximum nominal cumulative mercury dose from Thimerosal-preserved flu shots alone could be roughly 1.8 to 2.2 times the cumulative dose from the 1999/2000 routine vaccination schedule for healthy children when the only vaccines delivering the preservative-level doses of mercury in the USA were the then-Thimerosal-preserved DTaP/DT/Td/TT, Hib and Hepatitis B vaccines (about 9.5-10.5, “25 µg” doses).

Finally, unless Thimerosal-preserved flu shots are discontinued, by the time they are adults, the overall maximum cumulative exposure mercury dose from Thimerosal-preserved vaccines for the children born in 1999/2000 could be 2.6 to 3.1 times the mercury exposure they would have received under the 1999/2000 recommended routine vaccination schedule for healthy children.

Of course, those who are insiders and the well-informed public who demand and get the no-Thimerosal flu shots for their children as well as those who faithfully refuse flu shots will have very little risk of a vaccine-mercury-intoxication problem.

However, less than half of the people who get the annual flu vaccines will be able to get a no-Thimerosal inactivated-influenza vaccine with some having to “settle” for the easily spread, infectious no-Thimerosal live-virus nasal spray, some getting a reduced-Thimerosal flu shot, and most flu-shot-vaccinated children will still get a Thimerosal-preserved flu shot.

Moreover, *under the current scenario*, where the total doses of Thimerosal-preserved flu shots made annually is certainly not decreasing, what is apparently actually happening is that the severity of the diagnoses in those with an autism spectrum disorder diagnosis may be decreasing but the overall incidence level for those born in 1999/2000 is probably closer to or greater than 1 in 45 than it is to the CDC’s most recent, highly uncertain guesstimate of “1 in 88” for 8-year olds diagnosed with an autism spectrum disorder in the USA.

Finally, as far as this reviewer can ascertain, the reproductive toxicity studies required to prove that it is truly safe to give a Thimerosal-preserved flu shot to pregnant women (see footnote “20”) have not been conducted.

“All other studies reviewed, which were conducted with more robust epidemiological designs and in different countries, failed to identify any association with neurodevelopmental disorders.”

Since epidemiological studies cannot prove safety, why is GACVS bothering to discuss them in the context of safety?

²⁴ Shuchat A. ‘Vaccine Management. U.S. National Vaccination Advisory Committee’ presentation 2012 June 6: pages 1 – 32, last visited on 29 August 2012, where, on page 16, the number of flu shot doses is listed as “20” in the table from birth to 18 years but neither the pre-birth dose given to the mother nor the extra doses from the pandemic influenza vaccine are reported. Because the first influenza-vaccine doses at “6” and “7” and “18” and “30” months are half-doses but this reference did not count the pre-birth dose nor the up to 2 full doses of the pandemic influenza vaccines, the corrected number is a range of 19 – 21 doses of mercury from a Thimerosal-preserved influenza vaccines.

Do its members really think that they can continue to talk about non-relevant studies and not demand that the vaccine makers conduct the required scientifically sound and appropriate toxicity studies?

Does GACVS really think that this reviewer is the only person who notices that there are no FDA-recognized published NOAEL values for injected Thimerosal, when, for example, several are required for a Thimerosal-preserved flu shot to legally be given to everyone annually from before birth until the end of their lives?

Where are the required NOAELs?

In an attempt to provide rational estimates for the missing NOAELs, this reviewer has published two sets of values; the first are estimated NOAELs for injected Thimerosal based on an LOAEL (lowest observed adverse effect level) value derived from a chronic toxicity study that injected varying levels of a solution of Thimerosal into laboratory rats in the test group²⁵.

Based on the LOAEL reported, the estimated NOAELs are:

- a. NOAEL mercury from injected Thimerosal, developing child = < 0.005 µg of mercury from Thimerosal per kilogram of body weight per day [on any given day because Thimerosal's mercury is a bioaccumulative toxicant], and
- b. NOAEL mercury from injected Thimerosal, adult human = < 0.05 µg of mercury from Thimerosal per kilogram of body weight per day [on any given day because Thimerosal's mercury is a bioaccumulative toxicant].

