

Facility Automation Management Engineering Systems (*FAME Systems*)

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Wednesday, 19 September 2012 [Rev. 1; 28 Sep 2012]
[Rev. 2; 07 Nov 2012^b]

Introduction

Following this introduction page is this reviewer's analysis of a World Health Organization (WHO) report titled, "**Global Advisory Committee on Vaccine Safety, June 2012**". This reviewer originally 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: 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 "**33**" contains revisions in red to correct two typographical errors.

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

[Review is based on the English text]

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Draft Review of: 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 and the review thereof clearly establishes.

Report's Topics and Reviewer's Initial Commentary on Each Topic

Safety of Thiomersal (Thimerosal)

“□ 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,

Since there are no published recognized NOAELs, 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^{3,4}.

Until the vaccine makers 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 plain language 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 NOAEL 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 appropriate factor less than the “nontoxic” level.

For bioaccumulative toxins, 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.

The second paper⁶ revealed the approximate degree of intoxication in the fetus after a pregnant woman is injected with a vaccine preserved with Thimerosal (“*thiomersal*”) and confirmed the relative mercury exposure estimates reported in the paper cited in footnote “5”.

Safety of Aluminium (Aluminum) Adjuvants

“ the safety of aluminium adjuvants;”

See previous general comments for “*thiomersal*”, which also apply here with respect to the requirement for the applicable scientifically sound and appropriate NOAEL values for this class of toxicants.

Safety Profile of Influenza Vaccines During Pregnancy

“ the safety profile of influenza vaccines during pregnancy.”

Here, GACVS starts by substituting the term “*safety profile*” for what is required by science and, by the applicable U.S. statutes and laws: toxicological proof of safety.

The report does this because GACVS knows that the reproductive toxicity studies required to prove the safety of the use of Thimerosal-preserved inactivated-influenza vaccines in pregnant women have not been conducted.

That the U.S. Food and Drug Administration (FDA) recognizes that reproductive toxicity studies are required for vaccines given to pregnant women can be seen in a 1998 “points” document issued by the U.S. FDA’s Center for Biologics Evaluation and Research (see footnote “24”) citing the need for reproductive toxicity studies in males and females to prove safety regardless of the outcomes of any

trademarks need not be capitalized unless they are the first word in a sentence. Thus, whenever the US trade name of 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 not capitalize that trade name but rather will put it in parentheses as “thiomersal”.

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](#).

clinical trial (or, by inference, epidemiological studies) because no such studies can prove “safety” to the standard required by law!

The GACVS committee’s own words, used when discussing papers on “*Aluminum Adjuvants*”,
“*In general, ecological studies cannot be used to assert a causal association because they do not link exposure to outcome in individuals, and only make correlations of exposure and outcomes on population averages*”

also apply equally to all statistical population studies, including epidemiological studies, no matter what their design.

This is the case because all such can do is estimate the probability of any causal linkage at some level of confidence – scientifically, statistical studies cannot be used to prove safety or to prove that outcome “B” occurring after action “A” is confirmation that action “A” caused outcome “B”.

Safety of Inoculation with a Vaccine during Pregnancy and Lactation

“It also reviewed 3 general issues for vaccine pharmacovigilance:

safety of immunization during pregnancy and lactation;”

Absent the requisite scientifically sound and appropriate toxicity studies for each vaccine that prove the safety to both the mother and the child during pregnancy and lactation, which GACVS apparently does not have or does not offer to provide, there can be, and is, no “proof” that inoculation with any vaccine is safe during pregnancy or lactation.

Further, since, *in general*, the inoculation of a person with any vaccine does not provide lifetime or near-lifetime protection from the disease or diseases for which that vaccine is supposed to provide such protection, it is inappropriate to use the term “immunization”, which implies the provision of such extended protection.

This reviewer also finds that the use of terms, like “immunity”, “immunize”, and “immunization”, which might have seemed to be appropriate when scientists thought that a single dose of a vaccine could provide lifetime or near lifetime protection, should be stopped.

Today, the misuse of these terms should be stopped because both the scientific community and those who read the studies and increasingly hear about the need for “booster doses” or “additional doses” to prevent the “resurgence” of a disease understand that vaccines do not provide “lifetime” disease protection (“immunity”) but, at best, provided limited-duration protection to most of those who are multiply vaccinated.

Causality Assessment for Serious Adverse Events Following Inoculation

causality assessment for serious individual cases of adverse events following immunization (AEFI);”

First, GACVS should rename the AEFI acronym to stand for “*adverse events following*” inoculation and should immediately cease using any form of words like “immunization” and “immunize” when discussing the current prophylactic (preventive) vaccines.

GACVS should take this action because the current vaccines:

- ◆ Do not provide either lifetime or near lifetime protection from contracting a given disease to those inoculated with them,
- ◆ Do not provide this protection to all who are inoculated with them,
- ◆ Provide limited-spectrum protection which actually favors infection by other disease strains (e.g., the Meningococcal meningitis vaccines) and types (e.g., the haemophilis influenzae type b vaccines) and/or related diseases (e.g., the “pertussis” vaccines that have increased the incidence of cases of *Bordetella parapertussis* and *Bordetella holmesii*) to infect those who are inoculated with them),
- ◆ In some instances, only provide at best very short-term protection for limited periods of time to most of those inoculated with them (e.g., the influenza vaccine that are claimed to provide at most only annual protection),

- ◆ Are not in-use effective in preventing those who are inoculated with them and develop “sufficient” antibody titers (titres) that should provide protection from infection from contracting the disease (e.g., the influenza vaccines that, according to the U.S. CDC’s own studies have an in-use effectiveness of less than 50% ; in years that there is a ‘total strain mismatch’, provide near zero “0” protection from getting influenza; and, based on some recent studies in Canada⁷, including a Canadian ferret [animal model] study, and studies conducted elsewhere^{8,9}, may actually increase the inoculated person’s risk of getting influenza),
- ◆ Merely postpone the risk of contracting a disease to a time when having that disease causes much more harm to the persons who contract it then rather than during the “natural period” when, prior to the vaccine, most naturally contracted the disease and recovered with no serious long-term harm (e.g., mumps),
- ◆ Simply provide at best limited duration protection to those inoculated with them from getting the primary form of the disease while increasing the risk that those inoculated with these vaccines and the population as a whole will subsequently develop the secondary form of the disease (e.g., the varicella vaccines which only provide limited-duration protection from contracting chickenpox to about 75% of those inoculated with them but increase the risk of shingles in 100% of those inoculated with them as well as in the population that was not inoculated with them because they had already had chickenpox,
- ◆ In some cases, create disease carriers who both shed, and can continue to shed a disease-causing agent for an extended period of time after they are inoculated with certain vaccines (e.g., the viral shedders of the live oral polio and rotavirus vaccines, the viral shedders of the measles and chickenpox viruses after injection of vaccines containing these live-virus components, and those inoculated with a “pertussis-component” vaccine who on subsequent exposure to *B. pertussis* become silent carriers and spreaders of *B. pertussis* [so-called ‘Pertussis Harrys’]), and
- ◆ When the current live-virus vaccines are used, actually infect those inoculated with them with one or more diseases for which they are designed to provide protection as well as with some amount of adventitious viruses or potentially bioactive and/or immune-system disruptive DNA fragments that they may or are known to contain.

If GACVS wants to continue to use the “*AEFI*” acronym it should be redefined as “adverse event following inoculation” and, *to differentiate the acronyms*, this reviewer will use the acronym “AEFI_n” in the discussions addressing his appraisals of the proposed adverse-event assessment schema.

Of equal importance, if the system is intended to be scientifically sound¹⁰, all AEFI_n reports must be considered a possibly valid vaccine-related report until the scientific facts can unequivocally rule out the possibility that the vaccine was the major causal factor.

