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Sunday, 25 October 2009

To All:

The text following this page is a draft review of: “**General Questions and Answers on Thimerosal**”, dated September 14, 2009, 11:00 PM ET”, as downloaded by this reviewer on 14 October 2009 from the posting on the Internet by the Centers for Disease Control and Prevention (CDC) at: http://www.cdc.gov/h1n1flu/vaccination/thimerosal_qa.htm

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This draft response, titled “**Draft Review of the CDC’s: ‘General Questions and Answers on Thimerosal’**,” begins on the next page.

REVIEWER’S INTRODUCTORY REMARKS

First, to “*simplify*” this response, when portions of the article being reviewed are addressed in the review, the statements in this report will be quoted in a “Times New Roman” font.

Second, except for his introductory remarks, the remarks by this reviewer, Paul G. King, PhD, are presented in indented text following the section of the article that is being reviewed.

In addition, this reviewer’s remarks and suggested changes are in a “Garamond” font except, when he quotes: **a)** from or refers to any US or New Jersey statute or regulation, the text will be in a “**Franklin Gothic Medium Cond**” font or **b)** from other sources, the quotations will be in an “Arial Narrow” font.

When this reviewer quotes from statements made in the CDC’s unattributed web page, this reviewer will use an *italicized* “Times New Roman” font.

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

Respectfully,

<s>

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DRAFT REVIEW OF THE CDC'S: “General Questions and Answers on Thimerosal”

Dated: “September 14, 2009, 11:00 PM ET”

REVIEWER'S INTRODUCTION

The purpose of this review is to provide, where and as appropriate, an in-depth, fact-based, assessment of the CDC's statements or the statements attributed to other federal agencies (e.g., FDA) presented in terms of the pertinent factual realities from the viewpoint of CDC's stated basis topic, “*Questions and Answers on Thimerosal*”.

Thus, when the CDC's questions and answers veer from this reference frame, this reviewer has, in general, noted that either the question or the answer does not address the topic and proceeded to the next statement, question, or answer in the document.

However, this reviewer would be remiss if he did not point out that the original article is replete with the CDC's “interesting”, and carefully framed, questions as well as equally well-crafted answers that appear to be more doublespeak¹ (Orwellian Newspeak) than honest discourse.

As disseminating false information to the public is illegal, this reviewer trusts that those in any government agency who receive a copy of this draft will independently:

- a. Verify the accuracy of the statements made by the CDC or any other agency cited by the CDC and
- b. Actively seek to correct any statement that they confirm is inaccurate or false.

Finally, at times this document makes strong assertions.

Nonetheless, this reviewer has made objective assessments based on the facts, as he clearly understands and, where critical, documents them.

¹ Doublespeak is “a deliberate, calculated misuse of language in which a statement is intended to do one or more of the following:

- mislead
- distort reality
- pretend to communicate
- make the bad seem good
- avoid, or shift, responsibility
- make the negative appear positive
- create a false view of factual reality
- limit, corrupt, and/or prevent thinking
- make the unpleasant seem attractive or tolerable, and
- create a disconnect between what is reality and what is being said, or not said”.

Thus, doublespeak can be viewed as a fusion of “doublethink” and “Newspeak”, constructs created by George Orwell in his book, **1984**. In Orwell's fictional world, using “doublethink”, the people could hold two opposing ideas in their minds at the same time without questioning the validity of either, and “Newspeak” was the official language used to express the ideas of doublethink.

“What is thimerosal?”

Thimerosal is a mercury-based preservative that has been used for decades in the United States in multi-dose vials (vials containing more than one dose) of some vaccines to prevent the growth of microorganisms, such as bacteria and fungi, which may contaminate them.”

The preceding statement is false because it misrepresents Thimerosal² (49.55% mercury by weight) by using Orwellian Newspeak to obscure:

- ❑ Thimerosal’s chemical identity (sodium ethylmercurithiosalicylate), and
- ❑ Thimerosal’s very hazardous nature (a highly toxic organic mercury compound that has been found to be a carcinogen, mutagen, teratogen and immune-system disruptor at Thimerosal levels below 1 ppm [$< 0.0001\%$]; a “California Proposition 65” reproductive toxin; and a compound with no published safety level for the injection of Thimerosal-containing liquids into humans, much less developing humans) as well as
- ❑ The reality that, *based on a chronic toxicity study in rats where low levels of Thimerosal were injected into rats on a twice weekly basis for a period of one (1) year and the rats monitored for an additional year*³, the apparent NOAEL (no observed adverse-effect level) for injected Thimerosal is:
 - Less than ($<$) 0.086 micrograms (μg) of Thimerosal/kilogram (kg) of body weight/day [or $< 0.042\ \mu\text{g}$ of mercury/kg/day] in humans and
 - $< 0.0086\ \mu\text{g}$ of Thimerosal/kg/day [or $< 0.0042\ \mu\text{g}$ of mercury (Hg)/kg/day], for developing humans.

[**Note:** To put these values in perspective, the estimated “acceptable” reference dose (RfD) published by the US Environmental Protection Agency (EPA) for ingested mercury is $0.1\ \mu\text{g}$ of Hg/kg/day for developing humans. Thus, the EPA’s Rfd_{ingested mercury, developing humans} is more than 23 times higher than the safe NOAEL_{injected mercury, developing humans} ($< 0.0042\ \mu\text{g}$ of Hg/kg/day).]

Thus, factually, Thimerosal is a mercury-containing organic acid salt that:

- ❑ Has been used as a preservative in biological drug products and other drug products “for decades in the United States”,
- ❑ Is still being used as a preservative in some vaccines and other drug products without the requisite proofs of safety for that use as required since 1973 by **21 CFR § 610.15(a)**, and
- ❑ Is being used in vaccines at a maximum level, nominally $100\ \mu\text{g}$ (maximally $125\ \mu\text{g}$) of Thimerosal per mL of vaccine [nominally $50\ \mu\text{g}$ of Hg/mL injected; maximally $62.5\ \mu\text{g}$ of Hg/mL injected] that, because mercury is a bioaccumulative poison⁴ and the typical vaccine dose is “0.5 mL”, *obviously* exceeds the NOAEL_{injected mercury, humans}

² Because Thimerosal is a trade name for a chemical compound, American English requires that it be spelled with an uppercase “T” rather than the lowercase “t” that, *except when it is the first word in a sentence*, the article being reviewed chooses to use – apparently to reduce the risk that the reader will understand the nature of the term “Thimerosal” also commonly also called “Merthiolate” and, in the United Kingdom and some European countries, “Thiomersal”.

³ Mason, M., et al., Toxicology and Carcinogenesis of Various Chemicals Used in the Preparation of Vaccines. *Clinical Toxicology*, 1971; 4(2):185-204.

⁴ For bioaccumulative poisons, like mercury, where the half-life for the bioaccumulated mercury is known to be about two decades in the human brain and the worst case is the person inoculated excretes less than half of the mercury inoculated, the averaging of a bolus dose (one that exceeds the estimated NOAEL by more than a factor of 10) across time to convert the peak dose into an average dose is not scientifically sound.

(< 0.042 µg of Hg/kg/day) by more than a factor of 500 (and exceeds the calculated no observed adverse-effect level for developing humans [NOAEL_{injected mercury, developing humans} of < 0.0042 µg of Hg/kg/day] by more than a factor of 5,000.

Moreover, up until 2003, in-date single-dose vials and syringes of some vaccines and other drug products were preserved with Thimerosal.

In addition to those approved vaccine formulations that are still preserved with Thimerosal, some other vaccines and other drug products (e.g., eye drops, nasal sprays, ear drops, nasal drugs, snake antivenins, and monoclonal antibody drugs) do contain, or may contain, preservative levels of Thimerosal or some other organic/inorganic mercury compound.