The second set of NOAEL values is based on the extrapolation of the response below the LOAEL²⁶ and the estimated NOAEL values are expressed as:

- a. NOAEL mercury from injected Thimerosal, developing child = about 0.002 µg of mercury from Thimerosal per kilogram of body weight on any given day because Thimerosal's mercury is a bioaccumulative toxicant, and
- b. NOAEL mercury from injected Thimerosal, adult human = about 0.02 µg of mercury from Thimerosal per kilogram of body weight on any given day since Thimerosal's mercury is a bioaccumulative toxicant.

If GACVS has any more-valid NOAEL values for injected mercury from Thimerosal, this reviewer would appreciate it if GACVS would publish those values along with the data from which they were derived.

Until then, the NOAEL values published by this reviewer are the only sound basis for determining the level of mercury in a Thimerosal ("*thiomersal*")-containing vaccine that is safe.

Based on the preceding reality, then, for the typical nominal 25- or 50-ppm concentration of mercury from Thimerosal in a Thimerosal-preserved vaccine (delivering a 12.5 or 25 µg dose of Thimerosal-derived mercury), these levels of Thimerosal-derived mercury are not safe for a developing child unless the developing child weighs *significantly more than* 12.5/0.005 = 2500 kg (5512 pounds) for the lower dose or 5000 kg (11023 pounds) for the higher dose — weights well outside any possibility for humans.

On this basis, Thimerosal-preserved vaccines are clearly not safe²⁷.

“ Recently published studies confirm that in all populations studied, including pre-term and low birth-weight babies, the half-life of ethyl mercury in blood is between 3 and 7 days.”

Does GACVS really think that public will continue to be misled by its focus on the clearance of Thimerosal-derived mercury from the blood?

Because the estimated half-life for tissue-retained inorganic mercury species in the brain is longer

²⁵ [THE 'TRUTH' ABOUT THE TOXICITY OF THIMEROSAL, 12 August 2009, 6 pages.](#)

²⁶ [The 'Anything But Mercury' Realities, 14 May 2012, 10 pages.](#)

²⁷ In a now-sealed early 1970s memo found in Eli Lilly records, Lilly scientists reportedly told Eli Lilly management that a 0.0001 % level of Thimerosal (a 0.00005 % level of mercury from Thimerosal) in their Thimerosal-preserved vaccines dosed into children in 0.5-mL doses was not safe. Based on that now-unavailable document, Lilly scientists reported that the safe level of Thimerosal-derived mercury to inject into children was much less than (<<) 25.0 µg of mercury from Thimerosal.

than 120 days for Macaque monkeys [Burbacher TM, et al. (2005)] who may only live for 10 years and the human half-life in adult brain has been estimated as 18 – 20 years in the Japanese [Sugita (1978)], who have an average lifespan of roughly 80 years, at a minimum, GACVS needs to publish the vaccine maker's scientifically sound and appropriate primate toxicity studies that definitively:

- Show that the half-life for brain-tissue-retained inorganic mercury in developing children is much less than the half-life for adult humans and
- Reveal what are the scientifically sound and appropriate NOAEL values for injected mercury derived from Thimerosal-preserved vaccines injected into developing children.

Until then, GACVS needs to stop trying to create this misdirective 'smoke screen' based on its representations about blood-clearance studies that do not address either body-clearance or, more importantly, brain clearance, and are studies which cannot prove the safety of injected mercury from Thimerosal-preserved vaccines .

“A quantitative risk assessment model for cumulative toxicity of thiomersal in humans by US Federal Drug Administration (FDA) was also reviewed. This methodology is based on a pharmacokinetic model of ethyl mercury and provides a framework for interpreting studies in animals and humans that evaluate linkages among dose, blood and brain levels, and toxicity.”