Thus, incomplete reports that do not unequivocally rule out a possible causal link should be considered as possibly valid AEFI_n reports instead of being discarded simply because certain information was not provided.

-
- ⁷ Skowronski DM, De Serres G, Crowcroft NS, Janjua NZ, Boulianne N, et al. [Association between the 2008–09 Seasonal Influenza Vaccine and Pandemic H1N1 Illness during Spring–Summer 2009: Four Observational Studies from Canada](#). *PLoS Med* 2010; **7**(4): e1000258. doi:10.1371/journal.pmed.1000258
- ⁸ Skowronski Dm, Hamelin ME, De Serres G, Janjua NZ, Li N, et al. [Prior Receipt of 2009-09 Trivalent Inactivated Influenza Vaccine Increases Pandemic H1N1 Severity In Ferrets: Randomized Double-blind Placebo-controlled Experiment](#). *ICAAC* 2012, **2012** Session V-400d, Sunday, 2012 Sep 9. San Francisco, California.
- ⁹ Bodewes R, Fraaij PL, Geelhoed-Mieras MM, van Baalen CA, Tiddens HA, van Rossum AM, van der Klis FR, Fouchier RA, Osterhaus AD, Rimmelzwaan GF. [Annual vaccination against influenza virus hampers development of virus-specific CD8⁺ T cell immunity in children](#). *J Virol*. 2011 Nov; **85**(22): 11995-12000. Epub 2011 Aug 31.
- ¹⁰ In science, any causally related sequence of events must be accepted as possibly connected until the scientific facts can unequivocally rule out the connection. Thus, except for adverse outcomes that occur before one or more vaccines are administered, all reported AEFI_ns must be considered as causal and, unlike today’s short-term windows (within “x” days” of inoculation), the timeframes for possible AEFI_ns should extend for not less than 5 years post-inoculation for those adverse events that are known to take years before a definitive diagnosis can be made (e.g., multiple sclerosis).

Core Variables for AEFI Monitoring

“□ core variables for AEFI monitoring.”

Given the paucity of information provided about these “*core variables*”, there is little that this reviewer can discuss about these “*core variables*”.

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 the mercury species in eaten fish are absorbed into the human body¹¹.

Based on that 2006 RfD estimate, the EPA reported that a safe level of ingested mercury (from eating fish) for developing children might be 0.1 microgram of mercury exposure from dietary fish consumption per 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 body¹².

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 this value more than 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 “11”), 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 “12”), *at a minimum*, the EPA estimate for American children’s tolerable level for the daily ingestion (consumption) of dietary organic mercury exposure 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 “RfD” value set by the U.S. EPA is not an appropriate limit for the Thimerosal in an injected Thimerosal-preserved vaccine, which 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.”

11 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/.

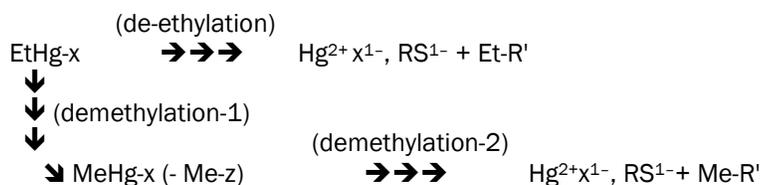
¹⁸ EPA, 2001a.”

12 Ouedraogo 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.

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



[See the results from mercury speciation studies in rats by Rodriques JL, et al. (2010)¹³.]

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 ethylmercury compounds are comparatively slightly more toxic than the methylmercury compounds studied¹⁴.

Further, other studies had established how toxic the ethylmercury compounds were¹⁵ 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 rat¹⁶.

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 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 variable¹⁷.

“ 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

¹³ 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.

¹⁴ 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 136-146 especially, Figures 55-57 (pages 144-145) showing poisoning effects of inhaled ethylmercury chloride and ethylmercury phosphate in guinea pigs and rabbits, respectively.

¹⁵ 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”.

¹⁶ Goncharuk GA. Experimental investigation of the effect of organomercury pesticides on generative functions and on progeny. *Hyg Sanit.* 1971; **36**: 40-43.

¹⁷ Jalili MA, Abbasi AH. *Poisoning by Ethyl Mercury Toluene Sulphonamide.* *Brit J Industr Med.* 1961; **18**(4): 303-308.

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)¹⁸.

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 infants¹⁹ 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)²⁰ 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 show that the mercury injected is rapidly eliminated in the feces of babies administered the “*thiomersal*”-preserved vaccines.

Moreover, the studies by Takeda Y, et al. (1968)²¹ in rats do not support either rapid or complete elimination via the fecal route of radiolabeled [²⁰³Hg] mercury species from the ²⁰³Hg-labeled ethylmercury compounds administered.

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) which show that, after a single ethylmercury chloride dose,

“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)”

- ◆ 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 tissue 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” on this page).

¹⁸ 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.

¹⁹ 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 “20”)

²⁰ 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.

²¹ 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.

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 (~ 0.042 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 the study by Burbacher TM, et al. (2005)²² 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)²³, 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, 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 report’s unsubstantiated “*clears the body*” claim 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, given the studies showing 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, 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,

unless the committee members have elected to intentionally and knowingly lie about the clearance of injected Thimerosal from developing babies to conceal its toxicity?

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 women²⁴), why did GACVS waste

²² 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.

²³ 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](#).

²⁴ 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:

time reviewing studies which 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 peer-reviewed journals, 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

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; 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).

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 slowly²⁵ replacing the Thimerosal-preserved stocks as the preserved vaccines were used up. I

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 2002²⁶, 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 2001-2002 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 “26”) – 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

²⁵ 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.

²⁶ 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. ...”

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 recommendations²⁷.

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

Consequently, GACVS’ assertion, “*despite removal of thiomersal from most vaccines*”, is a knowingly duplicitous claim, which implies that it is only the number of “thiomersal”-preserved vaccines 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 U.S. CDC, the U.S. FDA, and the vaccine makers have done is colluded to fold the preservative-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” 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 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 doses²⁸.

Currently, 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 which they would have

²⁷ [The ‘No Thimerosal-Preserved Vaccines’ Lie, 12 August 2009, 9 pages.](#)

²⁸ [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.

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 and some getting a reduced-Thimerosal flu shot.

Thus, most flu-shot-vaccinated children will probably 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 “24”) 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?

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 the 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 group ²⁹.

Based on the LOAEL value found, 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 LOAEL³⁰

Here, 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

²⁹ [THE ‘TRUTH’ ABOUT THE TOXICITY OF THIMEROSAL, 12 August 2009, 6 pages.](#)

³⁰ [The ‘Anything But Mercury’ Realities, 14 May 2012, 10 pages.](#)

would appreciate it if GACVS would publish those values along with the data from which they were derived.

Until then, the NOEL 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 safe³¹.

“ 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 than 120 days for Macaque monkeys [Burbacher TM, et al. (2005)] who may only live for 10 years and the human half-life in adults 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 NOEL 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 the 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 did not even compute 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 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

³¹ 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.

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 or older 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^{32,33}.

32 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 “33”) 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?

33 [21 CFR 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 (mercuochrome)
Mercufenol 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

“ 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.

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 tissues³⁴.

Hopefully, the reader will grasp the obvious, GACVS is simply lying 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 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 non-labeled 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:

Phenylmercuric nitrate
Any other ingredient containing mercury
(ii) Approved as of November 5, 2002.
Octoxynol 9

³⁴ Jalili MA, Abbasi AH. [Poisoning by Ethylmercury Toluenesulphonanilide](#). *Br J Ind Med* 1961; **18**(4): 303-308.

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)^{35,36}.

“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 is 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 ...”³⁷, 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 has not, as required by law, 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”.

³⁵ 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.

³⁶ 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”.

³⁷ 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, ...”.

“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 having access to “*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 formulations for the DTaP, DTwCP, 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.

