

The ‘Anything but Mercury’ Realities

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Introduction

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

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

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

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

However, *before the 1980s*, these medical conditions in children were either rare (e.g., asthma and obesity) or unknown (e.g., childhood type 2 diabetes¹ and childhood Kawasaki’s syndrome²).

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

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

Proving Safety

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

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

² Yeter D, Deth R. ITPKC susceptibility in Kawasaki syndrome as a sensitizing factor for autoimmunity and coronary arterial wall relaxation induced by thimerosal’s effects on calcium signaling via IP3, *Autoimmun Rev* 2012, doi: 10.1016/j.autrev.2012.03.006. [Available online 31 March 2012.]

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

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

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

However, to prove that a given level of exposure to a defined substance³ is safe for a given population group (e.g., developing children), scientifically sound and appropriate toxicological studies in an animal species having known differential response ratios to the corresponding human responses for the substance being tested must be used to establish the level of exposure by a given exposure pathway (e.g., ingestion, inhalation, injection) below which there is no observed adverse effect – where, the toxicologists call this level the NOAEL_{exposure pathway for substance, population segment}⁴.

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

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

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

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

Meeting the Safety Standards for Preserved Biological Drug products

Under the current good manufacturing practice (CGMP) requirement minimums⁵ for biologi

³ Such substances can be a chemical compound that is ‘toxic’, known as a ‘toxicant’ or a biological component that can be toxic, known as a toxin. For vaccines, Thimerosal and other chemical compounds used as preservatives and aluminum adjuvants are examples of toxicants and the live or inactivated viruses, modified bacterial components (e.g., the tetanus and diphtheria toxoid) or bacterial or viral fragments (e.g., Lipid A and the hepatitis B fragments) are toxins.

⁴ For example, for substances that are injected into developing children, the NOAEL_{injection, developing children} is the required NOAEL.

⁵ Under the CGMP framework, all establishment requirements are, as stated, minimums that must be met and, below which, a drug product to which they are applicable is considered an adulterated drug product, which is illegal to be marketed.

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

“... Any preservative used shall be sufficiently nontoxic so that the amount present in the recommended dose of the product will not be toxic to the recipient, ...”

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

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

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

Injected Thimerosal’s Estimated NOAEL and Its Derived “Safe” (“Nontoxic” and “Sufficiently Nontoxic”) Levels

Based on an FDA-recognized chronic rat study that injected low-level doses of Thimerosal, administered twice weekly, over an extended period of time, this author has estimated⁶ that the NOAEL (for injected Thimerosal in developing children) is less than ($<$) 0.0086 microgram (μg) of Thimerosal [$<$ 0.0042 μg of organic mercury] per kilogram (kg) of body weight (per day) and, *from the imputed incidence and the calculated “0” exposure residual effects*, the probable NOAEL_{injected Thimerosal, developing children} is about 0.004 μg of Thimerosal per kg of body mass (per day) or, in terms of the injected organic mercury, about 0.002 μg of organic mercury per kg of body mass (per day)^{7,8}.

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

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

⁶ http://dr-king.com/docs/090812_fnldrft_TheTruthAboutTheToxicityOfThimerosalr5b.pdf, last revisited on Monday, 30 April 2012

⁷ The estimated NOAEL was imputed from the apparent small difference in computed percentage of animals affected for the lowest level Thimerosal that was administered and the computed zero “0” exposure level.

⁸ Since the half-lives for the final organic mercury metabolite, tissue-retained inorganic mercury is on the order of one to two decades, averaging the amount injected per kilogram over the number of days between injections to reduce the peak amount injected is not appropriate because the toxicant’s terminal ‘metabolites’ are bioaccumulative toxicants with half-lives in humans of from 10 to 20 years (from 3652.5 to 7305 days), depending upon the tissue [see, Sugita M. The biological half-time of heavy metals. The existence of a third, “slowest” component. *Int Arch Occup Environ Health* 1978; **41**(1): 25-40].

and to the child at 6 months, 7 months and annually thereafter, the “sufficiently nontoxic” Thimerosal injection level for these Thimerosal-preserved vaccines probably is about 0.00004 µg of Thimerosal (0.00002 µg of organic mercury) per kg of body weight (per day)⁹ [or about 0.04 nanogram of Thimerosal (0.02 nanogram of organic mercury) per kg of body weight (per day)].