Having dealt with responses from US FDA officials which do not even report the correct daily average dose for a given level of Thimerosal injected twice a week into rats in a chronic rat toxicity study, absent: **a)** the pharmacokinetic model, **b)** the pharmacokinetic data for the distribution of the Thimerosal-derived mercury and **c)** the speciation of the mercury-containing components in the brain and other tissues at multiple time points from the time of dose injection until more than 99% of the initial dose has been proven to have been excreted (in the hair, nails, sweat, feces, urine, and any other body secretion), this reviewer cannot speculate as to whether the model is appropriate.

Further, even with complete mass balance data for the disposition of the mercury in every tissue and the excreted materials from dosing until more than 99% of the mercury dosed has been excreted, pharmacokinetic models alone cannot be used to prove safety.

Only scientifically sound and appropriate toxicology studies can prove whether the amount of Thimerosal injected into a pregnant woman or developing child is safe for herself, her fetus or her developing child after he or she is born!

Again, why is GACVS trying to change the narrative from proof of safety (which requires toxicity studies) to pharmacokinetic studies that, were they done properly, can only prove redistribution, but cannot prove safety?

Please stop these diversionary tactics and, *for example*, show the public the scientifically sound and appropriate NOAEL values for Thimerosal-preserved inactivated-influenza vaccines injected into:

- a. The pregnant woman and entering her unborn child (including full reproductive toxicity studies for both the males and the females from birth through the end of their normal reproductive life as well as multigenerational reproductive toxicity-effect studies for the offspring of pregnant women given such vaccines),
- b. The developing child: **i)** before the liver bile system is fully functioning and **ii)** after the liver bile system is fully functioning,
- c. The prepubescent child,
- d. The adolescent,
- e. The young adult,
- f. The mature adult, and
- g. The elderly adult

for each of the Thimerosal-preserved flu vaccines that can be given to pregnant women and/or annually to humans from 6 months of age until death, using the Macaque monkey as the model for human response.

If GACVS cannot provide most of the required NOAEL values and the data that supports them to qualified independent scientists for review and confirmation, **then**, GACVS needs to demand that the use of Thimerosal-preserved flu vaccines must stop until there is scientifically sound proof that such

vaccines are safe^{28,29}.

“ Using this framework, the GACVS concluded that animal or human toxicity studies suggest that the levels of ethyl mercury attained in the blood and brain from cumulative doses of vaccines do not reach toxic levels, making biologically implausible any relation between thiomersal in vaccines and neurological toxicity.”

First, numerous studies using weight-corrected doses of Thimerosal-containing solutions injected into animals, including rats, golden hamsters, and Macaque monkeys at one to a few doses of vaccine-equivalent-amounts of Thimerosal have shown the significant neurotoxic effects exhibited by organic mercury compounds.

Further, in vitro studies have not only shown similar toxicities for Thimerosal solutions but also helped illuminate the mechanisms by which Thimerosal-containing solutions damage multiple systems in the human body.

Does GACVS really expect the reader to think that unsubstantiated conclusions based on some undisclosed artificial “*framework*” are valid and all of the experimental studies are invalid?

How arrogant GACVS must be to have no shame in telling us that we should disregard the ever-growing body of toxic and bioaccumulative effects of injected Thimerosal at vaccine levels and lower in a variety of animal models from snail neurons to macaque monkeys.

In addition, there is proof the ethylmercury compounds are bioaccumulative toxicants.

²⁸ Importantly, in 1998, the U.S. FDA banned the use of Thimerosal (“*thiomersal*”) as an ingredient in over-the-counter (O-T-C) topical antiseptics and vaginal contraceptives (see footnote “²⁹”) on the grounds that such products were neither safe nor effective.

Since these were applied topically and not injected and the maximum nominal level of Thimerosal in these O-T-C drug products (0.1%) was only 10 times the nominal maximum level in an FDA-approved Thimerosal-preserved vaccine (0.01%), how is it that one or two drops of such an antiseptic (about 0.05 to 0.1 mL), a typical dose for a small cut, of a 0.1% Thimerosal solution in alcohol (called a “Tincture of Merthiolate”) is not safe while 0.5-mL of a vaccine solution or suspension containing nominally 0.01% Thimerosal is safe?