Furthermore, the vaccines for the other highly contagious viral childhood diseases (i.e., measles, mumps, rubella, polio, rotavirus, and varicella [chickenpox]) for which there is an FDA-licensed vaccine 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 vaccines ³⁸ 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 an exaggeration.

Since only a few of the routinely recommended childhood vaccines use Thimerosal (“*thiomersal*”) as a preservative in their multi-dose formulations and several other vaccines ³⁹ use an alternative preservative system for multi-dose vaccine formulations, then the GACVS’ “*no other safer and equally efficacious alternative has been identified for many vaccines*” claims are 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.

³⁸ 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.

³⁹ 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.

No Proof of Safety for the Aluminum (Aluminium) Adjuvants in Vaccines

“Aluminium adjuvants

The GACVS reviewed 2 published papers alleging that aluminium in vaccines is associated with autism spectrum disorders^{3,4} and the evidence generated from quantitative risk assessment by a US FDA pharmacokinetic model of aluminium-containing vaccines. GACVS considers that these 2 studies^{3,4} are seriously flawed.

³ Tomljenovic L, Shaw CA. Do aluminum vaccine adjuvants contribute to the rising prevalence of autism? *Journal of Inorganic Biochemistry*, 2011; 105: 1489–1499.

⁴ Tomljenovic L, Shaw CA. Aluminum vaccine adjuvants: are they safe? *Current Medicinal Chemistry*, 2011; 18(17):2630–2637.”

Again, when the studies do not meet GACVS’ expectations and show evidence of harm, like what was done for the use of “*thiomersal*” as a preservative in vaccines, the report proclaims (emphasis added),

“GACVS considers that these 2 studies^{3,4} are seriously flawed”.

Ironically, the studies’ results were based on “a U.S. FDA pharmacokinetic model of aluminium-containing vaccines”.

Apparently, only those studies that use a U.S. FDA pharmacokinetic model for aluminum (“aluminium”) and find no evidence of harm are considered valid by GACVS.

In this instance, GACVS did at least identify the specific published articles that were ‘bothersome’ to at least the majority of its members and, as we *shall* see, attempted to provide some ‘justification’ for its “*are seriously flawed*” assessment.

“The core argument made in these studies is based on ecological comparisons of aluminium content in vaccines and rates of autism spectrum disorders in several countries. In general, ecological studies cannot be used to assert a causal association because they do not link exposure to outcome in individuals, and only make correlations of exposure and outcomes on population averages.”

Here, GACVS does speak its perspective on the use of statistical population studies to prove a causal outcome linkage to the hypothesized antecedent event: statistical population studies, including ecological studies, “*cannot be used to assert a causal association*”.

However, the facts are that such studies can, for different levels of a possible causal input followed by appropriately time-displaced observed outcomes, provide, *at some confidence level*, valid statistical estimates for the probability that a given event level or event is associated with risk of the time-displaced outcome observed.

Thus, *in this instance*, such statistical population studies provide estimates of the risk that the injection of a certain level of a given aluminum adjuvant will result in some given rate of, *in this case*, “*autism spectrum disorders*” in the population studied at some confidence level.

However, contrary to GACVS’ view, when the proposed linkage is plausible (outcome “B” occurs after input “A”) and such studies predict a relative risk that exceeds 2.0 at a confidence level of 95% or higher, then, the judicial system generally accepts that the linkage is probably causal.

“ Therefore”[,] “their value is primarily for hypothesis generation.”

Contrary to GACVS simplistic view, *in the absence of direct proof that, for example, the level of aluminum-adjuvant exposure causes autism spectrum disorders*, the courts generally accept valid population statistical studies that produce relative risk estimates in excess of 2.0 at a confidence level of 95% or higher as evidence of a causal linkage.

Consequently, the primary value of such studies is their ability to show a statistically significant, probable causal linkage between an event (i.e., aluminum-adjuvant exposure) and the relative risk of a subsequently observed, appropriately time-offset outcome (i.e., neurological or other obvious harm).

Secondarily, the value of such statistical population studies lies in their ability to provide statistical evidence that supports the hypothesis generated, where such hypotheses are usually from simple observations of the possible causal events and the time-shifted clustering of one or more observed outcomes (e.g., the injection of a dose of vaccine “a” and the clustering of “seizure events”

or deaths at 5 – 7 days after the date of injection).

In general, *in the absence of some apparent connected pattern*, other statistical approaches are better suited to hypothesis generation (e.g., factor analysis and cluster analysis).

“ However, there are additional concerns with those studies that limit any potential value for hypothesis generation. These include: incorrect assumptions about known associations of aluminium with neurological disease, uncertainty of the accuracy of the autism spectrum disorder prevalence rates in different countries, and accuracy of vaccination schedules and resulting calculations of aluminium doses in different countries.”

Since the studies in question were used to evaluate a hypothesis and not to generate one, GACVS' initial obtuse and disinformative statement here should simply be ignored.

Moreover, because the studies were used to evaluate the hypothesis that there is a plausible causative link between the level of aluminum-adjutant exposure and the risk of a child's subsequent diagnosis of an autism spectrum disorder, all of the GACVS' list of concerns, *except for the first one*, are only factors whose effect should be considered in evaluating the strength of findings reported.

In general, to the extent that the GACVS concerns are accurate reflections of reality, *unless there is some systematic bias, and none is alleged*, the uncertainties combine to support the reality that the reported relative risk values are minimums relative to the actual values that would have been reported if the factors stated were all accurately known.

Given the outcomes observed in the cited studies, GACVS' claim of “*incorrect assumptions about known associations of aluminium with neurological disease*” is obviously contradicted by: **a)** the outcomes reported in the cited studies and **b)** the reality that “*aluminium*” (aluminum) compounds can be neurotoxic to the central nervous system when present in the brain⁴⁰.

“ The GACVS also reviewed the US FDA risk assessment model of aluminium in vaccines. The FDA calculations incorporate the most recently published aluminium risk assessments by adjusting for gastrointestinal absorption and uptake from the site of injection. The FDA analysis indicates that the body burden of aluminium following injections of aluminium-containing vaccines never exceeds safe US regulatory thresholds based on orally ingested aluminium even for low birth-weight infants. GACVS concludes that this comprehensive risk assessment further supports the clinical trial and epidemiological evidence of the safety of aluminium in vaccines. Current research on pharmacokinetics of aluminium in vaccines is ongoing and should be encouraged as a means of further validating and improving this model.”

Here, it appears that GACVS is intentionally ignoring reality or does not understand the significant differences in the route of administration and observed outcomes for the aluminum adjuvants (injection while suspended in a vaccine dose) where the aluminum adjuvants are virtually insoluble and have dissolution half-lives of 1 to 3 years⁴¹, and ingested polymeric aluminum adjuvants where the aluminum adjuvants dissolve and dissociate in the stomach's gastric fluid to become much more readily absorbable free aluminum species.

This fundamental difference precludes any conclusion about the safety of a given amount or amounts of injected aluminum adjuvants based on the safety of an equal amount or amounts of ingested aluminum adjuvants.

Further, while the “toxic effects” of the dissolved aluminum species from the ingested aluminum adjuvants contribute to the general toxic effects of exposure to solubilized aluminum species, the insoluble aluminum adjuvants, which, *as all immunologic adjuvants are supposed to do*⁴², “activate” the immune system by essentially poisoning the macrophagic portion of the human immune system,

⁴⁰ Walton JR. Cognitive Deterioration and Associated Pathology Induced by Chronic Low-Level Aluminum Ingestion in a Translational Rat Model Provides an Explanation of Alzheimer's Disease, Tests for Susceptibility and Avenues for Treatment. *Int J Alzheimer's Dis.* 2012; 2012: ID 914947, 17 pages.

⁴¹ Hem SL. Elimination of aluminum adjuvants. *Vaccine* 2002 May 31; 20(Suppl 3): S40-S43.