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

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

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

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

[~~12.5 µg of organic Hg from Thimerosal~~ divided by ~~0.00002 µg of organic Hg from Thimerosal~~ per kg of body weight], or
[6,250,000 divided by the child’s weight in kg].

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

- a. The “sufficiently nontoxic” level (as required by **21 C.F.R. § 610.15(a)**) by a factor of 125,000 to 3,125,000 or twice these when the vaccine dose delivers 25 µg of organic mercury and
- b. The “safe” (“nontoxic”; estimated NOAEL) level (as required by the statutory requirements set forth in **42 U.S.C. § 262(a)(2)(C)(i)(I)**) by a factor of 1,250 to 31,250 or, when the dose is 25 µg organic mercury, twice these factors.

Thus, it is clear that even the minimum vaccine dose (0.25-mL) is not “safe” for a Thimerosal-

⁹ Because the data in animals indicates that most of the mercury dosed is retained in the tissues for long periods of time that translate into half-lives that are a significant fraction (on the order of 15% to 30%) of the animals’ expected lifetimes, it is less than appropriate to average the dose over the period between doses when the period between dosings (1 month to 1 year for humans) is significantly less than the half-life in the animal in question (for humans, that half-life in the brain is on the order of 18 to 20 years – making the inter-dosing periods between 0.42% and 5.5% of the half-life of the ultimate toxicant, “tissue retained mercury”. In the original rat study using rats with a life expectancy of 24 months, the dosing was 2-times a week for 50% of the rats’ life expectancy. In rats, the half-life of the mercury is on the order of 6 months (180 days) and the between-dosing period was 3.5 days in the chronic dosing study or about 2 % of the retained mercury’s half-life with more than 75% of any dose’s being long-term retained. Thus, averaging of the dose over time is not appropriate because that model presumes that the toxic substance dosed is rapidly cleared from the body, which is not the case in this instance. [See: Takeda Y, Kunugi T, Hoshino O, Ukita T. Distribution of Inorganic, Aryl, and Alkyl Mercury Compounds in Rats. *Toxicol Applied Pharmacol* 1968; **13**: 156-164, and Takahashi T, Kimura T, Sato Y, Shiraki H, Ukita T. Time-Dependent Distribution of ²⁰³Hg-Mercury Compounds in Rat and Monkey as studied by Whole Body Autoradiography. *J Hygenic Chem* 1971; **17**(2): 93-107.]

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

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

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

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

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

“(a) General rule

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

(1) ..., and

(2) make or assure improvements in, and otherwise use the authorities of the Secretary with respect to, the licensing, manufacturing, processing, testing, labeling, warning, use instructions, distribution, storage, administration, field surveillance, adverse reaction reporting, and recall of reactogenic lots or batches, of vaccines, and research on vaccines, in order to reduce the risks of adverse reactions to vaccines”.

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

Since, *even before the NVICP was enacted*, scientifically sound and appropriate studies had proven that adding Merthiolate (another trade name for Thimerosal) to a vaccine formulation at preservative levels increased the adverse reactions to that vaccine formulation¹⁰, the Secretary’s repeated refusal to remove Thimerosal from all Thimerosal-containing vaccines and revoke the licenses for all Thimerosal-containing vaccine formulations that are covered by the NVICP in the more than 25 years that have elapsed since this mandate became effective on December 22, 1987 are actions by the Secretary that: **a)** clearly have been “unlawfully withheld”, **b)** are “not in accordance with law”, **c)** are “short of statutory right”, and **d)** have been taken “without observance of procedure required by law”¹¹.