Further, in spite of all the claims of safety for Thimerosal used as a preservative in vaccines, as of 15 October 2009,

- ❑ Neither the responsible federal government agencies (the US Food and Drug Administration [FDA], the US Centers for Disease Control and Prevention [CDC], and/or the US National Institutes for Health [NIH])
- ❑ Nor the manufacturers of Thimerosal-preserved biological drug products, including vaccines,

have published the applicable scientifically sound and appropriate toxicity studies that, by law (21 CFR § 610.15(a)), the manufacturers of Thimerosal-preserved vaccines are required to conduct in order to be operating in compliance with the current-good-manufacturing-practice (CGMP) minimums required for the production of drugs that are not adulterated (as per 21 U.S.C. § 351(a)(2)(B)).

The quoted text that follows contains the applicable “FINDINGS” in the 2003 Congressional report, “**Mercury in Medicine – Taking Unnecessary Risks**”⁵:

“A. Findings

Through this investigation of pediatric vaccine safety, the following findings are made:

1. **Mercury is hazardous to humans. Its use in medicinal products is undesirable, unnecessary and should be minimized or eliminated entirely.**
2. For decades, ethylmercury was used extensively in medical products ranging from vaccines to topical ointments as preservative and an anti-bacteriological agent.
3. **Manufacturers of vaccines and thimerosal, (an ethylmercury compound used in vaccines), have never conducted a adequate testing on the safety of t himerosal. The FDA has never r equired manufacturers to conduct adequate safety testing on thimerosal and ethylmercury compounds.**
4. **Studies an d p apers d ocumenting t he h yperallergenicity an d t oxicity of T himerosal (ethylmercury) have existed for decades...**
- ...
8. **The FDA acted too slowly to remove ethylmercury from over-the-counter products like topical ointments an d ski n cr eams.** Although an advisory committee determined that ethylmercury was unsafe in these products in 1980, a rule requiring its removal was not finalized until 1998.
9. **The FDA and the CDC failed in their duty to be vigilant as n ew vaccines containing thimerosal were approved and added to the immunization schedule.** When the Hepatitis B and Haemophilus Influenzae Type b vaccines were added to the recommended schedule of childhood immunizations, the cumulative amount of ethylmercury to which children were exposed nearly tripled.

⁵ Subcommittee on Human Rights and Wellness, Committee on Government Reform of the House of Representatives, “**Mercury in Medicine**” report, Washington, DC, as published in the *Congressional Record*, pgs. E1011-E1030, May 21, 2003.

10. **The amount of ethylmercury to which children were exposed through vaccines prior to the 1999 announcement exceeded two safety thresholds established by the Federal government for a closely related substance - methylmercury.** While the Federal Government has established no safety threshold for ethylmercury, experts agree that the methylmercury guidelines are a good substitute. Federal health officials have conceded that the amount of thimerosal in vaccines exceeded the EPA threshold of 0.1 micrograms per kilogram of bodyweight. In fact, the amount of mercury in one dose of DTaP or Hepatitis B vaccines (25 micrograms each) exceeded this threshold many times over. Federal health officials have not conceded that this amount of thimerosal in vaccines exceeded the FDA's more relaxed threshold of 0.4 micrograms per kilogram of body weight. In most cases, however, it clearly did.
11. **The actions taken by the HHS to remove thimerosal from vaccines in 1999 were not sufficiently aggressive...**
12. **The CDC's failure to state a preference for thimerosal-free vaccines in 2000 and again in 2001 was an abdication of their responsibility.** As a result, many children received vaccines containing thimerosal when thimerosal-free alternatives were available...
- ...
14. **The CDC in general and the National Immunization Program in particular are conflicted in their duties to monitor the safety of vaccines,** while also charged with the responsibility of purchasing vaccines for resale as well as promoting increased immunization rates. ...
- ...
17. **To date, studies conducted or funded by the CDC that purportedly dispute any correlation between autism and vaccine injury have been of poor design, under-powered, and fatally flawed.** The CDC's rush to support and promote such research is reflective of a philosophical conflict in looking fairly at emerging theories and clinical data related to adverse reactions from vaccinations...

The Food and Drug Administration's (FDA) mission is to 'promote and protect the public health by helping safe and effective products reach the market in a timely way, and monitoring products for continued safety after they are in use.' However, the FDA uses a subjective barometer in determining when a product that has known risks can remain on the market. According to the agency, 'at the heart of all FDA's product evaluation decisions is a judgment about whether a new product's benefits to users will outweigh its risks. No regulated product is totally risk-free, so these judgments are important. FDA will allow a product to present more of risk when its potential benefit is great—especially for products used to treat serious, life-threatening conditions.' **This argument—that known risks of infectious diseases outweigh a potential risk of neurological damage from exposure to thimerosal in vaccines—is one that has continuously been presented to the Committee by government officials. FDA officials have stressed that any possible risk from thimerosal was theoretical: that no proof of harm existed. However, the Committee, upon a thorough review of the scientific literature and internal documents from government and industry, did find evidence that thimerosal did pose a risk...**

...

Thimerosal used as a preservative in vaccines is likely related to the autism epidemic. This epidemic in all probability may have been prevented or curtailed had the FDA not been asleep at the switch regarding the lack of safety data regarding injected thimerosal and the sharp rise of infant exposure to this known neurotoxin. Our public health agencies' failure to act is indicative of institutional malfeasance for self-protection and misplaced protectionism of the pharmaceutical industry". [Emphasis supplied.]

Based on item "3" in the published findings, the Congressional committee found:

- The "[m]anufacturers of vaccines and [T]himerosal, (an ethylmercury compound used in vaccines), have never conducted adequate testing on the safety of [T]himerosal", a finding that indicates said vaccine manufacturers *knowingly*⁶ failed to comply with the CGMP requirement minimum set forth in 21 CFR § 610.15(a), which states: "Any preservative used shall be sufficiently nontoxic so that the amount present in the recommended dose of the product will

⁶ 21 U.S.C. § 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."

not be toxic to the recipient” and, when true, renders any Thimerosal-preserved vaccine for which no adequate safety testing was conducted for the Thimerosal used as a preservative an adulterated drug under **21 U.S.C. § 351(a)(2)(B)**.

- “The FDA has never required manufacturers to conduct adequate safety testing on [T]himerosal and ethylmercury compounds”, a finding that establishes that FDA administrators **knowingly** have illegally approved Thimerosal-preserved vaccines because the CGMP regulations set forth in **21 CFR § 601.4(a)** require “**Sec. 601.4 Issuance and denial of license. (a) A biologics license shall be issued upon a determination by the Director, Center for Biologics Evaluation and Research or the Director, Center for Drug Evaluation and Research that the establishment(s) and the product meet the applicable requirements established in this chapter**”. Since proof of safety to the standards set forth in **21 CFR § 610.15(a)** is one of the “**applicable requirements**” for Thimerosal-preserved vaccines, the accountable FDA administrators could not have legally approved a “**biologics license**”, or a legal modification thereof, for a Thimerosal-preserved vaccine unless, prior to that issuance, the manufacturer of said Thimerosal-preserved had met the clear requirements of **21 CFR § 610.15** – which the Congressional committee found said manufacturers had not done. [Note: In addition, since 1999, the manufacturer of any biological drug product has been required by **21 CFR § 601.2(a)** to submit both proof of compliance and certification of compliance with all of the applicable drug policies, regulations and statutes in said product’s biologic license application (BLA).]