⁴² http://en.wikipedia.org/wiki/Immunologic_adjuvant, last visited on 29 August 2012.

“In immunology, an adjuvant is an agent that may stimulate the immune system and increase the response to a vaccine, without having any specific antigenic effect in itself.^[1] The word “adjuvant” comes from the Latin word *adiuvare*, meaning to help or aid.^[2] “An immunologic adjuvant is defined as any substance that acts to accelerate, prolong, or enhance antigen-specific immune responses when used in combination with specific vaccine antigens.”^[3] Adjuvants have been whimsically called the *dirty little secret of vaccines*^[4] in the scientific community. This dates from the early days of commercial vaccine manufacture, when significant variations in the effectiveness of different batches of the same vaccine were observed, correctly assumed to be due to contamination of the reaction vessels. However, it was soon found that more scrupulous attention to cleanliness actually seemed to *reduce* the effectiveness of the vaccines, and that the contaminants – “dirt” – actually enhanced the immune response. There are many known adjuvants in widespread use, including oils, aluminium salts, and virosomes”.

which is dispatched by the body to get rid of these foreign substances that are irritating the cells touching the aluminum adjuvants and their absorbed components.

This is the case because, *even when it engulfs some of the adjuvant particles*, the macrophage cannot rapidly dissolve these virtually insoluble polymeric aluminum species and eliminate the cellular irritation.

This causes the macrophages to release cytokines (immune-system signaling compounds) that activate other parts of the circulating immune system, which imbalance the immune system towards the inflammatory mode of operation and reduces the body's circulating immune system components' ability to differentiate between what is "self" and what is "not self" — leading to an increased risk of autoimmune attack by the activated immune system components on the body's own cells.

Thus, even when the level of aluminum does not exceed the toxic threshold, the inflammatory processes triggered by the injected aluminum adjuvants can cause damage by triggering inflammatory processes in the brain⁴³.

Given the factual reality of the preceding effects of injected aluminum adjuvants, it should be obvious that the model that simply sees aluminum toxicity as the problem is fatally flawed and should be abandoned or seriously revised to address the inflammatory triggering toxicity of injected aluminum adjuvants.

Based on the preceding facts, the unsupported declarations made by GACVS should simply be ignored here.

No Proof of Vaccine Safety in Pregnancy and Lactation

"Vaccine safety in pregnancy and lactation

Several available vaccines have the potential to reduce maternal and fetal morbidity and mortality from preventable diseases."

While this reviewer agrees that GACVS has the view of vaccines that it states here, this sentence admits that these unspecified "*available vaccines*" only have, *at best*, the "*potential to reduce maternal and fetal morbidity and mortality*".

However, there is little data from inoculation/periodic-disease-agent-challenge studies for each vaccine with the disease or diseases it is intended to prevent that conclusively proves that any vaccine truly protects all or even almost all of those inoculated with said vaccines from ever contracting the disease or diseases against which the vaccine is claimed to provide protection.

Moreover, the reality is that most vaccination series only postpone the susceptibility to the disease or diseases for some variable period of time that is often significantly less than the protection and protection duration provided by having the disease or diseases and recovering from it or them.

Further, in most of those inoculated with any of the prophylactic vaccines, what really prevents the inoculees from contracting the vaccine-covered diseases is the lack of subsequent exposure to any strain of the disease-causing agent or agents.

Based on the preceding facts, the current vaccines provide only limited-duration protection to some percentage of those inoculated with them from vaccine-postponable diseases .

Finally, contrary to what is implied by GACVS' implicit assertion, [vaccine-]"*preventable disease*", the proper terminology should be "possibly vaccine-postponable diseases".

"Thus, optimal protection against preventable diseases that pose a higher risk for disease and death in pregnant woman and their offspring should be balanced against the risk of malformations, abortions, stillbirth or other adverse outcomes that theoretically could affect the fetus as a result of vaccination in pregnancy."

Since:

- ◆ Absent exposure to the disease, there is no disease risk;
- ◆ As this reviewer has shown, there are no [vaccine-]"*preventable diseases*"; and

⁴³ Authier F-J, Cherin P, Creange A, Bonnotte B, Ferrer X, Abdelmoumni A, Ranoux D, Pelletier J, Figarella-Branger D, Granel B, Maisonobe T, Coquet M, Degos J-D, Gherardi RK. [Central nervous system disease in patients with macrophagic myofasciitis](#). *Brain* 2001 May; **124**(5): 974-983.

- ◆ Neither the protection, *if any*, that a vaccine may provide to any person nor its duration, nor the harm that a vaccine may cause is an *a-priori* known,

there can be no scientifically sound and appropriate or ethical balancing of these unknowns against the admitted known risks that most vaccines may have, since, *according to their package inserts*, many are not rigorously tested to prove they have no carcinogenicity, mutagenicity, teratogenicity, reproductive toxicity or immune-system-harm risks for either each specific pregnant woman or her developing fetus or fetuses.

Given the preceding realities and unknowns, GACVS needs to stop its programs to vaccinate pregnant women until the vaccines can be proven, *in appropriate toxicity studies*, to not be carcinogenic, mutagenic, teratogenic, reproductively toxic, and/or immune-system toxic to all pregnant women and all of their unborn children (regardless of their genetic make-ups and epigenetic gene expressions).

Absent the requisite proofs of safety, the members of GACVS and the other vaccination apologists and acolytes who espouse similar positions on such clinical studies, are supporting, and/or are engaged in, human experimentation that clearly violates one or more of the constraints on human experimentation set forth in the Nuremburg Code (see footnote “46”).

“ Maternal antibodies induced by vaccination during pregnancy are actively transferred to the fetus and confer passive protection in the infant after birth.

Here, the GACVS report makes a statement that combines an assertion, which may be true,

“[m]aternal antibodies induced by vaccination during pregnancy”,

with a claimed outcome,

“confer passive protection in the infant after birth”)

that has no basis in fact.

First, only some of the induced “*maternal antibodies*” cross the placental barrier and enter the developing fetus.

Since there is no proof that, *in general*, any level of antibodies universally provides any protection from disease and, *in many instances*, it is known that antibody levels do not correlate with either the probability of, or degree of, disease protection, GACVS is apparently making a knowingly false generalization here when it states that the maternal antibodies “*confer passive protection in the infant*”.

“ GACVS recently established a subgroup to review the safety profile of several important vaccines for pregnant and lactating women.”

Until these unspecified “*important vaccines for pregnant and lactating women*” have been proven to be safe in toxicity studies that meet all of the applicable statutes and current good manufacturing practice (CGMP) regulations in the USA and/or the corresponding “proof of safety” requirements established by other nations’ statutes and laws (regulations), it is inappropriate for any subgroup of GACVS to review the “*safety profile*” of vaccines that have not been proven to be safe in the applicable scientifically sound and appropriate toxicity studies that establish that these unidentified vaccines are safe – not carcinogenic, not mutagenic, not teratogenic, not reproductively toxic, and not immune-system toxic at a minimum!

Thus, until all these vaccines have the equivalent of a “Pregnancy Class A” rating and are proven to meet all of the other requirements for a safe vaccine that this reviewer has outlined, this subgroup of reviewers has no safe vaccines to review.

“In addition to the review of available data on influenza vaccines described below, the committee also reviewed the accumulated safety data for rubella-containing vaccines when inadvertently administered to pregnant women to complement the review conducted in June 2008.

Since neither the “*available data on influenza vaccines described below*” nor “*the accumulated safety data for rubella-containing vaccines when inadvertently administered to pregnant women*” were from studies designed to prove or establish safety in a controlled clinical trial nor were any in-depth or extended studies conducted on the long-term effects to the pregnant women and their offspring, such reviews of “at birth” outcomes are, *at best*, inappropriate.