¹⁰ [Nelson EA, Gottshall RY. Enhanced toxicity for mice of pertussis vaccines when preserved with Merthiolate. *Appl Microbiol.* 1967; 15: 590-593](#), last visited on 15 April 2012.

¹¹ “TITLE 5 - GOVERNMENT ORGANIZATION AND EMPLOYEES

Because § 300aa-27(a)(2) is a statutory mandate, the Secretary of the Department of Health and Human Services (DHHS) and the officials (e.g., the Commissioner of the Food and Drug Administration [FDA]) who, and agencies that, report to said Secretary (e.g., the CDC, the FDA, National Institutes of Health [NIH], and the Public Health Service [PHS]) have no administrative discretion¹² to ignore compliance with any aspect of this absolute statutory directive and, therefore, *to the extent that their activities directly affect vaccine safety*, aforesaid officials and agencies have, with respect to Thimerosal-preserved vaccines, been knowingly¹³ operating outside of the Secretary's legal mandate to make vaccines safer for more than a quarter of a century.

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

“(a) General rule

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

(b) Notice

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

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

“Sec. 702. Right of review

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

PART I - THE AGENCIES GENERALLY

CHAPTER 7 - JUDICIAL REVIEW

Sec. 706. Scope of review [emphasis added]

To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall -

(1) compel agency action unlawfully withheld or unreasonably delayed; and

(2) hold unlawful and set aside agency action, findings, and conclusions found to be -

(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

(B) contrary to constitutional right, power, privilege, or immunity;

(C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;

(D) without observance of procedure required by law ...”

¹² See the limitations placed on administrative discretion by the U.S. Supreme Court in *Berkovitz v. United States* 486 U.S. 531 (1988): “The agency has no discretion to deviate from this mandated procedure. ¹⁰ Petitioners' claim, if interpreted as alleging that the DBS licensed Orimune in the absence of a determination that the vaccine complied with regulatory standards, therefore does not challenge a discretionary function. Rather, the claim charges a failure on the part of the agency to perform its clear duty under federal law. When a suit charges an agency with failing to act in accord with a specific mandatory directive, the discretionary function exception does not apply.”

¹³ 21 U.S. C. § 321. Definitions; generally

§ 321(bb) The term “knowingly” or “knew” means that a person, with respect to information -

(1) has actual knowledge of the information, or

(2) acts in deliberate ignorance or reckless disregard of the truth or falsity of the information.

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

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

- a. The proven ongoing failure of flu-shot vaccine providers to provide truthful information about the nature of the level of Thimerosal in, and/or the prohibitions for the administration of, inactivated-influenza and live-virus influenza vaccines to pregnant women, where it is not possible to reliably determine the nature of the Thimerosal level (Thimerosal-preserved, reduced-Thimerosal, or no-Thimerosal) in an inactivated-influenza vaccine dose in a syringe presented for administration to an individual from the possible future adverse outcomes for those members of CoMeD seeking no-Thimerosal, inactivated-influenza vaccines as well as
- b. The proven coercion of certain pregnant CoMeD members into being vaccinated with Thimerosal-preserved inactivated-influenza vaccines using the threat that their developing babies would die if that pregnant CoMeD member did not get the Thimerosal-containing flu shot being offered – even though one or more of these pregnant CoMeD members subsequently lost their fetus to fetal death shortly after they were vaccinated and suffered the on-going mental injury that such losses can engender in those who grieve for the loss of a child as well as, in one instance, prolonged loss of feeling in one arm.

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

Beyond Unsafe: Thimerosal, the Marginal Vaccine Preservative

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

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

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

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

Thus, although a 100-ppm Thimerosal solution may pass the requirements in the USP's <51> "Antimicrobial Effectiveness Testing" method¹⁴, Thimerosal at this level is a less-than-effective preservative because: **a)** since 1948, *when definitive studies were conducted*, Thimerosal has been found to be bacteriostatic¹⁵ at Thimerosal (Merthiolate) levels of 1,000 ppm and below¹⁶, and **b)** in the presence of proteins containing sulfhydryl groups (-SH) and other sulfur-containing components, even Thimerosal's bacteriostatic action is inhibited¹⁷ and its preservative effectiveness is diminished¹⁸.