Finally, these collusive actions between government administrators and the manufacturers of Thimerosal-preserved vaccines (that, since at least 1973, have **knowingly** held themselves above the law requiring them to prove that Thimerosal, when used as a preservative, is “**sufficiently nontoxic so that the amount present in the recommended dose of the product will not be toxic to the recipient**”) apparently fall clearly within the strictures established by the criminal RICO (Racketeering, Influencing, and Corrupt Organizations) statutes as set forth in **18 U.S.C.A. Sec 1961 et seq.**

Thus, *in light of the ongoing licensing of Thimerosal-preserved influenza vaccines from 1973 until the present*, this reviewer is again compelled to request the Justice Department and, *in States having applicable State RICO statutes*, the Attorney General of those States to initiate and to pursue the appropriate RICO actions.

“What are preservatives and why are they used in vaccines?”

In vaccines, preservatives are used to prevent the growth of bacteria and fungi in the event that they get into the vaccine. This may occur when a syringe needle enters a vial as a vaccine is being prepared for administration. Contamination by germs in a vaccine could cause serious illness or death. In some vaccines, preservatives are added during the manufacturing process to prevent microbial growth.”

This reviewer generally agrees with the statements made by the CDC in this section.

“Will the 2009 H1N1 influenza vaccine contain thimerosal?”

The 2009 H1N1 influenza vaccines that FDA is licensing (approving) will be manufactured in several formulations. Some will come in multi-dose vials and will contain thimerosal as a preservative. Multi-dose vials of seasonal influenza vaccine also contain thimerosal to prevent potential contamination after the vial is opened.”

The CDC's statement about manufacture "*in several formulations*" is accurate as far as it goes.

This is the case because, in addition to the several manufactured formulations, the CDC is proposing that, *in a non-CGMP-compliant environment*, an adjuvant may be added to a manufactured vaccine at the site where the 2009 Type A, H1N1 vaccines are being dispensed – thus rendering the manufactured formulation vaccine products adulterated drugs under **21 U.S.C. § 351(a)(2)(B)**.

The CDC's second statement is also misleading because, in addition to the some formulations "*in multi-dose vials*" (e.g., CSL Ltd's, Novartis' and Sanofi's multi-dose A/H1N1 formulations), the single-dose formulation of Novartis' A/H1N1 vaccine will also contain Thimerosal (nominally at 2% of the Thimerosal level in its Thimerosal-preserved formulation).

The CDC's third statement is inaccurate in its "*to prevent potential contamination after the vial is opened*" assertion because the multi-dose vials are not "*opened*"⁷.

Thus, since the vials are not "*opened*", the preservative level of Thimerosal is added to protect against the failure of those administering the shots of vaccine to rigorously adhere to, and practice, the proper sterile techniques and/or the failure of the needles and/or syringes used to be sterile.

“Some vaccine manufacturers will be producing 2009 H1N1 influenza vaccine in single-dose units, which will not require the use of thimerosal as a preservative. In addition, the live-attenuated version of the vaccine, which is administered intranasally (through the nose), is produced in single-units and will not contain thimerosal.”

Again, the CDC's first statement is misleading because the single-dose A/H1N1 inactivated-influenza vaccine formulation produced by Novartis contains Thimerosal albeit at a level lower than the level in Novartis' multi-dose A/H1N1 inactivated-influenza vaccine.

The CDC's second statement is also misleading because all of the live-virus influenza vaccines manufactured by MedImmune, the sole approved supplier of these live-virus vaccines, contain bioengineered cold-adapted live viruses that are not "*attenuated*" in the traditional sense of the term where "*attenuated*" means weakened.

The CDC's statement is especially misleading for the cold-adapted Type A influenza virus because, though "adapted" (bioengineered) to rapidly replicate at temperatures below the normal body temperature (which is typically, 36 – 37.8 °C [97 - 100 °F]), the live A/H1N1 virus

⁷ Instead, *supposedly using sound sterile technique*.

- After mixing the contents of the multi-dose vial thoroughly, a sterile needle connected to a sterile syringe, which has been adjusted to contain 0.25-plus mL of air for inoculating those under 36 months of age or 0.5-plus mL of air for those 36 months of age or older, penetrates the polymeric septum that seals the multi-dose vial,
- The air in the syringe is completely expelled into the vial and the corresponding dose of vaccine (0.25-plus or 0.5-plus mL) is withdrawn,
- After adjustment of the syringe to the exact volume and wiping off any liquid on the outside of the needle with a sterile gauze pad, the proper 0.25-mL or 0.5-mL dose of vaccine is appropriately injected into the child or adult, and
- The needle is withdrawn, and the needle and syringe are properly discarded.

can replicate, with progressively less rapidity, at body temperatures up to 39 °C (102.2 °F) according to the manufacturer's package insert.

Given that the live A/H1N1 influenza virus in the "intranasal" vaccines replicates rapidly in the nasal sinuses and can replicate in the body, especially of those whose typical sublingual body temperature is less than 37 °C (98.6 °F), it would seem that:

- ❑ Most of those who are inoculated intranasally will contract some type of a case "head flu" and shed live virus of some significant period of time (as the package insert indicates) in which they can infect others (as the package insert also indicates) and
- ❑ Some who are inoculated will develop full blown cases of the "novel" A/H1N1 influenza with which they were inoculated or some other strain to which they may be concomitantly exposed.

"I have concerns about the use of thimerosal. Is thimerosal still being used?"

People have a right to expect the vaccines they receive are safe and effective. CDC and FDA also hold vaccines to the highest standards of safety."

This reviewer strongly agrees with the CDC's first statement, "[p]eople have a right to expect the vaccines they receive are safe and effective".

However, compared to conventional drugs where:

- ❑ The pre-approval study period for adverse reactions extends to years,
- ❑ Complete safety profiles are worked up for each segment of the population to which the drug is to be administered, and
- ❑ The safety of the components of the drug, *which are themselves drugs*, is established to the degree required for each component,

neither the CDC nor the FDA holds vaccines to even the *minimum standards of safety* required by:

- ❖ Statute (e.g., **42 U.S.C. § 300aa-27(a)(2)** and **21 U.S.C. § 351(a)(2)(B)**) for all vaccines) and/or
- ❖ Law (regulation) (e.g., **21 CFR 610.15(a)**, **21 CFR 601.2(a)**, and **21 CFR 601.4(a)**) for, *for the regulations cited*, Thimerosal-preserved and adjuvant-containing vaccines).

"That is why CDC and FDA continually evaluate new scientific information about the safety of vaccines."

The CDC's statement here ignores the reality that both the CDC and the FDA continually ignore and/or disparage any "*new scientific information*" that casts any doubt on the safety of any vaccine or is at odds with the Establishment's views about vaccines and their value to public health.

In addition, under the guise of independent review, the CDC has repeatedly hired the National Academy of Science's Institute of Medicine (IOM) to "look into vaccine safety" but has given the IOM review committees instructions not to find any safety problems or, if such are found, for the IOM to ignore them in the reports the IOM issues.

Worse, by making this statement, the CDC is **knowingly** protecting the manufacturers of vaccines who, *as all drug manufacturers do*, have an absolute, non-dischargeable duty to prove their vaccines and vaccine components are safe to the applicable CGMP **minimums** – a duty that the makers of Thimerosal-preserved vaccines admit they have **knowingly** failed to discharge – a duty to prove safety that the FDA has, *as found by Congress in 2003*, **knowingly** ignored.

Factually, vaccines are the “safest” of drugs for which the drugs’ safety has **knowingly not** been proven.

