



safeMinds

Sensible Action For Ending Mercury-Induced
Neurological Disorders

What is Thimerosal?

Thimerosal (or thiomersal) is a mercury-based medical preservative, developed in the 1920s, that contains 49.6% ethyl mercury by weight. As part of the Food and Drug Administration (FDA) Modernization Act, an assessment of thimerosal's use in vaccines was conducted from 1997 to 1999. The FDA investigation was unable to locate any clinical studies formally evaluating the use of thimerosal before its initial marketing in the 1930's. The only study found was from 1931 where thimerosal was administered to individuals suffering from meningitis. The study was not designed to specifically examine toxicity; no clinical assessments were described nor were laboratory studies reported prior to its introduction as a preservative. Since the 1930's thimerosal has been used in a wide range of medical applications both as a preservative in vaccines (human and veterinary), immunoglobulin preparations, antivenins, ophthalmic, otic and nasal products, and in numerous laboratory reagents. The continued use of thimerosal in the 21st century has come under increased scrutiny and several countries have already phased out the use of thimerosal in medical products.

What Impact Does it Have on the Environment?

According to a report issued by the U.S. FDA, there are 219 pharmaceutical products which contain mercury. Those products result in approximately 75 to 80 kilograms of mercury consumption on an annual basis in products such as nasal solutions/sprays, ophthalmic solutions/ointments, otic solutions, vaccines, and other injectable products. Thimerosal is also used in numerous laboratory reagents for routine lab testing. The manufacturing and disposal process for these products also results in human exposures, as does the elimination of these products into our municipal waterways from both human and animal waste. In fact, one study suggests that wastewater that results from vaccine production processes are polluted with thimerosal concentrations ranging from 25 to 50 mg/L, 500 to 1000 times the European limit for mercury effluent discharges of 0.05 mg Hg/L. The typical concentration of ethyl mercury used in injectable products preserved with thimerosal is 50,000 ppb. In the United States, the Environmental Protection Agency (EPA) requires liquid waste which exceeds 200 ppb of mercury to be sent to a hazardous waste landfill and drinking water cannot exceed 2 ppb of mercury. Unused thimerosal-preserved vaccines must be disposed of as hazardous waste.



End Thimerosal Pollution

View Summary of Science Demonstrating the Harmful Nature of Mercury
at <http://www.safeminds.org/research/science-summary.html>

Is Thimerosal Toxic?

Hundreds of scientific studies published over the past five decades have demonstrated the significant toxicity of thimerosal, calling for the removal or restriction of its use in all products. The scientific evidence that thimerosal causes reproductive and developmental toxicity is well documented and acknowledged by the manufacturer's Material Safety Data Sheet. Thimerosal is recognized as a reproductive toxin and exposure during pregnancy can disrupt the development of the fetus or cause fetal death. Once injected, thimerosal disassociates in the body into ethyl mercury and evidence for its reproductive toxicity includes severe mental retardation or malformations in infants whose mothers were exposed to ethyl mercury or thimerosal while pregnant and studies in animals documenting developmental toxicity. Experts contend that there are "windows of vulnerability" during neurological development and that specific types of developmental outcomes may have separate windows of vulnerability. These critical periods occur during both prenatal development of the fetus and postnatal development of the infant and may be relatively short in duration. Even minor neurological impairment can have profound societal effects when amortized across the entire population and life span.

What is Being Done to Reduce Exposure?

Government regulators, public health officials and pharmaceutical companies have recognized that the level of concern that arises from the utilization of mercury in products, especially those to which people are directly exposed, justifies a preventive approach to minimize all exposure. In 1999 the U.S. Public Health Service which includes the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC) and the Health Resources and Services Administration (HRSA) along with the American Academy of Pediatrics jointly called for the reduction or elimination of thimerosal from vaccines. In 2004, the Institute of Medicine urged that full consideration be given to removing thimerosal from any biological product to which infants, children, and pregnant women are exposed. That same year the United Kingdom Department of Health announced it would no longer use thimerosal in infant vaccines. In June, 2005, the European Council endorsed the European Commission's Mercury Strategy and underlined the importance of addressing residual uses of mercury including vaccines. The European Parliament, in its March 2006 resolution on the mercury strategy, called upon the Commission to address the issue with a view to achieve restriction of thimerosal use, and eventually a total ban.

What Are the Alternatives and Costs?

According to a survey of U.S. FDA approved preservatives conducted by Co-Med two other alternatives readily exist, phenol and 2-phenoxyethanol. Phenol is used as a preservative in Typhoid Vi Polysaccharide vaccine (Typhim Vi) manufactured by Sanofi Pasteur and the Pneumococcal Polysaccharide vaccine (Pneumovax 23) manufactured by Merck. 2-phenoxyethanol is used in the DTaP vaccine (Infanrix), the Hepatitis A vaccine (Havrix), and the Hepatitis A and

B vaccine (Twinrix) manufactured by Glaxo Smith Klein and the injectable polio vaccine (IPOL) manufactured by Sanofi Pasteur. The cost increase based on current U.S. dollars to purchase 2-phenoxyethanol in comparison to thimerosal is estimated to be \$0.001839 per dose. This small increase in cost would be offset by the reduction in pollution and need for pollution control measures related to the use of a mercury-based product.

How to Reduce Exposure.

It is important to note that none of the "live" vaccines including oral polio, measles, mumps, rubella (MMR), yellow fever or tuberculosis (BCG) have ever contained thimerosal and current immunization programs will not be impacted. However, thimerosal is still used in many diphtheria, pertussis and tetanus (DPT), tetanus toxoid (TT), hepatitis B, influenza vaccines and possibly others, especially in developing countries. To date it has been relatively easy to replace, reduce, or eliminate thimerosal as a preservative in single and multi-dose vaccines in most industrialized countries. The World Health Organization maintains that a preservative is necessary in multi-dose vaccine preparations, especially in developing countries. Fortunately, there are other readily available products that are approved for use as vaccine preservatives such as 2-phenoxyethanol, benzethonium chloride and phenol that do not contain mercury, are much less toxic, and whose cost is comparable to that of thimerosal. The continued use of thimerosal is unjustifiable and urgent efforts are needed to phase out its use in all products globally. It is unethical and unjust to continue the exportation of thimerosal-containing products from countries where they are no longer accepted into other less-developed countries.