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

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

This study compared 0.01-% (100-parts-per-million [100-ppm]) levels of Thimerosal and 2.5-% levels of 2-phenoxyethanol, used as a preservative, and assessed the comparative preservative-effectiveness for both the substances by themselves and in the Prev(e)nar 13 formulation¹⁹.

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

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

Specifically, viable *Serratia marcescens* bacteria was found in the multi-dose vials of the finished packaged Fluvirin product²⁰.

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

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

¹⁴ http://www.microbiol.org/wp-content/uploads/2010/07/sutton.pda_.2002.6.pdf, last visited on 1 May 2012.

¹⁵ Bacteriostatic (Biology) adjective "Referring to inhibition of bacterial growth and/or reproduction" from "McGraw-Hill Concise Dictionary of Modern Medicine. © 2002 by The McGraw-Hill Companies, Inc.", in <http://medical-dictionary.thefreedictionary.com/bacteriostatic>, last visited 1 May 2012.

¹⁶ Morton HE, North LL, Engley FB. The bacteriostatic and bactericidal action of some mercurial compounds on hemolytic streptococci. *JAMA* 1948; **136**: 37-41.

¹⁷ Engley FB. Evaluation of mercurial compounds as antiseptics. *Annals of the New York Academy of Sciences* 1950; **53**: 197-206.

¹⁸ Stetler HC, Garbe PL, Dwyer DM, et al. Outbreaks of group A streptococcal abscesses following diphtheria-tetanus toxoid-pertussis vaccination. *Pediatrics* 1985; **75**: 299-303.

¹⁹ Khandke L, Yang C, Krylova K, Jansen KU, Rashidbaig A. Preservative of choice for Prev(e)nar 13TM in a multi-dose formulation. *Vaccine* 2011 Sep 22; **29**(41): 7144-7153.

²⁰ <http://www.in-pharmatechnologist.com/Processing/FDA-report-sheds-light-on-Chiron-s-problems>, last visited on 1 May 2012.

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

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

Further, since Thimerosal (a/k/a Merthiolate) is known to increase the adverse effects caused by a vaccine formulation²¹, the on-going failure of the Secretary of Health and Human Services to mandate the removal of Thimerosal from all vaccines is a violation of § 300aa-27. Mandate for safer ... vaccines²² (at § 300aa-27(a)(2)) of the “National Vaccine Injury Compensation Program” (NVICP; as set forth in 42 U.S.C. §§ 300aa-10 through 300aa-34), which mandates that the Secretary must use all of the Secretary’s authorities “in order to reduce the risks of adverse reactions to vaccines”.

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

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

Note to the Reader

Should anyone find any significant factual error in this article for which they have independent²³, scientifically sound, peer-reviewed published substantiating documents, the author asks that he or she submit that information to the author so that he can improve his understanding of factual reality and, where appropriate, revise his views and this article.

²¹ [Nelson EA, Gottshall RY. Enhanced toxicity for mice of pertussis vaccines when preserved with Merthiolate. *Appl Microbiol.* 1967; 15: 590-593](#), last visited on 15 April 2012.

²² In the original, the word “childhood” was included because, as enacted, the NVICP only covered children’s federally recommended prophylactic vaccines. However, the U.S. code was subsequently amended to include vaccines that the federally recommended for mass use in adults. Given the addition of the federally recommended adult vaccines, the § 300aa-27 mandate now extends to all of the federally recommended prophylactic vaccines.

²³ To qualify, the study should be published by researchers who have no conflicts of interest from their ties to either those commercial entities who profit from the sale of vaccines or those entities, academic, commercial or governmental, who actively promote inoculation programs using vaccines.

About the Author

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

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

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

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