The deception is so pervasive that, *for the limited “safety” testing that is done*, the comparative vaccine “placebo”, supposedly “a preparation containing no active ingredients” [*Encarta* on-line Dictionary], allowed by the FDA is **not** restricted to the scientifically sound and appropriate sterile pH-balanced isotonic saline dose but allowed to be a liquid that contains components known to cause adverse reactions, like aluminum adjuvants and other approved or experimental vaccines, or, for Merck’s Gardasil® HPV vaccine safety studies, the entire vaccine formulation minus the virus-like antigenic particles. [Note: The FDA permits this obviously deceptive and scientifically unsound practice to obscure the reality that components in the vaccine other than the disease antigens can and do produce significant adverse effects.]

“Since 2001, no new vaccine licensed by FDA for use in children has contained thimerosal as a preservative, and all vaccines routinely recommended by CDC for children under six years of age have been thimerosal-free, or contain only trace amounts, except for multi-dose formulations of influenza vaccine.”

Factually, while possibly true, the CDC’s “[s]ince 2001, no new vaccine licensed by FDA for use in children has contained [T]himerosal as a preservative” claim is based on the validity, *or lack thereof*, of the FDA’s claim that the vaccines licensed by the FDA for the “novel” A/H1N1 influenza virus are just a modification of the manufacturers’ existing “*influenza vaccine*” licenses.

However, *unlike the basis licenses*, which are for trivalent (three-component) influenza vaccines, the A/H1N1 vaccines are monovalent vaccines supposedly for a “novel” influenza virus variation, which is claimed to be **not** only much more infective than the existing human influenza strains but also to have a different population susceptibility profile.

To the extent that the previous agency claims of novelty, increased infectivity, and different susceptibility profile are true, the vaccine for this “new” A/H1N1 influenza virus is a new vaccine.

If the agency’s claims are **not** true, then:

- ❑ The CDC’s statement is not true, and
- ❑ The government and the A/H1N1 vaccine makers are misleading the public.

However, the CDC’s second claim that “[s]ince 2001, ... all vaccines routinely recommended by CDC for children under six years of age have been thimerosal-free, or contain only trace amounts, except for multi-dose formulations of influenza vaccine”, is, at best, misleading and, at worst, **knowingly** false.

Factually in-date Thimerosal-preserved vaccine doses for the Hib, Hep B, DTaP, and then Aventis’/now Sanofi’s Menomume® A, C, Y & W-135 meningococcal vaccine that were

recommended for administration to children in the 21st century did not all expire until in the mid 2000s.

Moreover, neither the Secretary of Health and Human Services (HHS) nor the CDC or FDA banned the administration of these Thimerosal-preserved vaccine doses to children in 2000 so that none of these in-date Thimerosal doses could legally be administered to children in 2001 or later.

In addition, the CDC's second claim is also misleading because:

- ❑ The vaccine “*routinely recommended*” by the CDC for administration to children who are “allergic” to the pertussis toxins, the DT vaccine includes a Thimerosal-preserved DT vaccine that is still licensed by the FDA and available (though not actively marketed in the US), and the CDC has not explicitly banned its use in children;
- ❑ Though no longer “*routinely recommended*”, the CDC has not explicitly banned the giving of Sanofi's FDA-approved Thimerosal-preserved multi-dose Menomune[®] meningococcal vaccine formulation to children as young as 2 years of age; and
- ❑ The CDC's recommendations for administration of influenza vaccines to pregnant women and children, starting in 2002 with children 6 months to 23 months of age and widening until the current recommendation is 2 doses (at 6 and 7 months) followed by annual doses until age 18 coupled with the current recommendation that children under 10 years of age get 2, A/H1N1 inoculations and those 10 and over get 1, A/H1N1 inoculation has had the effect of increasing the maximum total dose of mercury to the point that, worst case, a child whose mother receives a Thimerosal-preserved flu shot during the child's pregnancy and then vaccinates that child with a Thimerosal-preserved flu shot at 6 and 7 months and annually thereafter will, unless the administration of Thimerosal-preserved shots to pregnant women and children is completely banned immediately, be exposed to nearly twice as much mercury as the maximum amount of mercury to which a child vaccinated under the 1999 schedule would have been exposed.

If, *as CDC and FDA officials claim*, compound toxicity depends upon the total “dose” for bioaccumulative toxins like the end metabolites of Thimerosal have been shown to be, then it is clear that the CDC's recommendations for influenza vaccination as well as its and the FDA's failure to even state a preference for “no Thimerosal” vaccines much less act as the controlling statute (**42 U.S.C. § 300aa-27(a)(2)**) demands and ban Thimerosal-preserved vaccines have increased the maximum dose of mercury from vaccines to which a child may be exposed from before birth until 18 years of age rather than reduced the maximum dose or, *as the cited controlling statute clearly mandates*, banned the use of Thimerosal in the manufacture of vaccines.

“This was done as a precautionary step and not because there was evidence confirming that thimerosal-containing vaccines were causing health problems.”

While this reviewer accepts that the preceding statement is the CDC's stated views, this reviewer notes that the safety requirement for preserved “[T]himerosal-containing vaccines” that had not, and has not, been met is proof of an absence of safety to the explicit CGMP *minimum* set forth in **21 CFR § 610.15(a)**: “sufficiently nontoxic so that the amount present in the recommended dose of the product will not be toxic to the recipient”.

Unless and until the scientifically sound and appropriate toxicity studies establish that injecting 0.5 mL of sterile solutions of Thimerosal at minimally 1,000 ppm (parts per million; 0.01%) of Thimerosal (10 times the nominal level of 100 ppm Thimerosal [100 µg/mL]) have a no observed adverse-effect level (NOAEL) on all groups of human recipients who may be directly, or in the case of the fetus, indirectly exposed to such doses, then there is, and will remain, no direct proof of safety for the use of Thimerosal as a preservative in vaccines.

Moreover, given this reviewer's findings on the putative NOAEL values for the toxicity of injected Thimerosal in humans based on the results from a chronic toxicity study of injected Thimerosal solutions in rats, it is crystal clear that Thimerosal at the 100-ppm level is well above the NOAEL for injected Thimerosal in even adult humans and, therefore, Thimerosal used as a preservative at 100 ppm in a vaccine formulation is **not** "sufficiently nontoxic so that the amount present in the recommended dose of the product will not be toxic to the recipient".

"The most recent and rigorous scientific research does not support the hypothesis that thimerosal-containing vaccines are harmful."

Based on this reviewer's assessment of the toxicity for injected Thimerosal (http://mercury-freedrugs.org/docs/090812_fnldrft_TheTruthAboutTheToxicityOfThimerosalr5b.pdf) and a recent peer-reviewed journal publication (Geier DA, King PG, Sykes, LK, Geier, MR. A comprehensive review of mercury provoked autism. *Indian J Med Res* 2008 October; 128: 383-411), the CDC's statement is *knowingly* false.

In addition, for Thimerosal-preserved Hepatitis B vaccines:

- A primate neonatal study⁸, where the vaccine used was Thimerosal-preserved and the doses administered were adjusted to be weight proportional to those received by US children in the 1990s, found serious delays in the development of neonatal reflexes only in the treated neonatal primates but not in the control neonatal primates.
- A recent study, titled "Hepatitis B Vaccination of Male Neonates and Autism"⁹, published in the journal *Annals of Epidemiology* found that "Boys who received the hepatitis B vaccine during the first month of life had 2.94 greater odds for ASD [autism] compared to later- or unvaccinated boys".
- A recent study published in the journal *Neurology* called "Hepatitis B vaccine and the risk of CNS inflammatory demyelination in childhood"¹⁰ found that the Engerix B vaccine, which was Thimerosal-preserved when the children in the study were administered it, for Hep B appears to increase the risk of central nervous system inflammatory demyelination.
- A recent study published in *Toxicological and Environmental Chemistry* titled

⁸ Hewitson L, Houser LA, Stott C, Sackett G, Tomko JL, Atwood D, Blue L, White ER, Wakefield AJ. Delayed Acquisition of Neonatal Reflexes in Newborn Primates Receiving a Thimerosal-containing Hepatitis B Vaccine: Influence of gestational age and birth weight. *Neurotoxicology* 2009 October 1, published online.

