

Thimerosal for Vaccines: AAP Endorses WHO Statement

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The American Academy of Pediatrics (AAP) has endorsed the World Health Organization's (WHO's) Strategic Advisory Committee (SAGE) recommendation that thimerosal, a preservative used to prevent contamination in multidose vaccine vials, be exempted from a pending international treaty aimed at reducing global health hazards by limiting exposure to mercury, according to a statement [published online](#) December 17 in *Pediatrics*.

The Pediatric Infectious Diseases Society and the International Pediatric Association have also endorsed the WHO SAGE recommendation.

In 1999, the AAP, in a joint statement with the US Public Health Service, advocated for elimination of mercury in vaccines but retired that recommendation in 2002. Three commentaries published simultaneously in *Pediatrics* support the AAP endorsement, provide perspective, and advocate for the continued use of thimerosal in vaccines.

At this time, the United Nations Environmental Program is developing an international treaty that would call for elimination of any controllable mercury pollution and exposure around the world. Under consideration, in addition to removing mercury from thermometers and other medical devices, is the removal of thimerosal from vaccines.

Such an action, according to WHO's SAGE [document](#) and the current commentators in *Pediatrics*, would severely limit current vaccine programs, particularly in developing countries, primarily because of limited manufacturing capacity to eliminate thimerosal and switch to single-use vials. In addition, no consensus alternative preservatives currently exist.

Thimerosal contains ethyl mercury, which has not been associated with any of the toxic effects linked to its relative compound, methyl mercury, a known neurotoxin. Studies since the late 1990s have found no evidence of harm from using thimerosal in vaccines, and the WHO endorsed the use of thimerosal in vaccines in 2008.

Overwhelming Evidence

In one of the [commentaries](#), Walter A. Orenstein, MD, from Emory University in Atlanta, Georgia, and colleagues write, "Overwhelmingly, the evidence collected over the past 15 years has failed to yield any evidence of significant harm, including serious neurodevelopmental disorders, from use of thimerosal in vaccines."

They add that increases in manufacturing costs in switching from multidose to single dose would "vary greatly from country to country, ranging from 200% to >500%. Single-dose vials would reduce manufacturing capacity and increase the amount of transportation and storage space required more than threefold. The resulting cold-chain requirements would be untenable in many areas of the world because of programmatic challenges and increased workload."

Although thimerosal is not generally used in the United States, where vaccines are now single-dose, it is still used for seasonal influenza vaccines, Dr. Orenstein and colleagues write. "Even in the United States, thimerosal could be critical for dealing with emergencies and the need to rapidly increase vaccine supply and delivery, such as during a serious pandemic of influenza."

In [another commentary](#), Louis Z. Cooper, MD, a pediatrician with the College of Physicians and Surgeons at Columbia University, New York City, and Samuel L. Katz, MD, a pediatrician with the School of Medicine at Duke University, Durham, North Carolina, write that the 1999 recommendation was a quick response to a US Food and Drug Administration review of mercury content in biological products after passage of the Food and Drug Modernization Act of 1997. The review authors at that time concluded that the cumulative amount of mercury from vaccines given to young infants "could potentially" exceed US Environmental Protection Agency guidelines, which had wide safety margins.

At the time, no studies had evaluated whether thimerosal was safe, so the AAP and the US Public Health Service "were obligated to full public disclosure," Dr. Cooper and Dr. Katz write. "Data were not sufficient to explain the pharmacology or toxicology of this product or to compare it with that for the other mercury compounds," they add, explaining that "[t]he priority to 'first, do no harm' guides all [US Public Health Service] and AAP recommendations."

Had they been working from today's knowledge base, they continue, "it is inconceivable to us that these organizations would have made the joint statement of July 7, 1999."

Global Justice

In the [third commentary](#), Katherine King, PhD, from the Keenan Research Centre, Li Ka Shing Knowledge Institute, St. Michael's Hospital, Toronto, Ontario, Canada, and colleagues write that some nongovernmental organizations oppose exempting thimerosal from the treaty, saying it would be "unjust to allow thimerosal to be used in [low- and middle-income countries] when its use has been all but phased out in wealthier nations." Quite the contrary, Dr. King and associates write, the nongovernmental organizations' "critique is misplaced. There is no injustice in allowing the use of thimerosal in vaccines. Rather, the real threat of injustice comes from considering the removal of this currently necessary and irreplaceable compound from the global vaccine supply, and the avoidable increases in morbidity and mortality that would inevitably result from disruptions to vaccination programs targeting already marginalized populations."

Eliminating thimerosal would effectively eliminate multidose vaccines such as tetanus toxoid, diphtheria-tetanus-whole cell pertussis, and hepatitis B vaccines, they explain.

"Currently, multidose vaccines containing thimerosal are used in >120 countries to immunize ~84 million children every year, saving the lives of ~1.4 million people annually," they write.

Dr. King and colleagues are members of the Ethical, Social, and Cultural Program for Global Health, which receives funding from the Bill & Melinda Gates Foundation. Authors of the other commentaries have disclosed no relevant financial relationships.

Pediatrics. Published online December 17, 2012. [Statement](#), [Orenstein commentary](#) [Cooper and Katz commentary](#), [King commentary](#)

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