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Thursday, 29 March 2012

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Dear Dr. Wood:

This letter is in response to the email you and the World Health Organization (WHO) sent to our organization, the Coalition for Mercury-free Drugs (CoMeD), Inc. on 22 March 2012. You invited CoMeD to participate in an open information session on 3 April 2012, regarding the presence of mercury (Thimerosal) in vaccines, acknowledging that this consultation is being convened for the purpose of scientific exchange. We appreciate that you recognize there are voices, in addition to those within WHO, that wish to be heard. While recognizing this, you noted, nonetheless, that the WHO informal consultation, which follows on 3 and 4 April 2012, to discuss this same topic, is closed to our participation.

This WHO consultation will respond to questions being asked by the nations involved in the United Nations Environmental Program (UNEP), through its Intergovernmental Negotiating Committee (INC), which is preparing a global legally-binding treaty on mercury. Specifically, you acknowledge that countries have requested additional information on alternative preservatives (e.g. 2-phenoxyethanol) for vaccines, and on the economic, programmatic and manufacturing implications of moving (globally) to single dose, preservative-free vaccines, before INC4, scheduled to be held 27 June ï 2 July, 2012 in Punta del Estes, Uruguay. Clearly, the nations understand that mercury-free vaccines set the standard in vaccine safety by avoiding the use of an unnecessary and dangerous neurotoxin, teratogen, mutagen, carcinogen and immune-system disruptor in human pharmaceuticals, especially in vaccines intended for the most vulnerable among us, pregnant women and children.

While CoMeD applauds WHO for giving the issue of mercury in vaccines and other drugs the urgent attention it merits, especially in light of 70 years of published scientific literature demonstrating harm from Thimerosal, my organization must also express its profound concern that independent scientists, who have sounded the alarm about the dangers of Thimerosal for decades, are being excluded from the WHO consultation.

CoMeD expresses this concern, in light of a history of óclosed doorô statements, made by WHO and others on Thimerosal that we have gathered over the years. We do not presume that you are familiar with these troubling statements or the óclosed doorô meetings in which they were made. By bringing them to your attention, we hope you will realize that any meeting sponsored by the WHO on Thimerosal must be absolutely transparent and open, if world leaders are to have confidence in the conclusions and recommendations which will result from such a meeting.

Therefore, let me cite the following examples of WHO statements on Thimerosal, issued behind óclosed doorsô, which CoMeD finds particularly troubling.

A 'closed door' meeting (7-8 June 2000) of US Health officials, pharmaceutical representatives and officials from WHO, took place at Simpsonwood United Methodist Retreat Center in Norcross, Georgia, USA. A confidential study: ñRisk of Neurologic and Renal Impairment Associated with Thimerosal-containing Vaccines,ò conducted by the US Centers for Disease Control and Prevention (CDC) and discussed at this meeting, revealed the following findings **[**emphasis added**]**:

> ñResults: we identified 3517 children with neurologic disorders, and 106 with renal disorders. We found a statistically significant positive correlation between the following measures of exposure and outcomes:
>
> * the cumulative exposure at 2 months of age and unspecified developmental delay
> * the cumulative exposure at 3 months of age and tics
> * the cumulative exposure at 6 months of age and attention deficit disorder
> * the cumulative exposure at 1, 3 and 6 months of age and language and speech delay
> * the cumulative exposure at 1, 3 and 6 months of age and neurodevelopmental delays in general
>
> Conclusion: **This analysis suggests that in our study population, the risk of tics, ADD, language and speech delays, and developmental delays in general may be increased by exposure to mercury from thimerosal containing vaccines during the first six months of life**..."