In other words: How is 50 to 100 µg of Thimerosal in 0.05 to 0.1 milliliter of alcohol not safe to put on skin, but it is safe to inject nominally 50 µg of Thimerosal used as a preservative in a 0.5-milliliter dose of a vaccine?

²⁹ [21 C.F.R. Sec. 310.545 Drug products containing certain active ingredients offered over-the-counter \(OTC\) for certain uses.](#)

(a) A number of active ingredients have been present in OTC drug products for various uses, as described below. However, based on evidence currently available, there are inadequate data to establish general recognition of the safety and effectiveness of these ingredients for the specified uses:

...
(27) Topical antimicrobial drug products -- (i) First aid antiseptic drug products.

Ammoniated mercury
Calomel (mercurous chloride)
Merbromin (mercurochrome)
Mercurfenol chloride (ortho-chloromercuriphenol, ortho-hydroxyphenylmercuric chloride)
Mercuric chloride (bichloride of mercury, mercury chloride)
Mercuric oxide, yellow
Mercuric salicylate
Mercuric sulfide, red
Mercury
Mercury oleate
Mercury sulfide
Nitromersol
Para-chloromercuriphenol
Phenylmercuric nitrate
Thimerosal
Vitromersol
Zyloxin

(ii) Diaper rash drug products .

Para-chloromercuriphenol
Any other ingredient containing mercury

(28) Vaginal contraceptive drug products -- (i) Approved as of October 22, 1998.

Dodecaethylene glycol monolaurate (polyethylene glycol 600 monolaurate)
Laureth 10S
Methoxypolyoxyethyleneglycol 550 laurate
Phenylmercuric acetate
Phenylmercuric nitrate
Any other ingredient containing mercury

(ii) Approved as of November 5, 2002.

Octoxynol 9

This proof comes from the data obtained from case studies where humans ingested varying levels of ethylmercury-based fungicides used to treat wheat seed through the mistaken making of bread from the seed.

Many consumed the bread and, after some period of delay, some developed serious adverse neurological conditions or died from the ethylmercury-compound-derived mercury that accumulated in their brains and other tissues³⁰.

Hopefully, the reader will grasp the obvious, GACVS is simply being less than honest here in a misguided attempt to protect the use of a chemical, Thimerosal (sodium ethylmercurithiosalicylate), in vaccine formulations rather than protect the children who are injected with these Thimerosal-containing biological drug products.

Factually, no safe level has been established for human exposure to Thimerosal (“*thiomersal*”) either by injection or by ingestion.

GACVS, show us the NOAELs for injected Thimerosal (“*thiomersal*”) that prove the injected amount of Thimerosal-derived mercury in the highest allowable vaccine dose is safe!

“ Based on the current evidence, GACVS considers that no additional studies of the safety of thiomersal in vaccines are warranted and that available evidence strongly supports the safety of the use of thiomersal as a preservative for inactivated vaccines.”

Evidence – what evidence?

All GACVS has provided the reader is their biased views, and an undefined model and framework.

GACVS has provided no evidence that any significant percentage of the mercury in the injected Thimerosal in a Thimerosal-preserved vaccine dose leaves the human body in a short period or that none accumulates in the human brain.

In contrast, actual studies using Macaque monkeys and both radiolabeled [²⁰³Hg] ethylmercury compounds (ethylmercury chloride and ethylmercury phosphate) and Thimerosal have proven that the inorganic mercury that forms in the brains of these monkeys does not rapidly leave these animals’ brains.

What should the reader trust – the actual results of published peer-reviewed studies from scientists around the world or the feeble rhetoric and pontifications of the GACVS committee members reflected in this anecdotal report, which neither provides nor cites any scientific data to support any of its statements?

The bottom line is clear – GACVS knows:

1. There are virtually no safety studies for injected Thimerosal in vaccines and
2. If scientifically sound and appropriate safety (toxicity) studies were to be conducted, the resulting NOAEL values for injected Thimerosal would be well below the current “0.005% – 0.01%” Thimerosal levels in most Thimerosal-preserved vaccine formulations.