“GACVS concludes that the data remain very reassuring for the use of vaccines during pregnancy, with no evidence of adverse fetal outcomes identified.”

Since the “data” is from events that are not critically monitored for non-apparent outcomes, the GACVS assertion here, “*no evidence of adverse fetal outcomes identified*”, is, even if true, scientifically meaningless.

Worse, the GACVS statement ignores the serious adverse outcomes of significantly increased reports of miscarriage and stillbirth in CDC/FDA-managed Vaccine-Adverse-Events Reporting System (VAERS) seen in the 2- influenza-vaccine (pandemic influenza and seasonal influenza) program in the 2009-2010 flu season [> 10x-fold increase] in the USA as compared the VAERS reports in either the 2008-2009 flu season or the 2010-2011 flu season (where a 2009-A-H1N1-like strain of influenza was included in the 2010-2011 seasonal vaccine)⁴⁴ (also, see footnote “5”).

Clearly, based on the outcomes observed in the 2009-2010 flu season, the influenza vaccines are not “nontoxic” and/or have no safety margin given the more-than-a-factor-of-10 jump in reports of fetal loss when a 2-influenza-vaccine-doses program was used in the USA over the number of such reports filed for the prior flu season’s 1-influenza-vaccine program for pregnant women.

Moreover, based on the analysis of the subsequent 2010-2011 flu-season’s VAERS reports (which were only slightly elevated over the VAERS reports in the 2008-2009 flu season when corrected for the difference in uptake), the probable causal factor for the increased fetal-loss reports to VAERS was the doubling of the maximum dose of Thimerosal that a pregnant woman might receive.

If, as the USA data clearly indicate, Thimerosal dose was a causal factor for the increase observed, these data clearly establish that, *when used as a preservative*, the Thimerosal level in a Thimerosal-preserved flu shot cannot meet the “sufficiently nontoxic ...” requirement for such preservatives as set forth in 21 CFR 610.15(a).

This is the case because this safety standard would require at least a 10-fold safety level since Thimerosal is a bioaccumulative poison that, by toxicologists, is a recognized human carcinogen, mutagen, teratogen, reproductive toxin and immune-system disruptor and, at best, the safety level is less than 1-fold (the level in the Thimerosal-preserved vaccines used in the USA).

Thus, had GACVS accurately reviewed the VAERS fetal-loss data from the 2009-2010 flu season and the prior and subsequent flu seasons as well as the CDC’s published studies confirming a low background rate for influenza-vaccine-associated reports of fetal loss in VAERS during the prior flu seasons, then GACVS could not have truthfully stated “*with no evidence of adverse fetal outcomes identified*”.

Based on the preceding reality either GACVS did not properly review the VAERS reports of fetal loss as outlined above or GACVS is knowingly making a statement that is apparently less than truthful.

“Protection of mothers at risk and their young infants will be critical to attain the reduction of morbidity and mortality due to infections that affect many populations around the world.”

Although no one can argue with the amorphous generalization that GACVS makes here, this reviewer notices that there is no mention that giving vaccines to pregnant women will achieve this goal especially when there is no proof that giving an inactivated-influenza vaccine to anyone truly

⁴⁴ See the applicable documents posted at <http://www.progressiveconvergence.com/H1N1-RELATED%20miscarriages.htm>:

- [HPV vaccine-related miscarriages and still births](#) (545). Spontaneous abortions and elective abortions. (Opens in new window or tab)
- [Miscarriage Cases](#)
- [VAERS Database](#) -- Miscarriages & Stillbirths. (PDF 2 MB). Opens in new window.
- [Statistical correction](#) (PDF 178 K) -- Based on analysis of data from two different sources... H1N1 vaccination program contributed to estimated 1,588 miscarriages and stillbirths. Authors: [Dr. Gary Goldman, PhD](#) (PDF 1.7 MB) and [Dr. Paul G. King PhD](#) (PDF 278 K)
- Press Release (Oct. 28, 2010): [CDC allegedly falsifies reports](#) -- (PDF 125 K) ignoring VAERS miscarriages from H1N1 Vaccine.
- [Official transcript](#) (p37). CDC’s Dr. Marie McCormick denies miscarriages, Sept. 3, 2010 ACCV. (PDF 105 K)
- [NCOW presentation](#) of findings to Advisory Committee, Sept 3, 2010 ACCV. (PDF 48 K).
- [Influenza Vaccine Safety Monitoring](#) (slide 20). CDC’s Dr. Tom Shimabukuro confirms NCOW data, Oct. 28, 2010 ACIP. (PDF 309 K).
- [BACKGROUND RATE](#) Dr. Pedro Moro (CDC) study, 2010 AJOG 20 spontaneous abortions reported to VAERS between 1990-2009 (PDF 5 M).

protects the person vaccinated with it or their unborn child or children or their nursing infant or infants from contracting influenza.

Use of Influenza Vaccines during Pregnancy without Proof of Safety

“Use of influenza vaccines during pregnancy

As the risk of influenza disease is increasingly recognized among pregnant women and a growing body of evidence supports the benefits to infants of maternal vaccination, the committee reviewed the safety data available for influenza vaccines derived from clinical trials, observational studies, and spontaneous reporting.

The data confirm the safety of non-adjuvanted trivalent inactivated seasonal influenza vaccines in pregnancy.”

As the citation- and link- supported references provided by this reviewer clearly indicate, these unsupported GACVS’ statements here are simply at odds with factual reality.

“ For example in the USA outcomes of pregnancy were assessed in 3719 vaccinated pregnant women compared with 45 866 controls in the Vaccine Safety Datalink during the period 1997–2002.”

First, since epidemiological studies cannot prove vaccine safety, the study mentioned, for which, interestingly, no outcomes are reported, is but another misdirective waste of the reader’s time.

Second, since the Vaccine Safety Datalink (VSD) database is based on administrative records and was not designed to evaluate the detailed outcomes of each pregnancy and follow the pregnant woman and her child/children for an extended period of time after birth and it is not a verified medical records database designed to provide in-depth medical assessments of the child’s true health after birth, it does not matter that the portion of the data that GACVS is reporting on involved some unverifiable⁴⁵ “3719 vaccinated pregnant women”.

Moreover, why did they only look at the period from 1997 to/through 2002 (5 or 6 years)?

Why did the study not extend through 2011?

Further, since there are about 4-plus million births a year in the USA, or 20-24 million in the period of this unreported study, how can anyone apply the findings from the non-random administrative records of “3719 vaccinated pregnant women” (< 0.0186% of all the births in the USA during that period) to a population of in excess of 20 million?

At the < 0.0186% level, adverse-outcome effects occurring at the 0.1 % level (1 in 1,000) would probably be missed – potentially missing more than 20,000 to 24,000 adverse outcomes during the period of this “study”.

“From 1990–2009, an estimated 11.8 million pregnant women were vaccinated in the USA. In addition, a review of spontaneous reports found no maternal deaths, no unexpected pattern of adverse pregnancy events or fetal outcomes, and no increased risk of adverse pregnancy outcomes when compared to background rates.”

Here, without providing any citation to the article from which this data was taken, the reports speaks of “*an estimated 11.8 million pregnant women were vaccinated in the USA*” in a period of 19? to 20? years (1990-2009).

However, again no result findings are reported for the adverse pregnancy events, fetal outcomes, increased risk of adverse pregnancy outcomes or what the “*background rates*” were or, for that matter, the database from whence the data came.

“ Extensive evaluation during the 2009 influenza A(H1N1)pdm09 pandemic supported the safety of adjuvanted and non-adjuvanted influenza vaccines when used in pregnant women; overall, the safety profile was comparable to seasonal influenza vaccine in non-pregnant adults, and there was no evidence of teratogenicity or any other negative impact on pregnancy outcomes.”