But, most significant for the purposes of this letter, the transcript records the following comments by Dr. Clements of the WHO (p. 247 of the transcript) **[emphasis added]**:

> "I am really concerned that we have taken off like a boat going down one arm of the mangrove swamp at high speed, when in fact there was not enough discussion really early on about which way the boat should go at all. And I really do want risk offending everyone in the room by saying that perhaps this study should not have been done at all, because the outcome of it could have to some extent, been predicted, and we have all reached this point now where we are left handing...But nonetheless, we know from many

experiences in history that the pure scientist has done research because of pure science. But the pure science has resulted in splitting the atom or some other process which is completely beyond the power of the scientists who did the research to control it. And what we have here is people who have, for every best reason in the world, pursued a direction of research. But there is no the point at which the research results have to be handled, and even if this committee decides that there is no association and that information gets out, the work that has been done and through the freedom of information that will be taken by others and will be used in ways beyond the control of this group. And I am very concerned about that as I suspect it is already too late to do anything regardless of any professional body and what they say. **My mandate as I sit here in this group is to make sure at the end of the day that 100,000,000 are immunized with DTP, Hepatitis B and if possible Hib, this year, next year and for many years to come, and that will have to be with Thimerosal-containing vaccines**..."

A second example of "closed door" statements which concern CoMeD is found in the report "WHO INFORMAL MEETING ON REMOVAL OF THIOMERSAL FROM VACCINES AND ITS IMPLLICATIONS FOR GLOBAL VACCINE SUPPLY," conducted on 21 May 2002 at the WHO Headquarters in Geneva, Switzerland. The text states [emphasis added]:

"As part of a number of other activities, WHO organized a meeting with manufacturers that supply vaccines to the United Nations agencies in order to achieve a better understanding of the different approaches taken by manufactures, to discuss the implications of the current WHO policy on keeping thiomersal in multidose vial presentations and to consider the implications of different actions for manufacturers. **The group considered two possible scenarios: to take thiomersal out of vaccines or keep it in.**"

Disturbingly, the document records:

"WHO is concerned about the current situation whereby manufacturers in developed countries have been forced to lower thiomersal content of their vaccines..."

Finally, the notes also indicate the following dubious WHO strategies **[emphasis added]**:

"On analysis of the Pros and the Cons of the various alternatives, the group considered that **the best option would be to maintain acceptance of thiomersal in vaccines for the global market.**

The actions required from WHO in order to ensure continued availability of these vaccines include the following:

* Clarify the regulatory situation
* Lobby Ministry of Health and senior regulators.
* Continue dialogue with EMEA, Korea and Canada
* Learn about the potential use of the USA export provisions
* Contact potential recipient countries (of bulk) to see if they would play a bigger regulatory role and become finishers of the vaccines

* **Develop a strong advocacy campaign to support ongoing use of thiomersal**
* Involve developing country regulatory agencies in all these decisions"

The results of these óclosed doorô meetings include repeated, and we believe untrue, declarations that there is no evidence of harm from the use of Thimerosal in vaccines and that vaccines in the developing world must contain Thimerosal. Such unfounded assertions have led to two standards of vaccine safety, one which is nominally mercury-free for developed ñwesternò countries, and one that is mercury-preserved for developing countries. The existence of a two-tier standard of vaccine safety clearly reveals a lack of ethics and honesty for all the world to see.

The inaction of WHO on the issue of mercury in medicine, and the absence of any steps by WHO to stop the use of Thimerosal in human pharmaceuticals, especially in vaccines, calls into question WHOôs leadership. Worse yet, the expressed commitment by WHO in these óclosed doorô statements to advocate the use of Thimerosal as an acceptable, ñsafeò component of vaccines, regardless of the risk, especially in developing countries, underscores how critical the need for an open and transparent process is at this time. This iatrogenic exposure is foisted among the most vulnerableð developing children and developing nations, while the ódeveloped worldô has ostensibly switched to Thimerosal-reduced and/or Thimerosal-free vaccines for its children.