Since this report talks about, but provides no evidence for, Thimerosal’s safety when used as a preservative in vaccines, any prudent person should understand:

The use of Thimerosal as a preservative in vaccines is not safe, was never safe, and, for 6-plus decades, the manufacturers and distributors of Thimerosal-preserved vaccines and the agencies which regulate them have known that the Thimerosal-preserved vaccines are not safe.

To prove this reviewer is wrong, all GACVS needs to do is publish the vaccine maker’s toxicity-study data dating from the 1970s and the NOAELs derived from each study that prove that each Thimerosal-preserved vaccine is safe (nontoxic) and, based on the requirement set forth in 21 C.F.R § 610.15(a) for preservatives in biological drug products, “sufficiently nontoxic ...” (below the “nontoxic” level by some factor of from 10 to 100)^{31,32}.

³⁰ Jalili MA, Abbasi AH. [Poisoning by Ethylmercury Toluenesulphonanilide](#). *Br J Ind Med* 1961; **18**(4): 303-308.

³¹ Because the mercury derived from Thimerosal has been repeatedly proven to be a bioaccumulative toxicant in the brain and kidneys of animals exposed to it at levels near, at, or below the levels resulting from the injection of a single dose of a Thimerosal-preserved vaccine into a developing child, safety factors of 10 to 100.

“GACVS believes that consideration of additional evidence suggestive of the contrary should be based on studies using the same high standards of epidemiological and causal inference needed for scientific research.”

Here, GACVS is again attempting to substitute “*epidemiological and causal inference*” for what are truly required — scientifically sound and appropriate toxicity studies that, with some safety margin, prove that the level of Thimerosal in a dose of Thimerosal-preserved vaccine is safe to the standard “sufficiently nontoxic ...”³³, where the applicable NOAEL levels establish the “nontoxic” level for each of the population group(s) to which the vaccine is approved to be administered.

Until the requisite NOAELs are determined and published for level of injected Thimerosal in the Thimerosal-preserved vaccine, and the level of Thimerosal in that Thimerosal-preserved vaccine found to be lower than the least of the applicable NOAEL values by an appropriate factor (i.e., 10 to 100-fold lower than the lowest applicable published NOAEL), the reality is that the use of Thimerosal at a preservative level will not have been proven to be safe for that vaccine.

Finally, what “*GACVS believes*” should be ignored because scientific studies require that the valid scientifically sound proof of, in this instance, safety, or the lack thereof, which cannot be based simply on what any committee “*believes*”.

“Thiomersal allows millions of people worldwide to have access to life-saving vaccines and to date, no other safer and equally efficacious alternative has been identified for many vaccines.”

Here, GACVS closes by first attempting to make the implied argument that, even if “*thiomersal*” is not safe for use as a preservative in vaccines, its use must continue because removing it from vaccines will somehow prevent “*millions of people worldwide*” from accessing “*life-saving vaccines*”.

Further, *though GACVS has not addressed the issue*, even it is not an effective sterility-preserving agent for all infectious bacteria in the vaccine matrices for which it purportedly is used as this type of preservative, its use must continue.

Fortunately, the Japanese and others have successfully removed “*thiomersal*” from their Japanese Encephalitis vaccines.

Now, only the U.S.-FDA-licensed, “*thiomersal*”-preserved, multi-dose CDC-recommended formulas for the DTaP, DTwP, DT, Td, TT, Hib and Hepatitis B vaccines, which were distributed in the USA prior to 2005, are still being produced by the original manufacturer or a subsidiary thereof, or by another firm under a formulation license or sublicense, and distributed mostly in the developing countries.

³² If clearance were truly “rapid” as the GACVS claims, then, it would be easy to show this clearance by appropriately monitoring the amount of mercury excreted in the feces, urine, hair, nails and other excretions until 99% of the dose (which usually occurs at 6.6 times the nominal average half-life) has been excreted and analyzing the samples collected for the mercury species excreted and the total amount of mercury excreted at each time point. If the body half-life were similar to the blood half-life about which GACVS continually speaks, then the monitoring program for the mercury should collect more than 99% of the mercury dose in less than 60 days in a test using Macaque monkeys, which are known to mercury accumulation and excretion pattern that is similar to the pattern in humans.