⁹ Gallagher CM, Goodman MS. Hepatitis B Vaccination of Male Neonates and Autism. *Annals of Epidemiology* 2009 September; 19(9): 659.

¹⁰ Mikaeloff Y, Caridade G, Suissa S, Tardieu M. Hepatitis B vaccine and the risk of CNS inflammatory demyelination in childhood. *Neurology* 2009; 72: 873-880.

“Hepatitis B triple series vaccine and developmental disability in US children aged 1-9 years”¹¹ stated, “the odds of receiving EIS [special education services] were approximately nine times as great for vaccinated male children as for unvaccinated male children after adjusting the raw data for confounders”. This study found statistically significant evidence to suggest that, *when the vaccines were Thimerosal preserved*, “male children in United States who were vaccinated with the triple series of the FDA-licensed Hepatitis B vaccine were more susceptible to developmental disability than were the unvaccinated male children”.

have:

- ❑ Clearly shown Thimerosal-containing Hepatitis B vaccines are harmful, when the Thimerosal content is at the preservative level and
- ❑ Established the reality that Thimerosal-containing vaccines can be harmful.

“Thimerosal is an important preservative that protects vaccines against potential microbial contamination, which may occur in opened multi-dose vials of vaccine. Such contamination could cause serious illness or death.”

Having studied the reported properties of Thimerosal in solutions containing proteins, Thimerosal’s solvolysis in aqueous solutions containing sodium chloride, and Thimerosal’s limited ability to kill microbes at Thimerosal concentrations ten times higher (0.1% Thimerosal) than the nominal highest level permitted in a Thimerosal-preserved vaccine (0.01%) [e.g., according to the literature, Thimerosal at 0.1% is, at best, bacteriostatic but not bactericidal], the results from the unbiased studies indicate that Thimerosal is a marginal antimicrobial preservative whose ability to stop microbial growth degrades as the released vaccine ages.

In addition, this reviewer again notes that “*multi-dose vials of vaccine*” are not “*opened*”.

Further, microbial contamination from the repeated withdrawal of doses of vaccine from a multi-dose vial, the source of the in-use microbial contamination of the vaccine in a multi-dose vial, is not a problem when the vaccines are packaged in single-dose formats.

“Since seasonal influenza vaccine is produced in large quantities for annual immunization campaigns, some of the vaccine is produced in multi-dose vials, and contains thimerosal to safeguard against possible contamination of the vial once it is opened.”

Factually, the only real limitation as to the number of doses that can be packaged in single-dose format is the manufacturers’ refusal to make the capital investment to modernize their filling lines by replacing their fully depreciated multi-dose vial fillers with the most modern high-speed aseptic single-dose filling equipment, which should actually increase the number of filled doses from a given batch of vaccine because there is no need for the significant volume overage in the single-dose container that is required for the multi-dose vial.

Thus, the CDC’s rationale for the continuing practice of making Thimerosal-preserved vaccine formulations for packaging in multi-dose vials is a self-serving justification for the failure of the

¹¹ Gallagher CM, Goodman MS. Hepatitis B triple series vaccine and developmental disability in US children aged 1-9 years. *Toxicological & Environmental Chemistry* 2008 September; **90**(5): 997 – 1008.

Secretary of HHS to comply with the Congressional mandate to safen vaccines by reducing the risk of adverse reactions (see 42 U.S.C. § 300aa-27(a)(2)).

This is the case because there are other much less bioaccumulatively toxic compounds (e.g., 2-phenoxyethanol and phenol) that have been, are, and could be, employed as preservatives for inactivated influenza vaccine formulations packaged in multi-dose vials if, contrary to the cited mandate for safening vaccines¹², multi-dose vials must be produced.

Moreover, the removal of Thimerosal from all vaccines has been shown to reduce the risk of adverse reactions¹³ in those inoculated with Thimerosal-containing vaccines and/or Thimerosal-containing solutions because injecting Thimerosal-containing liquids is known to cause hypersensitivity reactions, including anaphylaxis, in some who are administered vaccines containing Thimerosal.

“Three leading federal agencies (CDC, FDA, and NIH) have reviewed the published research on thimerosal and found it to be a safe product to use in vaccines. Three independent organizations [The National Academy of Sciences’ Institute of Medicine, Advisory Committee on Immunization Practices (ACIP), and the American Academy of Pediatrics (AAP)] reviewed the published research and also found thimerosal to be a safe product to use in vaccines. The scientific community supports the use of thimerosal in influenza vaccines.”

Again, the statements made here by the CDC are false and clearly at odds with the ever increasing body of the applicable scientifically sound and appropriate evidence on the toxicity of Thimerosal, sodium ethylmercurithiosalicylate, also known as Merthiolate and Thiomersal, that has:

- ❑ Been published in peer-reviewed scientific journals since the 1930s and
- ❑ Established human toxicity at levels below 1 ppm (more than 100 times lower than the level of Thimerosal in a vaccine preserved with nominally 0.01 % Thimerosal [100 ppm of Thimerosal; 100 µg of Thimerosal {49.55% mercury by weight} per mL of vaccine]).

Further, as any unbiased review of the vaccine literature will show, many of the independent researchers in the scientific community, including this reviewer, do not support any use of Thimerosal in any drug, vaccine or not, or medical procedure and strongly oppose any use of Thimerosal unless scientifically sound and appropriate comprehensive safety studies in at least two animal models having similar susceptibilities to mercury toxicity as humans prove that the level of injected Thimerosal is safe for humans to the standard “**sufficiently nontoxic so that the amount present in the recommended dose of the product will not be toxic to the recipient**” (set forth in **21 CFR**

¹² Since all preservatives are toxic to human cells and may cause and/or enhance adverse reactions in the inoculees, removing any preservative reduces the risks for adverse reactions.

¹³ a. Nelson EA, Gottshall RY. Enhanced toxicity for mice of pertussis vaccines when preserved with Merthiolate. *Appl Microbiol.* 1967; **15**: 590-593.
b. Suzuki T, Takemoto T, Kashiwazaki H, et al. Chapter 12 – Metabolic fate of ethylmercury salts in man and animal. In: **Mercury, Mercurials and Mercaptans**. Miller MW, Clarkson TW (eds). Springfield, IL: Charles C. Thompson Publisher, 1973, pgs. 209-232.
c. Itoi M, Ishii Y, Kaneko N. Teratogenicities of antiviral ophthalmics on experimental animals. *Jpn J Clin Ophthalmol.* 1972; **26**: 631-640.
d. Ellis FA. The sensitizing factor in merthiolate. *Journal of Allergy* 1947; **18**: 212-213.

§ 610.15(a) with a 100-fold safety margin because Thimerosal's mercury-containing metabolites have been shown to cross the blood-brain barrier and act as a source for the bioaccumulative neurotoxicity of mercury, a bioaccumulative toxin with an estimated half-life in the human brain that is about two decades¹⁴ (about one-fourth of the human life span).

Finally, the overall importance of the persistent mercury in the brain has been strengthened by the reality that a number of studies have shown that the dealkylation of alkyl mercury compounds in the brain to form some type of tissue-associated inorganic mercury is not a detoxification process.¹⁵

“Is thimerosal safe when used as a preservative in vaccines?”

“CDC places a high priority on vaccine safety, surveillance, and research.”

Here, the CDC is again misrepresenting where it actually places its priorities.