⁴⁵ Since independent researchers are not allowed to verify the validity of the claimed findings from CDC evaluations using the VSD and, *when questions have arisen about the validity of studies conducted by the CDC*, the CDC has claimed that it “lost” the data, this reviewer must, as any ethical scientist would, consider any findings, which cannot be independently verified, from the VSD as “non-reproducible findings” that should be ignored unless and until independent researchers can independently confirm their validity.

Here, the statements made by GACVS are clearly at odds with the findings reported by this reviewer based on his review of the fetal-loss (and other) adverse events reported to the VAERS database for the period from 1 July 2008 through 30 June 2011 encompassing the 2008-2009, 2009-2010 and 2010-2011 flu seasons in the USA.

Based on the reports to VAERS in the 2009-2010 flu season in the USA, the adverse-event for the “2009 influenza A(H1N1)... pandemic” “non-adjuvanted influenza vaccines when used in pregnant women” indicated more than an order of magnitude increase in fetal losses as compared to the previous flu season (see: **a**) the applicable files in footnote “44” and **b**) footnote “5”).

Moreover, in spite Dr. Marie McCormick denial of miscarriages related to the mostly Thimerosal-preserved, non-adjuvanted pandemic influenza vaccines used in the USA, the reports of fetal loss (miscarriages and stillbirths) was more than 30 times higher than the reports in the 2008-2009 flu season!

“In addition, preliminary data from a few studies of influenza vaccine in pregnant women have confirmed not only the benefit of providing protection in this vulnerable population, but positive effects in their infants, including the reduction of low birth weights, and a significant decrease in influenza-related pneumonia in young children.”

Since GACVS provides no citations to the studies that support its claims here, this reviewer cannot comment on the specific claims made.

In addition, because the report states “preliminary data from a few studies of influenza vaccine in pregnant women”, this reviewer respectfully requests that all of the data from all “studies of influenza vaccine in pregnant women” and the study identifiers be published by GACVS.

Absent that information, given the small size of the studies reported by GACVS in the VSD case, this reviewer must presume that: **a**) the participants were carefully screened to make certain they were truly healthy before they were accepted into these unidentified “studies”; **b**) the “size” of these studies was too small to make any valid population-wide generalizations, **c**) the reporting was possibly “biased” (cherry picked); and/or **d**) none of the studies used Thimerosal-preserved inactivated-influenza vaccines.

Finally, absent proof that all influenza vaccines that can be given to pregnant women have been proven to be toxicologically “safe” in toxicity studies including those that proved that the vaccines used did not adversely affect the woman’s or the child’s reproductive systems and, among their other characteristics, were non-carcinogenic, non-mutagenic, and non-teratogenic, it would appear that all who conducted these studies are guilty of violating points “2.” through “4.” of the “Nuremberg Code”⁴⁶ governing experimentation on humans (emphasis added):

⁴⁶ See http://en.wikipedia.org/wiki/Nuremberg_Code

“The ten points of the Nuremberg Code

The 10 points are, (all from United States National Institutes of Health) [2]

1. The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him/her to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonable to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment. The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.
2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.
3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment.
4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.
5. No experiment should be conducted where there is a prior reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.
6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.
7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.
8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.
9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.

- “2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.
3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment.
4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury”.

Though preclinical animal studies are required to prove that an influenza-preventive vaccine given to pregnant women to protect them and their children from the risk of contracting influenza is not: **a)** reproductively toxic, **b)** a carcinogen, **c)** a mutagen, **d)** teratogen, or **e)** an immune-system disruptor, there does not appear to be any valid animal experiments to establish the required levels of safety appropriate for a preventive (prophylactic) inactivated-influenza vaccine that is to be given to healthy pregnant women upon which these experiments could rely and, *given this deficit*, the studies were knowingly conducted in violation of Point “3.” of the “Nuremberg Code”.

Further, there are no studies that prove that the vaccine inoculations do provide protection from contracting influenza to the pregnant women inoculated and/or to their unborn child or children

In addition, *a priori*, one cannot identify whether or not a given person will develop the requisite level of antibodies after inoculation or, worse, have a serious immune-system reaction to the vaccine,

Since other mammals can and do contract human influenza and have similar immune and reproductive systems, these studies may also violate Point “2.” of the “Nuremberg Code” because the general results needed could have been procured by the appropriate animal studies.

Finally, *absent the requisite preclinical proofs of safety*, all these studies appear to violate Point “4.” of the “Nuremberg Code”.

Causality Assessment of Adverse Events Following Inoculation

“Causality assessment of Adverse Events following ~~Immunization~~ Inoculation

“Attribution of causality to ~~AEFI~~ AEFIn“, especially those considered severe, of public importance, and programmatically disruptive, are critical for ensuring vaccine safety.”

First, the reader should notice the change in terminology and, if he or she has not already, read this reviewer’s introductory remarks on this section (starting on page “3”) to understand why this change in terminology is crucial.

Here, this reviewer finds that GACVS’ statement here is, at best, confused.

Removing the comma (“-”) delimited clause, “*especially those considered severe, of public importance, and programmatically disruptive*”, the sentence should read:

“Attribution of causality to ~~AEFI~~ AEFIn “ ...” **is** “critical for ensuring vaccine safety” since the subject of this sentence is clearly “Attribution”.

In addition, in a science-based system, the “*especially*” considerations should be the severity of each AEFIn and the frequency of a given type of AEFIn.

Thus, GACVS’ “*public importance*” and “*programmatically disruptive*” considerations indicate that GACVS’ agenda is to develop a system that will minimize the reporting of too many AEFIns, “*especially those considered severe*” to minimize the risk that the reporting of AEFIns will be, as GACVS puts it, “*programmatically disruptive*”.

That this is the general agenda for those pushing vaccine inoculation programs around the world, one need only look at the passive nature of the adverse-event reporting systems, euphemistically called “*spontaneous*” in the GACVS’ discussion of adverse-event reporting related to the influenza-

10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgment required of him that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

[2] U.S. National Institutes of Health. “Nuremberg Code”. Retrieved on June 20, 2012”.

vaccine inoculations given to pregnant women, and the lack of serious penalties for any healthcare provider who sees, or hears about, but fails to report an AEFI.

If GACVS or, for that matter, the U.S. CDC or FDA, were serious about AEFI reporting, then there would be:

- Regulations with monetary penalties for those who administer vaccines to report all instances of a possible AEFI;
- Auditors to ensure that the healthcare providers were complying with these regulations;
- Serious adverse consequences for any healthcare provider who repeatedly failed to report and/or repeatedly failed to try to follow up to capture all of the possible short-term; and
- A cadre of independent competent forensic assessors to evaluate each possible reported AEFI and, where indicated, track that individual's health for an extended period of time or until the affected inoculee(s) die, recover, or stabilize.

Thus, at a minimum, as is the case for "notifiable" diseases, GACVS should be demanding that all post-vaccine-adverse-event systems must be based on active reporting that captures not less than 80% of all post-inoculation adverse events that may be causally linked to a given inoculation or set of inoculations occurring on any given day.

Until the AEFI reporting systems are active rather than passive and the non-science considerations, "*public importance*" and "*programmatically disruptive*", are removed from the approaches used for assessing causality, the proposed GACVS system should be recognized as a system designed to minimize the reporting of possible AEFIs and to dismiss as many AEFI reports because they "have not been proven to be causally linked" simply because some "key" piece of information was not reported — essentially, an anti-science approach to causality assessment.

" In 2005, WHO published an *aide-mémoire* to a systematic, standardized causality assessment process for serious ~~AEFI~~ AEFI (including clusters), providing a method for individual causality assessment to be used by staff of national immunization programmes, regulatory authorities and pharmacovigilance or surveillance departments.⁵

⁵ Aide-mémoire: Adverse events following immunization (AEFI): causality assessment. Geneva, World Health Organization, 2005. Available from http://whqlibdoc.who.int/aide-memoire/a87773_eng.pdf ; accessed July 2012."