For comparison, the level of the gadolinium-based contrast agent in the recently approved Bayer Gadovist 1.0®, gadobutrol-injection contrast agent, which can potentially release gadolinium, a potentially bioaccumulative dangerous heavy metal that can damage the kidneys and the muscles was shown to have a NOAEL injected gadobutrol, developing human based on studies in neonatal rats, which have kidneys that develop and function like human kidneys, that was 20 times higher than the recommended maximum exposure level for gadobutrol injection in the youngest child (2-year-olds) for which approval was being sought. [See: [Briefing Document for Gadobutrol Injection, NDA 201.277, Peripheral & Central Nervous System Drugs Advisory Committee, 21 January 2011](#), page 27 of 122 (emphasis added):

“Studies in neonatal rats

After a single i.v. injection to male and female neonatal rats on postnatal Day 4, Gadobutrol was well tolerated without signs of delayed treatment effects up to a high dose of 6.0 mmol/kg BW. For the rats given 6.0 mmol/kg BW and kept for recovery, these changes were either greatly reduced (vacuoles in kidneys) or absent (microglia cells) by Day 28 and were therefore not considered adverse. The NOAEL in this study was 2.0 mmol/kg BW, or 20 times the recommended clinical dose. The estimated clearance values in the neonates were 1.9 to 2.5 times lower than in the adult rats, reflecting the known immaturity of renal function in neonates. However, the increased exposure in neonates did not decrease the tolerability of Gadobutrol as compared to the adult animals”.

³³ See 21 C.F.R. § 610.15(a), which, in part, reads, “... 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 vaccines for the other highly contagious viral childhood diseases (i.e., measles, mumps, rubella, polio, rotavirus, and varicella [chickenpox]) are live-virus vaccines that, *in most countries*, require no preservative.

Thus, there is no need to remove “*thiomersal*” from such live-virus vaccines as it was, and is, not used in their manufacture.

In addition, since there are several FDA-approved no-Thimerosal vaccines for Hib and Hepatitis B as well as no-Thimerosal combination DTP-plus vaccines that contain these as a component, the companies who make these should be able to provide the needed vaccine doses.

Since only a few of the routinely recommended childhood vaccines use Thimerosal (“*thiomersal*”) as a preservative in their multi-dose formulations and several other vaccines³⁴ use an alternative preservative system for their multi-dose vaccine formulations, GACVS’ “*no other safer and equally efficacious alternative has been identified for many vaccines*” claims are, at best, an exaggeration.

Finally, if the World Health Organization (WHO) were to announce tomorrow that, starting in 2015,

- The only multi-dose preserved vaccines that would be acceptable for use in a WHO-acceptable mass vaccination program would be those that were not preserved with “*thiomersal*” and
- It would work with all of the currently WHO-acceptable suppliers of “*thiomersal*”-preserved vaccines to, as the U.S. FDA has done, expedite the approval of vaccines preserved with an alternative preservative,

this reviewer is certain that there would be no serious interruption in the supply of suitably preserved multi-dose formulations to the developing world although the supplier might change.

Reviewer’s Concluding Remarks

First, this reviewer would remind GACVS of one of Abraham Lincoln’s often-quoted observations,

“You may fool all the people some of the time, you can even fool some of the people all of the time, but you cannot fool all of the people all the time” – Abraham Lincoln (1809 – 1865)³⁵

and point out that, today, the vaccine apologists and acolytes have already been reduced to fooling “some of the people all of the time” with the number fooled dwindling in the USA as:

- More and more people realize that “what matters” is the total exposure to “*thiomersal*” (Thimerosal) (and not the number of vaccines that contain it), the recipient’s specific susceptibility to mercury intoxication, and the recipient’s total mercury body burden
- More evidence is uncovered that indicates that the U.S. CDC: **a)** colluded with others to publish papers that *falsely* claimed that the removal of “*thiomersal*” (Thimerosal) from vaccines caused the rate of autism to increase, when, in fact, after Thimerosal’s removal, the autism rate declined³⁶ and **b)** *falsely* claimed that there was no Thimerosal-dose-dependent causal risk connection between exposure and the subsequent risk of neurodevelopmental harm (and “lost” the datasets)³⁷ so no one could confirm the validity or non-validity of the CDC researchers’ published ‘findings’) [CDC’s own published 2003 study³⁸],

³⁴ Examples of vaccines that use alternative preservatives include, but are not limited to: **1)** Pfizer’s Prev(e)nar® and Prev(e)nar 13®, which uses 2-phenoxyethanol because the “*thiomersal*”-preserved formulations fail to meet the antimicrobial effectiveness requirements of the European Pharmacopeia; **2)** Sanofi Pasteur, SA’s IPOL®, inactivated polio vaccine, which also uses 2-phenoxyethanol because “*thiomersal*” degrades the inactivated polio virus; and both **3)** Sanofi Pasteur, SA’s Typhim Vi®, typhoid vi polysaccharide vaccine and **4)** Merck & Co, Inc’s Pneumovax 23®, pneumococcal polysaccharide vaccine, use phenol as a preservative.

³⁵ http://thinkexist.com/quotation/you_may_fool_all_the_people_some_of_the_time-you/145518.html

³⁶ http://dr-king.com/docs/20120331_FalsusInUnoFalsusInOmnibusAThimerosalpreservedVaccineConundrum_b.pdf

³⁷ See slide 77 in a 2005 presentation at <http://www.evidenceofharm.com/ppp/1-11.ppt>, (emphasis added).

“Federal Investigations

- The pro-mercury-poison (pro-Thimerosal) propaganda becomes ever more desperate, and
- The percentage of American children who will probably have at least one chronic lifetime illness continues to climb.

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About the Reviewer, Paul G. King, PhD

In addition to the general information available on his Internet web site, <http://www.dr-king.com/> (The Know Zone), Paul G. King, PhD Analytical Chemist, is the Science Advisor to, and current Secretary for, the Coalition for Mercury-Free Drugs (CoMeD, Inc., which is a 501(3)(c) not-for-profit corporation) that maintains 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 (DHHS) and the Commissioner of the FDA to comply with the statutes, laws (regulations) and policies that regulate the lawful conduct of the Secretary of the DHHS, the FDA commissioner and CDC and FDA official's. The second civil suit, 1:2009-cv-00015, is still being litigated.

Moreover, 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 and state regulations that are not in the public interest or appear to be at odds with the law, reviewed numerous documents, and written articles on a variety of vaccine-related and other issues.

Further, Dr. King has provided diverse groups with his analysis of various Congressional bills, resolutions and treaty documents as well as federal and state judicial proceedings.

In addition, he has been an author of several papers bearing on issues related to the toxicity of Thimerosal and other compounds and, if any, their connection to a range of 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; non-genetic childhood type 1 diabetes), or approaching (life-threatening peanut allergy) epidemic childhood levels in the USA.

Most recently, Dr. King was the co-author of a paper in the journal *Vaccine* with Dr. Gary S. Goldman³⁹.

■ HHS/OIG & CDC/OI: Special Agents investigating allegations that CDC officials blocked VSD access and lost, destroyed or did not properly maintain previously analyzed datasets (Verstraeten). A violation of Data Access Law and the Data Quality Act. ..."

38 Verstraeten T, Davis RL, DeStefano F, Lieu TA, Rhodes PH, Black SB, Shinefield H, Chen RT. [Safety of Thimerosal-Containing Vaccines: A Two-Phased Study of Computerized Health Maintenance Organization Databases](#). *Pediatrics* 2003 Nov 1; **112**(5): 1039-1048.

39 Goldman GS, King PG. [Review of the United States universal varicella vaccination program](#): Herpes zoster incidence rates, cost-effectiveness, and vaccine efficacy based primarily on the Antelope Valley Varicella Active Surveillance Project data. *Vaccine* 2012 May 31 online.