Based on the relative amounts spent for vaccine programs, supporting new vaccines and the establishment of new national vaccination programs as compared to the amounts spent by the CDC on “*vaccine safety*” and vaccine-adverse-event “*surveillance*”, the reality is that “*vaccine safety*” and vaccine-adverse-event “*surveillance*” have very low priorities.

“CDC is aware that the presence of the preservative thimerosal in vaccines and suggestions of a relationship to autism has raised concerns.”

From the title of this article, “*General Questions and Answers on Thimerosal*”, and its posting on a web page labeled, “http://www.cdc.gov/h1n1flu/vaccination/thimerosal_qa.htm”, it is clear that the CDC is aware of “[T]himerosal in vaccines”.

However, the CDC statement, “*CDC is aware that the presence of the preservative thimerosal in vaccines and suggestions of a relationship to autism has raised concerns*”, is but another cleverly worded, misleading example of empty rhetoric— a statement designed to be, at best, uninformative – that is best characterized as doublespeak.

Parsing the CDC's words, the statement reads:

“*CDC is aware that
the presence of the preservative thimerosal in vaccines and*

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- ¹⁴ a. Aschner M, Aschner JL. Mercury neurotoxicity: mechanisms of blood-brain barrier transport. *Neurosci Biobehav Rev* 1990; **14**: 169-176.
b. Sugita M. The biological half-time of heavy metals. The existence of a third, "slowest" component. *Int Arch Occup Environ Health* 1978; **41**: 25-40.
- ¹⁵ a. Charleston JS, et al. Changes in the number of astrocytes and microglia in the thalamus of the monkey *Macaca fascicularis* following long-term subclinical methylmercury exposure. *Neurotoxicology* 1996; **17**: 127-138.
b. Charleston JS, et al. Autometallographic determination of inorganic mercury distribution in the cortex of *Macaca fascicularis* following long-term subclinical exposure to methylmercury and mercuric chloride. *Toxicol Appl Pharmacol* 1995; **132**: 325-333.
c. Charleston JS, et al. Increases in the number of reactive glia in the visual cortex of *Macaca fascicularis* following subclinical long-term methylmercury exposure. *Toxicol Appl Pharmacol* 1994; **129**: 196-206.
d. Vahter ME, et al. Demethylation of methylmercury in different brain sites of *Macaca fascicularis* monkeys during long-term subclinical methylmercury exposure. *Toxicol Appl Pharmacol* 1995; **134**: 273-284.
e. Vahter M, et al. Speciation of mercury in the primate blood and brain following long-term exposure to methylmercury. *Toxicol Appl Pharmacol* 1994; **124**: 221-229.

*suggestions of a relationship to autism
has raised concerns”.*

Clearly, the CDC’s statement is not only grammatically incorrect on many levels but also as meaningful as the classic statement: “More people climb mountains than in Summer”¹⁶.

“These concerns make the decisions surrounding vaccinations confusing and difficult for some people, especially parents.”

Since the CDC’s previous “*concerns*” statement is, at best, confusing and grammatically deficient, this reviewer agrees that the CDC’s statement certainly “*make the decisions surrounding vaccinations confusing and difficult for some people, especially parents*”.

“Numerous studies have found no association between thimerosal exposure and autism.”

First of all, as stated, the CDC’s assertion here misrepresents reality.

Factually, several published statistical studies of vaccination records and diagnostic outcomes have only failed to find a *statistically significant* association between Thimerosal exposure and autism but, *when the records were examined for an association between the level of Thimerosal exposure and other neurodevelopmental disorders*, many of these studies did find a statistically significant association between the apparent level of Thimerosal exposure from vaccines containing Thimerosal and tics, a neurodevelopmental disorder category that includes childhood Tourette's disorder (a neurological condition that causes the affected child to make sounds or words [vocal tics] and body movements [motor tics] that are beyond the affected child’s control).

Unfortunately, in most all of the CDC’s “[*n*]umerous studies”, the original data sets, study designs and associated selection criteria and set parsing have been either been claimed to be “lost” or otherwise kept from qualified independent epidemiologists and biometricians.

Since the studies alluded to by the CDC cannot be independently replicated, their findings are suspect and each of them should not be used in any scientifically sound decision-making process.

In addition to the studies alluded to by the CDC, but not specifically cited, an approximately equal number of similar published peer-reviewed statistical studies that have been conducted independently using recognized databases containing diagnostic and vaccination records (including, in some instances, similar data sets from the Vaccine Safety Datalink (VSD) database that the CDC used, the Vaccine Adverse Events Reporting System (VAERS) database maintained by the CDC and the FDA, and other sources) and the same general statistical evaluation tools that the CDC recognizes as valid have found a statistically significant association between the incremental level of Thimerosal exposure from vaccines and Rho(D) products and various neurodevelopmental disorders, including autism spectrum disorders and, in some instances, autistic disorder (“*autism*”).

¹⁶ Perhaps the CDC meant to say: “*CDC is aware that the presence of*” Thimerosal “*in*” Thimerosal-preserved influenza “*vaccines and suggestions of*” Thimerosal’s “*relationship to autism*” have “*raised concerns*” – a statement that is both grammatically correct and meaningful.

Since the CDC and the FDA have failed to publish any scientifically sound and appropriate reanalysis of the datasets used in these independent studies though they have had full access to all aspects of these independent studies for more than 5 years in some instances, it is clear to this reviewer that the published independent statistical studies that found these statistically significant associative links between the level of Thimerosal exposure and the risk of any recognized developmental or neurodevelopmental disorder are valid studies despite unsupported statements by CDC officials and an Institute of Medicine committee's report that claimed some of these studies were uninterpretable.

Finally, the recent studies using Thimerosal-preserved hepatitis B vaccines or studying the risk of impairment differences between children that received the triple hepatitis B series at an early age and those children who did not (see footnotes 5 – 8) and a peer-reviewed published comprehensive review¹⁷ in which this reviewer was one of the authors have clearly established that there is scientifically sound outcomes evidence and/or a statistically significant link between the level of Thimerosal exposure and the risk of a number of neurodevelopmental disorders or developmental delays, including, *in some instances*, autism.

Thus, the CDC's implicit claim of “*no association between thimerosal exposure and autism*” is not supported by the scientifically sound and verifiable studies that have found evidence of a statistical link between the timing and/or level of Thimerosal exposure and postnatal neurodevelopmental disorders and/or delays including autism even though the statistical link for autism was not always statistically significant at the “ $p \leq 0.05$ ” level.

“Since 2001, no new vaccine licensed by FDA for use in children has contained thimerosal as a preservative and all vaccines routinely recommended by CDC for children under six years of age have been thimerosal-free, or contain only trace amounts, except for some formulations of influenza vaccine.”

First, the CDC's statement here:

“Since 2001, no new vaccine licensed by FDA for use in children has contained thimerosal as a preservative, and all vaccines routinely recommended by CDC for children under six years of age have been thimerosal-free, or contain only trace amounts, except for multi-dose formulations of influenza vaccine”

is simply a repeat of the CDC's jaundiced view of the reality concerning vaccines and the CDC's recommendations that this reviewer addressed earlier (see page 9).

In general, this reviewer's previous comments have addressed the issues the CDC either misrepresented or failed to recognize.

However, this reviewer would be remiss if he did not point out that, by increasing the mercury exposure from Thimerosal by, beginning in 2002, recommending that pregnant women and children 6 months to 23 months get a flu shot without proscribing the administration of Thimerosal-preserved flu shots to pregnant women and these children, the CDC actually increased the maximum mercury exposure that some children would receive *in utero* and after birth.