In general, in addition to the fundamental problem with the definition of the acronym "AEFI", this reviewer makes the following suggestions for improving the WHO's published 2005 "*aide-mémoire*":

1. Since vaccines are drugs or, more specifically biological drug products, the text immediately following the header, "Causality assessment of adverse events with vaccines versus drugs" should, at a minimum, be changed to read,
"Many safety monitoring systems deal with vaccines and" [other] "drug products together"[,] "yet there are important differences between them that affect causality assessment".
2. At a minimum, the first bullet under the "Causality assessment ..." heading needs to be revised to read,
"Vaccines are given to healthy populations and mostly (infants) at a vulnerable age; they are elective" or mandated with some exceptions (medical, religious and/or philosophical)", have a complex composition (biological products)," [have] "immunological considerations in addition to pharmacological, may cause the illness they are meant to prevent (e.g., VAPP)" [or other illnesses (e.g., glioblastomas caused by SV-40 contaminants in a polio vaccine)]", have a ~~short duration of exposure~~ "an undefined duration of exposure and/or effect on the human immune system"; a "long" time for response, and "minor" adverse events are important as they may indicate programme error" and/or an underlying vaccine safety problem."
3. Under "~~Routine AEFI~~ AEFI *review and triage*", change the first sentence to read,
"~~All AEFIs need to be screened and triaged by~~ [independent] ~~trained immunization programme~~ [inoculation-safety assessment⁴⁷] ~~staff to determine the subsequent steps needed ...~~"

⁴⁷ In order to minimize the appearance of bias, the persons doing the AEFI assessments should be from branches of the regulatory schema that have no potential vaccination program conflicts of interest. In the U.S., for example, those units of the CDC that handle the tracking and reporting of notifiable diseases might be suitable provided they do not report to those responsible for promoting vaccines and/or vaccination programs.

4. Under the heading “Systematic causality assessment” and the subheading, “WHO categories for causality³”:
 - a. All instances of the term “A clinical event” need to be replaced with the term “An abnormal health-, development- or behavior- related event”.
 - b. The last category, “Unclassifiable” needs to be renamed as “Indeterminate” and moved to just after the “Possible” category with the addition of a sentence “All such indeterminate adverse events that occur after an inoculation should be considered as a possibly causal until and unless the missing information is furnished to either classify the adverse event properly or eliminate it as an ‘Unrelated’ event is provided”.

“ After 7 years, several limitations had been identified during its use in the field, including: the need for more detailed guidance on the elements required to perform the assessment of causality, confusion over the terms used to classify the likelihood of association of the event to the vaccine, and the incomplete use of parameters for establishing causal association.

Following the GACVS decision to review the causality assessment system in December 2010, a working group was established to review the *aide-mémoire* and develop a method that would be simple, objective, adaptable and evidence-based when used by countries with different resources and capabilities. After concluding a thorough review of the most innovative methods available for determining causation for drugs and biologicals, an algorithmic scheme that incorporates additional elements of causation was designed. The guide was harmonized after the Clinical Immunization Safety Assessment (CISA) network’s newly developed algorithm which is available in the USA⁶ and the new definition of ~~AEFI~~ AEFI⁷ “proposed by the Council for International Organizations of Medical Sciences (CIOMS).”⁷

⁶ Halsey NA et al. Algorithm to assess causality after individual adverse events following immunizations. Vaccine, 2012. Available online at <http://www.ncbi.nlm.nih.gov/pubmed/22507656> , accessed July 2012.

⁷ Definitions and application of terms for vaccine pharmacovigilance. Geneva, World Health Organization/ Council for International Organizations of Medical Sciences, 2012. Available at http://whqlibdoc.who.int/publications/2012/9789290360834_eng.pdf, accessed July 2012.

Given that reference “6” to the basis document by Halsey NA et al. 2012 is to the abstract of the named article and not the article and that reference “7” is 195 pages in length and was only made available to the public recently, other than again suggesting that acronym “AEFI” be redefined as “Adverse Effects Following Inoculation”, this reviewer must defer commenting further on the 2012 document “Definition and Application of Terms for Vaccine Pharmacovigilance Report of CIOMS/WHO Working Group on Vaccine Pharmacovigilance”.

“ The new WHO proposed method allows the National Committees for ~~AEFI~~ AEFIⁿ “case review and causality assessment to screen serious cases reported by their surveillance system for completeness and quality of information, ensuring the objectiveness of the assessment.”

While this reviewer can accept that the “*proposed method allows the National Committees for AEFIⁿ case review and causality assessment to screen serious cases reported by their surveillance system for completeness and quality of information*”, this reviewer does not agree that this “*method*” can ensure “*the objectiveness of the assessment*”.

This reality arises because those who developed this report and the definitions and algorithms in it have obvious conflicts of interest as the initial “*public importance*” and “*programmatically disruptive*” considerations’ language in this section clearly reveals.

At this time, all that this reviewer “knows” is that the reporting system will facilitate the acquisition of the information that it requests and may facilitate the provision of the complete information requested.

However, since the system does not appear to require active surveillance for adverse events, it is fatally flawed because based on the history of reporting in VAERS, as few as 1% of the serious adverse events may be and are reported to the passive VAERS⁴⁸ – a reality that makes vaccines appear to be much safer than they actually are and a reality that precludes scientifically sound estimates of the population level incidence of such adverse events.

In addition, as long as the reporting system uses passive surveillance and the vaccine makers are allowed to report their Phase IV (post approval) adverse events to the AEFIⁿ systems, then, because more than one vaccine is generally given to children on most “well baby” visits, biased reporting will

⁴⁸ Kessler DA, the Working Group, Natanblut S, Kennedy D, Lazar E, Rhoenstein P, et al. [Introducing MEDWatch](#): a new approach to reporting medication and device adverse effects and product problems. *JAMA* 1993 Jun 2; **269**(21): 2765-2768.

occur for all of the concomitantly administered vaccines during the Phase-IV collection periods for a new vaccine making it even more difficult to get valid estimates of unbiased population incidence and prevalence rates for each type of adverse event observed.

“ Cases deemed incomplete are directed towards additional case investigation and review. A checklist containing the elements of causality assessment was included to guide the committee or the assessor to gather the evidence needed for case review, and when completed allows the application of an algorithm that helps determine if the ~~AEFI~~ AEFI “could be consistent or inconsistent with an association with the immunization, or is deemed indeterminate due to lack of evidence. A repository of all ~~AEFI~~ AEFI “ cases sorted through this new document is considered critical and recommended to allow for future signal detection and determining the need for additional epidemiological studies.

GACVS recognizes the boundaries of the newly developed method, mainly the limitations in the ability to associate novel, previously unknown ~~AEFI~~ AEFIs “potentially associated with immunizations, and restrictions due to insufficient information available for individual cases.

However, the new ~~AEFI~~ AEFI “causality assessment system will provide a standardized and transparent method that allows stakeholders to understand the nature of the decision-making process, and pave the way for future evaluation of the guide to refine its effectiveness. GACVS has recommended that this new WHO ~~AEFI~~ AEFI “causality assessment approach should be made public as soon as it is finalized, and that complementary materials and simple software be developed for use in countries to enable immunization staff to field-test the algorithm. Of the next steps deemed most important is the development of a booklet to codify the algorithm and train countries in its use. The committee encouraged the subgroup to further develop the product and endorsed the work process.”

Until such time as this reviewer can thoroughly review the cited “Report of the CIOMS/WHO Working Group on Vaccine Pharmacovigilance” titled, “Definition and Application of Terms for Vaccine Pharmacovigilance”, all that this reviewer can do is to suggest that: **a)** GACVS faithfully reflect upon and address this reviewer’s concerns; **b)** before the suggested approach to causality assessment is “finalized”, not after, the near-final draft should be shared with all those who use the U.S. VAERS database and have published articles in which the VAERS database or have used any other countries’ similar passive-surveillance database; and **c)** the proposed definitions and decision matrices verified to be free from biases introduced from giving any weight to the issues of an AEFI’s “*public importance*” and/or its potential “*programmatically disruptive*” effects.