This situation is clearly immoral, and has placed public confidence in the global vaccine program in jeopardy. With the new UNEP mercury treaty, the omnipresence of mercury in the global vaccine supply can no longer be denied, nor can the feasibility of replacing it with much safer alternatives. *(Please find enclosed CoMeD's own document, "The Viability of Using Non-mercury Preservatives in Vaccines", which has been circulated worldwide to the diplomatic and scientific participants in the UNEP INC process.)* The time for historic safety reforms in the manufacture of vaccines and other drugs has arrived.

CoMeD has a scientific team of world-renowned experts who have extensively published peer-reviewed scientific/medical publications and given presentations worldwide on the problems with the use of Thimerosal in vaccines. In addition, we can name professors from major universities in the United States and academic faculty from almost every continent who could make valuable contributions to any scientific meeting on this issue. We and others seek to be allies in the process of making vaccines safer and of safeguarding public trust in vaccines. We do not accept that vaccine safety is static nor that a known neurotoxin, with no established toxicological safety limit for its use in injectable vaccines, must be used in the manufacture of human pharmaceuticals. To the contrary, we assert that if the global immunization program is to continue, mercury must be banned, and banned immediately, from vaccines.

In light of the óclosed doorô statements we have herein quoted, and the expertise we freely offer, we urge you to initiate not a closed, but an open scientific and ethical re-consideration of the use of Thimerosal in vaccines and other drugs. Yet another 'closed door' meeting of WHO personnel, intent on protecting the place of Thimerosal in vaccines, will only increase the global distrust in the vaccine program. CoMeD is committed to ensuring a safe and effective worldwide vaccine program, with <u>one standard</u> of safety for all.

As CoMeD published in our 2007 study, "A Review of Thimerosal (Merthiolate) and its ethylmercury breakdown product: specific historical considerations regarding safety and effectiveness" in the *Journal of Toxicology and Environmental Health B: Critical Reviews*,

> ñWith no warning, recall, or ban of mercury in vaccines and other drugs as of yet, the victim of this mandated, unwarranted, and massive mercury exposure is still an unsuspecting public, and most especially its unborn and newborn children.ò

As a religious leader, an advocate for vaccine safety, and the mother of a child disabled for life by Thimerosal in his vaccines, I ask you to give this request, and the critical information it contains, your utmost consideration.

Sincerely,

Reverend Lisa K. Sykes, President
Coalition for Mercury-free Drugs (CoMeD, Inc.)

Enclosure: CoMeD document: *"The Viability of Using Non-mercury Preservatives in Vaccines"*

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-phenoxyethanol (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 1930ôs by Eli Lilly, Thimerosal remains in use today without any proof of safety even though proof of safety to the toxicological standard ñsufficiently nontoxic é ò has been mandated by the FDA since 1973 (see **21 CFR 610.15(a)**).

[2] ñManufacturers 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.ò (ñMercury in Medicineð Are We Taking Unnecessary Risks?ò Government Reform Committee, May 2003)

[3] **21 CFR 610.15(a)**: ñAny 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,ò

[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 doesnôt 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 é "

(Dr. Roger Bernier, Chief Science Advisor to the CDC, ñMercury in Medicineð Are We Taking Unnecessary Risks?ò ï Sworn Testimony to the Government Reform Committee, July 18, 2000, Serial No. 106-232)

ñResolved: 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: é ban the presence of any mercury compound in pharmaceutical products or vaccines, prescribed or over-the-counter.ò

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

Industry Concerns Regarding the Use of Thimerosal:

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

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

ñThe 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 <u>real</u> hazard from giving small amounts of mercury preservativeé ò

(Merckôs Vaccine Task Force Report, ñThimerosal (Merthiolate) Preservative ï Problems, Analysis, Suggestions for Resolutionò, 1991)

ñConclusions...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.ò

(ñDevelopment of a Multi-Dose Formulation of Prevenar 13ò 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)*:

ñ...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.ò

(ñMercury in Medicineð Are We Taking Unnecessary Risks?ò Government Reform Committee, May 2003)

ñé based on the publicly available informationé 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.ò

(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.