In addition, by the CDC's continuing to recommend that both pregnant women and increasingly

¹⁷ Geier DA, King PG, Sykes, LK, Geier, MR. A comprehensive review of mercury provoked autism. *Indian J Med Res* 2008 October; 128: 383-411.

older children get flu shots without proscribing the administration of Thimerosal-preserved influenza vaccines, the FDA's continuing to approve Thimerosal-preserved inactivated-influenza vaccines, and the manufacturers of the approved inactivated-influenza vaccines continuing to produce mainly Thimerosal-preserved doses, the 2009 reality is that the maximum exposure to mercury that a child vaccinated under today's programs will, if continued without further modification, significantly increase a child's maximum exposure to mercury from Thimerosal-preserved vaccines .

This is the case because a child may be exposed to up to 50 µg of mercury from Thimerosal in the seasonal and the A/H1N1 vaccine before birth and at 6 and 7 months both 2, 0.25-mL doses of Thimerosal-preserved seasonal flu and 2, 0.25-mL doses of a Thimerosal-preserved A/H1N1 vaccine may be administered (for an additional exposure to 50 µg of mercury) or a total exposure of nominally 100 µg of mercury by seven months of age.

Then, even if no additional A/H1N1 vaccine doses are administered, the child may be exposed to 12.5 µg of mercury from a Thimerosal-preserved influenza vaccine each flu season until he or she is 3 years old (25 µg of mercury in total) and the up to 25 µg of mercury annually from 3 to 18 years of age (for 15 to 16 more 25- µg doses of mercury [375 – 400 µg of mercury) just from Thimerosal-preserved flu shots – a for a nominal maximum exposure of 500 – 525 µg of mercury.

In contrast, a child being vaccinated according to the CDC's 1999 U.S. vaccination schedule (with DTaP and/or DT and or Td, Hib and Hep B) from birth to 18 years of age with only the FDA-approved Thimerosal-preserved vaccines the CDC recommended at the time (which excludes the Thimerosal-preserved influenza vaccines) would have a maximum nominal exposure to 300 µg of mercury from Thimerosal-preserved vaccines.

Thus, the CDC's, FDA's and manufacturers' knowing actions have combined to actually increase (rather than decrease) a child's maximum nominal exposure to mercury from Thimerosal-preserved vaccines by two-thirds.

“Unfortunately, we have not seen reductions in the numbers of children identified with autism indicating that the cause of autism is not related to a single exposure such as thimerosal.”

Here, the CDC begins by stating “*we have not seen reductions in the numbers of children identified with autism*”, a fact with which this reviewer generally agrees if one takes the CDC's use of the word “*autism*” as a surrogate for general term: autism spectrum disorder (ASD) – which the CDC's and most other surveys actually address.

However, because:

- ❑ The maximum dose of mercury exposure from Thimerosal-preserved shots that a child may receive has not been reduced and
- ❑ In general, the studies being published to date have studied older children (mostly five to eight-year olds born in the period from 1992 to 2000 – a period before Thimerosal was reduced in, much less removed from, any type of vaccine that was Thimerosal-preserved and recommended for administration to children in that period,

no scientist, reviewing these facts, should expect to see “*reductions in the numbers of children identified with*” an autism spectrum disorder.

Further, as this reviewer has shown, the maximum exposure to Thimerosal (49.55% by weight mercury) from Thimerosal-preserved vaccines is actually increasing even though fewer routinely recommended vaccines are Thimerosal-preserved because:

- The CDC has recommended, without the generally required proofs of:
 - Safety for the Thimerosal in the Thimerosal-preserved flu shots for pregnant women, the fetus and children of all ages and
 - In-use effectiveness that is generally required for all drugs, an “annual” influenza vaccination program for pregnant women and children that has increased the doses of a Thimerosal-preserved vaccine to which a child may be exposed from gestation to 18 years of age,
- The FDA has **knowingly** continued to illegally approve Thimerosal-preserved vaccine formulations, including those for several manufacturers’ inactivated-influenza vaccines, for which the manufacturers have **knowingly** failed to prove the safety of the Thimerosal used as a preservative to the required CGMP minimum: “**sufficiently nontoxic so that the amount present in the recommended dose of the product will not be toxic to the recipient**” as required by **21 CFR § 610.15(a)**, and
- The vaccine manufacturers of Thimerosal-preserved vaccines have **knowingly** continued to not only illegally manufacture and distribute Thimerosal-preserved vaccine formulations that are adulterated drugs under **21 U.S.C. § 351(a)(2)(B)** because of the manufacturers’ knowing failure to comply with **21 CFR § 610.15(a)** since 1973 and, since 1999, **21 CFR § 601.2(a)** but also, *in the case of the inactivated-influenza vaccines*, to manufacture most doses of these flu shots as Thimerosal-preserved flu shots.

Thus, the rest of the CD’s statement, “*indicating that the cause of autism is not related to a single exposure such as thimerosal*”, is a knowing attempt to mislead the reader because the maximum exposure to Thimerosal has not been reduced.

Moreover, until:

1. All use of Thimerosal and all other mercury compounds is banned from vaccines and other drugs,
2. All in-date vaccines containing Thimerosal are recalled and properly destroyed, and/or
3. The children being studied:
 - 3.1 Are at least 8 years old and
 - 3.2 Have never been exposed to Thimerosal-containing vaccines or other mercury-containing drug from conception until the completion of the study,

no rational person should expect to see any significant “*reductions in the numbers of children identified with autism*” if, *as the studies cited by this reviewer indicate*, Thimerosal exposure and the risk of autism are truly linked.

Thus, if: **a)** all Thimerosal-preserved vaccines and other drugs containing added mercury compounds were banned and **b)** an immediate recall of all in-date doses of these vaccines and other drugs was initiated today in the U.S., one would need to wait until 2019 (studying the cohort of U.S. children born in 2011) before one could be ensured of finding a general population effect.

Of course, if one were to study healthy children¹⁸ who have never been vaccinated with a Thimerosal-containing vaccine or given another drug containing added mercury solely because of their parents pre-existing opposition to vaccination and the use of drugs for other than for life-threatening infections, then, *after finding a suitably large group of these children and matched control groups of children who had been exposed to varying levels of injected Thimerosal-preserved vaccines (e.g.:*

- *in pregnancy only;*
- *in first year of life only;*
- *in pregnancy and in first year of life;*
- *from 6 months to 23 months only;*
- *in pregnancy and from 6 months to 23 months;*
- *from 6 months to 36 months of age only;*
- *in pregnancy and from 6 months to 36 months of age;*
- *6 months to 5 years of age only;*
- *in pregnancy and from 6 months to 5 years;*
- *from 6 months to 8 years of age only; and*
- *in pregnancy and from 6 months to 8 years of age),*

one could do a study that would determine the statistical significance of the relative risks among the various levels of vaccination and the unvaccinated with respect to “*autism*” (and other neurodevelopmental and developmental disorders and diseases).

From the results obtained, one could then determine the link between Thimerosal dose and the relative risk of “*autism*” (and other neurodevelopmental and developmental disorders and diseases).

However, the CDC has steadfastly refused to even attempt such studies. This stonewalling further indicates to this reviewer that the governmental agencies involved know that Thimerosal from Thimerosal-preserved vaccinations is a significant causal factor in the epidemic increases in:

- ❑ All of the neurodevelopmental disorders (e.g., autistic disorder, PDD-NOS, Asperger’s, ADHD, ADD, OCD, tics, and various learning delays) [to levels as high as 1 in 91, or higher, in 2009] and
- ❑ Many other childhood disorders (e.g., childhood asthma, childhood COPD, childhood Type 2 diabetes, childhood obesity, failure to thrive, mitochondrial dysfunction, food allergies, food intolerances, childhood gastric reflux, childhood MS and other autoimmune diseases, irritable bowel syndrome and celiac disease, to name a few) [to levels that in one instance, asthma, exceed 1 in 10]

that, *when this reviewer finished high school in the 1960s*, were either virtually unknown (e.g., childhood type II diabetes) or rare, having incidence rates of on the order of <1 in 5,000 (e.g., autistic disorder; peanut allergy).

