

September 22, 2011

Mr. Fernando Lugris, Chair The Intergovernmental Negotiating Committee, UNEP Ministro Consejero Embajada de Uruguay Budapest Street No. 32 10787 Berlin Germany

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Honorable Chair Lugris:

Please accept the enclosed introduction and review of a US Government filing, "Scientific Information Regarding the Use of Thimerosal As a Preservative in Vaccines", which follows this cover letter as a submission by the Coalition for Mercury-free Drugs (CoMeD, Inc.) to the Intergovernmental Negotiating Committee (INC3) to be held in Nairobi, Kenya from Oct. 31-Nov. 4, 2011.

The review provides a point-by-point rebuttal of the unsigned and unattributed US Government filing as well as the science that clearly shows that, in general, the statements in the US filing fail to use a scientifically sound toxicity estimate for the level at which injected Thimerosal, a mercury-containing compound used in vaccines, is "nontoxic".

Further the US document fails to provide any toxicity data demonstrating that the Thimerosal level in a Thimerosal-preserved vaccine meets the binding US regulation for preservatives in biological drug products as set forth in Title 21 of the US Code of Federal Regulations in Section 610.15(a) [21 CFR Sec. 610.15(a)], required by US law since 1973.

Hopefully, this review will help the delegates to understand the fundamental toxicological problems involved in proving that the Thimerosal used as a preservative in Thimerosal-preserved vaccines is "sufficiently nontoxic sufficiently nontoxic so that the amount present in the recommended dose of the product will not be toxic to the recipient" as set forth in 21 CFR Sec. 610.15(a).

As Russia did in 1983, the Scandinavian countries did in the 1990s, and other nations are currently in the process of doing, we urge that all those participating in INC3 support the inclusion of human pharmaceuticals in Annex C of the revised text for the legally binding instrument on mercury.

Respectfully,

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Encl.: Introduction and A Review of 'Scientific Information Regarding the Use of Thimerosal As a Preservative in Vaccines', 69 pages