Core Variables for AEFI Monitoring?

“Core variables for AEFI” AEFI “monitoring

Collection of harmonized data on ~~AEFI~~ AEFI “allows for better comparison and pooled analysis with findings from vaccine safety surveillance systems. In collaboration with a network of countries and independent experts, a preliminary list of core variables had been proposed.

This list was subsequently compared with the reporting forms from the WHO Programme for International Drug Monitoring (Uppsala Monitoring Centre) to verify which variables are captured by the current reporting forms. Through this exercise, it became apparent that vaccine safety monitoring needs tools which are more specific to the type of variables required for proper ~~AEFI~~ AEFI “surveillance and that the current web-based interface developed for reporting of suspected drug reactions (VigiFlow) should be adapted for ~~AEFI~~ AEFI “reporting.

To address these issues, the GACVS in December 2011 suggested developing a simpler and vaccine-specific user interface to enter ~~AEFI~~ AEFI “data. A subgroup of GACVS was tasked to address those issues and presented the status of ongoing activities at the June 2012 meeting.”

Here, this reviewer can only reiterate that, *to the extent possible*, GACVS should remove all of the subjective biases and/or apparent biases inherent in a system that strives to include “*public importance*” and consideration for “*programmatically disruptive*” effects within a supposedly science-based system for addressing causality issues for AEFI reports.

Moreover, recognizing that vaccines do not provide “immunity”, GACVS and the WHO should: **a)** stop all use of that term and related terms like “immunization” with respect to the current prophylactic vaccines; **b)** replace those terms in this report with the corresponding globally more accurate terms, “inoculate” and “inoculation” or “vaccinate” and “vaccination”, as appropriate, **and c)** universally redefine the acronym “AEFI” as “Adverse Effect Following Inoculation” (this reviewer’s “AEFI”).

Collection of Basic and Advanced AEFI Information?

Collection of basic and advanced AEFI AEFIn “information

It is recognized that for the purpose of signal detection, data collection tools should remain as simple as possible.

However, when signals are detected, or in cases of serious AEFI AEFIn “, additional data are essential to allow inferences to be drawn on the association with vaccines and to assess the need for further investigation and action. The subcommittee presented GACVS with 22 core variables that should be collected for any AEFI AEFIn “(basic information) and an additional 33 variables of interest for a more detailed case review (advanced information).

Basic information collected needs to be prioritized because the AEFI AEFIn “data collection, collation, transmission, analysis and feedback systems in different countries are heterogeneous. In addition, quantitative and qualitative aspects of data need to be considered.

The suggested approach proposes a basic minimum of 22 variables with 10 identified as critical. This simple structure is expected to encourage countries that do not yet have an AEFI AEFIn “surveillance system in place to develop one. It is proposed that the reporting tool include the WHO-ART dictionary in order to standardize the terminology used to record signs, symptoms or a diagnosis, as well as a vaccine dictionary that will include details pertaining to all of the vaccines suspected. For the advanced information, details on the nature and frequency of reporting for events such as in campaigns or in routine immunization programmes, breast or bottle feeding, status of previous vaccination are proposed.

Absent the details of all of the preceding items and the list of variable defined and their detailed definitions, this reviewer cannot comment in detail here.

However, in keeping with his proposed changes in terminology, this reviewer would propose that the “*status of previous vaccination*” phrase be recast as “status of previous inoculations” or failing that, “*status of previous vaccination[s]*” since, except before birth or at birth in the USA and at birth in a few countries, more than one inoculation is given at the same time either by using a suitable combination vaccine that may contain components for up to 6 diseases (the ‘hexavalent vaccines’) or multiple inoculations with vaccines that contain the disease-protective components for 1, 2, 3 or 4 diseases.

“VacciFlow”?

“VacciFlow

VacciFlow” will be developed as the adaptation of drug-specific VigiFlow 4.2 to facilitate the entry of vaccine-related AEFI AEFIn “data including immunization programme errors. Ideally “VacciFlow” will be used by both the national regulatory authority and the immunization programme staff. The possibility of incorporating this new interface with minimal computer capabilities and mobile phone technology was encouraged by GACVS.

There will be 3 flexible levels created in “VacciFlow” enabling national and subnational level users to analyse and use the data available for action at each level. Automatic feedback to reporters on the status of the report will be built in. Adapting (modifying) existing AEFI AEFIn “reporting systems to adjust to the data proposed in this core set of variables will require an educational and dissemination effort in many countries. It is expected that the upcoming “VacciFlow” will be sufficiently simple and user-friendly to allow tailor-made adjustment for locally collected information. ”

While the preceding approach sounds interesting and appealing, unless:

- a. The systems for adverse-events require active-surveillance on at least the level required in the USA for notifiable disease reporting and
- b. These databases are appropriately open to credentialed independent researchers,

all that the creation of this new strategy and databases will accomplish is to energize those who are increasingly concerned about vaccine safety to think that these efforts are but the latest pro-vaccination ploys to hide the risks and promote inoculation with vaccines as if these practices could provide “immunity” and “herd immunity” when the facts are that both “immunity” claims are false.

In the USA, at least 5% of the population are currently fully aware that vaccines do not provide immunity to disease; another 20% are becoming aware of this reality; another 25% are just beginning to be engaged on vaccine issues; about 25% are becoming skeptics and the rest believe that their lives and the lives of their loved ones are being saved by vaccines – in a nation where, *at last count*, more than 26% of its children are projected to have one or more chronic lifetime diseases and about half of the applicable 2006 NHANES cohort of children evaluated had at least one chronic disease at some time during their childhood.

Reviewer's Concluding Remarks

In closing, this reviewer would recommend that GACVS spend less time “spinning” their narrative remarks in a manner that suits the pro-vaccination status quo and began to expend more of its energy in telling the public the truth about vaccines and the inoculation programs that use them.

Further, GACVS should remember 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)⁴⁹

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:

- The mandates to vaccinate become ever more restrictive,
- The pro-vaccine propaganda becomes ever more outrageous, and
- The percentage of American children who will probably have at least one chronic lifetime illness continues to climb.

Obviously, the current protective (prophylactic) vaccination programs are increasingly failing to protect the health of American children and the fiscal and physical health of the American public.

The brainwashing propaganda continually bombards the American people with the need to use vaccines to protect the health of our children and ourselves, while our children's and our health keeps declining.

Soon, *given these trends and the fiscal realities that are being or will soon be thrust upon the USA and most all of the nations of the world*, the time to tell the people the truth about vaccines and the inoculation programs used to deliver them will expire.

Acknowledgements

For contributing valuable insights and providing their personal experience-based knowledge in various areas, this reviewer thanks Mark R. Geier, MD, PhD, David A. Geier, BA, Gary S. Goldman, PhD, and the book writers, Neil Z. Miller and Walene James.

In addition, this reviewer thanks Dr. F. Edward Yazbak, MD, FAAP, Gary S. Goldman, PhD, Rev. Lisa K. Sykes, MDiv, and Melissa R. Troutman, MA, BS, R.T. (R)(CT), for their support, suggestions, corrections and alternative wordings, which have helped this reviewer to finalize this assessment.

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.

On several occasions, Dr. King has 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 at odds with the law, reviewed numerous documents, and written on a variety of vaccine-related and other issues.

⁴⁹ http://thinkexist.com/quotation/you_may_fool_all_the_people_some_of_the_time-you/145518.html

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.

Most recently, Dr. King was the co-author of a paper in the journal *Vaccine* with Dr. Gary S. Goldman⁵⁰.

⁵⁰ 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.