“The federal government is committed to assuring the safety of vaccines. This is achieved by FDA oversight of rigorous pre-licensure trials and post-licensure monitoring by CDC and FDA. This

¹⁸ Because “*autism*” (autistic disorder) is much more prevalent in males than in females (3 – 7 males to 1 female), the groups should be restricted to healthy males in studies where the risk of a diagnosis of “*autism*” is being assessed.

commitment not only stems from our scientific and medical dedication, it is also personal – for most of us who work at CDC are also parents and grandparents. We too, place tremendous value on the health and safety of children.”

For all of the evidence-supported reasons provided by this reviewer, it is obvious that the closing paragraph of the CDC’s article is but empty rhetoric and the unending propaganda and doublespeak that pervades all of the CDC’s pronouncements concerning the believers’ professed “safety” for vaccines, which are factually drugs whose safety:

- ❑ Has never been properly established,
- ❑ Is supported by belief and propaganda as well as biased, misdesigned, and incomplete pseudo-safety studies but not by the scientifically sound and appropriate preclinical and clinical toxicity studies required of the manufacturers by law for all drugs, and,
- ❑ In the case of Thimerosal-preserved vaccines, not supported by the applicable CGMP-mandated toxicity testing because:
 - The manufacturers of said vaccines have *knowingly not* done (as required by **21 CFR § 610.15(a)**, in effect since late 1973) and/or not submitted (as required by **21 CFR § 601.2(a)**, in effect since late 1999) the requisite testing, and
 - The FDA has violated the law (**21 CFR § 601.4(a)**, in effect since early 1977) by approving the licenses of Thimerosal-preserved vaccines without the required proof of safety for the Thimerosal, which demands that the manufacturers prove that the Thimerosal level in their 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**” (see **21 CFR § 610.15(a)**) for each direct recipient group (pregnant women, children by birth cohort and/or developmental stage, adults by age group, and the elderly [those over 60]) as well as, *in the case of pregnant women*, the fetus/quickening child, the indirect recipient of exposure to some portion of the dose (based on animal studies, typically, > 60%).

In closing, this reviewer finds that the actions of the Secretary of HHS, the CDC, the FDA, the NIH and other responsible agencies reporting to the Secretary of HHS speak so loudly that this reviewer cannot hear the doublespeak-filled propaganda, like this article, that they almost continuously issue.

IF they were truly the caring “*parents and grandparents*” who “*place tremendous value on the health and safety of children*”, as claimed here, THEN, in the late 1960s and by 1999 at the latest, “they” would have:

- ❑ Postponed adopting an “annual” influenza vaccination program for women and developing children until:
 - All in-date doses of all of the FDA-approved influenza vaccines were not Thimerosal preserved or
 - The manufacturers of said vaccines had: **a)** proven the safety of their Thimerosal-preserved vaccine formulations to the safety standard set forth in **21 CFR § 610.15(a)** for the fetuses in each trimester of pregnancy, the pregnant

women and developing children and **b)** submitted that proof safety to the FDA in the manufacturers' BLAs as required by **21 CFR § 601.2(a)**.

- ❑ At a minimum, proscribed the administration of any Thimerosal-preserved vaccine to pregnant women and developing children until the proof of safety required by **21 CFR § 610.15(a)** was provided by the manufacturers of each Thimerosal-preserved vaccine formulation,
- ❑ Banned all use of Thimerosal, sodium ethylmercurithiosalicylate, a proven human carcinogen, mutagen, teratogen, and immune-system disruptor at Thimerosal levels below 1 pm, as a preservative in medicine unless the manufacturer could prove, with a 100-fold safety margin, that the Thimerosal meets the requirements set forth in **21 CFR § 610.15(a)** for each recipient group, and
- ❑ Recalled all in-date packages of all drugs containing any added mercury compound for which the requisite proof of safety is missing or the data shows toxicity, and properly destroyed them as the hazardous waste such drugs are.

Since “they” have taken none of the suggested actions that those who do “*place tremendous value on the health and safety of children*” would have taken, it is clear that their actions belie their implicit claim that they are parents and grandparents who “*place tremendous value on the health and safety of children*”.

Finally,

- ❑ The timing of the CDC’s recommendations to vaccinate pregnant women and young children (in early 2002, when the Thimerosal-preserved RhoGAM was being phased out and, for young children, the supply of Thimerosal-preserved DTtaP, Hib and Hep B vaccine doses was beginning to decline) and
- ❑ The CDC’s broad recommendations to vaccinate:
 - Pregnant women who would be in their 2nd and 3rd trimesters of pregnancy with a Pregnancy Category C drug for which there were no proofs of reproductive or fetal safety and
 - Young children, 6 – 23 months of age, even though the available studies indicate that influenza vaccine doses provided no more protection to children under 2 years of age from contracting the influenza virus during the flu season than a placebo injection of pH-balanced sterile isotonic saline

clearly indicate a deliberate action by the CDC to replace the mercury doses being lost by the phase out of certain Thimerosal-preserved drugs (i.e., RhoGAM and several early childhood vaccines) with mercury doses from the Thimerosal-preserved inactivated-influenza vaccines added by the CDC’s April 2002 recommendations¹⁹ without any real concern about the potential adverse health effects that these actions might cause.

When viewed in the light of the preceding realities, it is clear that the CDC did not and, *because it continues to refuse to even state a preference for the “no Thimerosal” flu shots*, does not care about the “*health and safety of children*” nor about the potential adverse reproductive health effects of Thimerosal-preserved vaccine doses on pregnant women.

¹⁹ 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.

REVIEWER'S CONCLUDING REMARKS

Hopefully, the Secretary of Health and Human Services and the CDC that reports to the Secretary will provide this reviewer, the readers of this review and the American public, with scientifically sound and factual studies that address the toxicity and risk issues as well as the court case citations that establish that the Secretary, CDC, FDA and/or the vaccine manufacturers are not bound by the U.S. policies, laws and statutes governing vaccines, in specific, and drugs, in general.

Absent a satisfactory response that addresses all of the salient points raised in this review with proof and not, *as the original document mostly does*, unsupported rhetoric, this reviewer must recommend that CoMeD take appropriate action, under the applicable provisions of the applicable codified statutes and current regulations issued to comply with the "Data Quality Act" as enacted by Congress in the FY 2001 Consolidated Appropriations Act (Public Law 106-554) at section 515 (with underlining added for emphasis):

"Sec. 515. (a) In General. – The Director of the Office of Management and Budget shall, by not later than September 30, 2001, and with public and Federal agency involvement, issue guidelines under sections 3504(d)(1) and 3516 of title 44, United States Code, that provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies in fulfillment of the purposes and provisions of chapter 35 of title 44, United States Code, commonly referred to as the Paperwork Reduction Act.

(b) Content of Guidelines. – The guidelines under subsection (a) shall –

(1) apply to the sharing by Federal agencies of, and access to, information disseminated by Federal agencies; and

(2) require that each Federal agency to which the guidelines apply –

(A) issue guidelines ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by the agency, by not later than 1 year after the date of issuance of the guidelines under subsection (a);

(B) establish administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency that does not comply with the guidelines issued under subsection (a); and

(C) report periodically to the Director –

(i) the number and nature of complaints received by the agency regarding the accuracy of information disseminated by the agency; and

(ii) how such complaints were handled by the agency".