The Viability of Using Non-mercury Preservatives in Vaccines

Prepared by the Coalition for Mercury-Free Drugs (CoMeD), Inc., 2010 ©

At question: The use of Thimerosal[1], a recognized human carcinogen, mutagen, teratogen, reproductive toxin, and immune-system disruptor that is 49.55% by weight bioaccumulative mercury, in vaccines[2].

Eli Lilly Thimerosal MSDS Warning: *"Exposure to mercury in utero and in children may cause mild to severe mental retardation and mild to severe motor coordination impairment."*

Summary:

- Use of Thimerosal as a preservative in biologics is both historic and indefensible, in terms of 21st Century science, medicine, law[3] and ethics.
- In 1999, The U.S. Public Health Service and the American Academy of Pediatrics jointly called for Thimerosal to be removed from vaccines as soon as possible.
- The prudent and ethical transition to a safer and more effective preservative is encountering massive resistance from industry and health agencies.
- Issues of damage and liability are preventing institutions, which perpetuate the use of Thimerosal, from objectively judging this public health issue.
- As lead was eliminated from paint and gasoline, so too will mercury compounds, which are 10 to 100 times more toxic than their lead analogs, be banned from vaccines and other drugs only after they have already damaged generations of children.

The Alternatives

Based on a survey of U.S.-FDA-approved preserved vaccines, other viable alternatives to Thimerosal as a preservative in commercial vaccines packaged in multidose vials are:

- **phenol** [used in the Typhoid Vi Polysaccharide (Typhim Vi; Sanofi Pasteur, SA) and the Pneumococcal Polysaccharide (Pneumovax 23; Merck & Co, Inc) vaccines], and
- **2-phenoxyethanol** [used in the DTaP (Infanrix®; GSK), Hepatitis A (Havrix ®; GSK), Hepatitis A/Hepatitis B (Twinrix ®; GSK) and IPV (IPOL®; Sanofi Pasteur, SA) vaccines]

Relative Toxicities

In decreasing order, the relative toxicities (human cell to bacterial cell) of the following compounds are:

Thimerosal (> 330-fold) >> Phenol (12.2-fold) > 2-phenoxyethanol (4.6-fold)[4].

With respect to the least toxic compound, 2-phenoxy ethanol (2-PE):

- Vaccine makers have already replaced Thimerosal with 2-PE in many vaccines,
- 2-PE is more than 100-fold safer to use at vaccine preservative levels (2.5%) than Thimerosal (0.01%), and
- 2-PE is not converted into a bioaccumulative toxin (tissue-bound inorganic mercury) like Thimerosal is.

Progress in vaccine safety demands rapid movement to less toxic preservatives if public confidence in the vaccine program is to be preserved.

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[1] Though patented in 1928 and first marketed as a preservative for biologics in the 1930's by Eli Lilly, Thimerosal remains in use today without any proof of safety even though proof of safety to the toxicological standard "sufficiently nontoxic …" has been mandated by the FDA since 1973 (see **21 CFR 610.15(a)**).

[2] "Manufacturers of vaccines and thimerosal, (an ethylmercury compound used in vaccines), have never conducted adequate testing on the safety of thimerosal. The FDA has never required manufacturers to conduct adequate safety testing on thimerosal and ethylmercury compounds." ("Mercury in Medicine—Are We Taking Unnecessary Risks?" Government Reform Committee, May 2003)

[3] **21 CFR 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,"

[4] Geier DA, Jordan SK, Geier MR. The relative toxicity of compounds used as preservatives in vaccines and biologics. ***Med Sci Monit***. 2010 Apr 28; **16**(5): SR21-SR27.

The 2-phenoxyethanol (2-PE) Alternative to Thimerosal is Economical

The U.S.-$-per-0.5-mL-dose cost[5] for:

- Thimerosal, USP, in a 0.01% Thimerosal-preserved vaccine is about: **U.S. $ 0.000441**;
- 2-phenoxyethanol, Ph Eur, in a 2.5% 2-phenoxyethanol-preserved vaccine is: **U.S. $ 0.00228**.

This apparent **U.S. $ 0.001839** increased cost per dose would be offset by:

- The reduced costs associated with its handling, and
- The 2+% reduction in the amount of water-for-injection needed per dose.

Thus, the reduction in the hazard would offset the minor increase in the per-dose cost for using 2-PE.

Elimination of the Use of Thimerosal:

"We agree that we do not need to have thimerosal in vaccines. If it doesn't need to be there, we should take it out. And we should take it out as rapidly as possible. We have agreed to that. The Public Health Service, the vaccine manufacturers, and the academies are all in agreement …"

(Dr. Roger Bernier, Chief Science Advisor to the CDC, "Mercury in Medicine—Are We Taking Unnecessary Risks?" – Sworn Testimony to the Government Reform Committee, July 18, 2000, Serial No. 106-232)

"Resolved: The United Methodist Church support all efforts to protect the public, especially children, from mercury-containing drugs by calling on the World Health Organization, international and national health officials/agencies to: …ban the presence of any mercury compound in pharmaceutical products or vaccines, prescribed or over-the-counter."

(The Book of Resolutions of the United Methodist Church, 2008, pp. 372-377)

Industry Concerns Regarding the Use of Thimerosal:

"In other words, Merthiolate [i.e, Thimerosal] is unsatisfactory as a preservative for serum intended for use on dogs… we have tested Merthiolate on humans and find that it gave a more marked…reaction than does phenol or tricresol."

(July 22, 1935, the Pitman-Moore Company in a letter to Eli Lilly and Company)

"The ethical justification for continued use of Thimerosal-preserved multidose vials in developing countries would be based on the greater importance of disease prevention than the real hazard from giving small amounts of mercury preservative…"

(Merck's Vaccine Task Force Report, "Thimerosal (Merthiolate) Preservative – Problems, Analysis, Suggestions for Resolution", 1991)

"Conclusions...Thimerosal is not an effective preservative compared to 2-PE [i.e., 2-phenoxyethanol] ... The data support the use of 2-PE as a more effective preservative with the potential to replace thimerosal, the most commonly used preservative in multi-dose vaccine formulations."

("Development of a Multi-Dose Formulation of Prevenar 13" Lakshmi Khandke, et al., supported by the World Health Organization, GAVI Alliance, UNICEF, the Bill & Melinda Gates Foundation, and Pfizer)

US Government Concerns Regarding the Use of Thimerosal *(non-health agencies)*:

"...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...Our public health agencies' failure to act is indicative of institutional malfeasance for self-protection and misplaced protectionism of the pharmaceutical industry."

("Mercury in Medicine—Are We Taking Unnecessary Risks?" Government Reform Committee, May 2003)

"…based on the publicly available information…it appears there may be sufficient evidence to find a substantial likelihood of a substantial and specific danger to public health caused by the use of thimerosal/mercury in vaccines because of its inherent toxicity."

(US Special Counsel Scott Bloch, Letter to Congress, May 20, 2004)

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[5] Based on Sigma-Aldrich on-line pricing on 23 Dec 2010 for the USA.