

Ban on Thimerosal in Draft Treaty on Mercury: Why the AAP's Position in 2012 Is So Important

A draft treaty under consideration by the United Nations Environmental Program has been prepared to greatly reduce global health hazards from environmental mercury.¹ In response to the draft treaty, the World Health Organization urges removal of a provision in the treaty that calls for a ban on thimerosal (which contains ethyl mercury) in vaccines, a position recently endorsed by the American Academy of Pediatrics (AAP) and the US Public Health Service (USPHS).

Removal of the ban on thimerosal-containing vaccines (TCVs) represents a significant reversal of the position expressed in an AAP/USPHS joint statement in 1999 that called for elimination of mercury in vaccines and the subsequent actions taken in the United States.² Understanding the circumstances that led 14 years ago to the 1999 statement and the knowledge accumulated in these subsequent years can reinforce the importance of the 2012 AAP/USPHS position. AAP representatives and other members of national pediatric societies within the International Pediatric Association advocating for deletion of the provision banning TCVs need to know why the elimination of thimerosal was initially called for in 1999 but is no longer indicated.

This commentary describes the circumstances that led to the 1999 joint statement based on the personal observations at that time of 2 participants in the process: one who then was a member of the AAP Board of Directors (L.Z.C.) and one who is a former chair of both the AAP Committee on Infectious Diseases and the Advisory Committee on Immunization Practices of the USPHS (S.L.K.). The rationale for the current AAP position is summarized by a commentary entitled "Global Vaccination Recommendations and Thimerosal" presented in this issue of *Pediatrics*.³

The 1999 recommendations were written as a prompt response to findings from a broad Food and Drug Administration (FDA) review of the mercury content in biological products mandated by the Food and Drug Modernization Act of 1997. This review revealed that multiple vaccines used thimerosal (containing ethyl mercury) as a preservative in multidose vials and that the cumulative amount of mercury, when given according to the recommended immunization schedule at the time for young infants, could potentially exceed the US Environmental Protection Agency guidelines based on data for elemental, inorganic, or methyl mercury.

The total amount of ethyl mercury did not exceed that of 2 other US federal guidelines, from the Agency for Toxic Substances Disease Registry and the FDA.⁴ All 3 guidelines included broad margins of safety. But the absence of clear data for ethyl mercury did not allow any assumption to be made about its safety. Data were not sufficient to explain the pharmacology or toxicology of this product or to compare it with that for the other mercury compounds. Specifically, no studies

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KEY WORDS

thimerosal, vaccines, global immunization, public trust

ABBREVIATIONS

AAP—American Academy of Pediatrics

FDA—Food and Drug Administration

TCV—thimerosal-containing vaccine

USPHS—US Public Health Service

Drs Cooper and Dr Katz conceptualized this commentary and are fully responsible for the material.

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evaluated the safety or potential harm from the amount of ethyl mercury in the US infant immunization schedule.

Other factors influenced the timing and detail of the joint recommendations: (1) Recognition that mercury levels might exceed even 1 government guideline was cause for concern. (2) Absent more specific data on the safety of ethyl mercury in the form of thimerosal, prompt public disclosure was warranted to protect public trust. (3) Ongoing hearings of a US congressional committee chaired by a legislator convinced that vaccines had harmed his grandchild were amplified by parents with similar views. (4) These allegations were receiving increasing media attention along with charges that the public health establishment was not fully transparent about the risks of vaccines.

Once the FDA calculations revealed that even 1 federal guideline was exceeded, the AAP and USPHS were obligated to

full public disclosure. With that disclosure, it was important to demonstrate a response that could prevent exceeding the guideline levels and also to continue to protect infants by still ensuring full immunization. The joint statement met those obligations while demonstrating an abundance of caution: putting safety first.

The priority to “first, do no harm” guides all USPHS and AAP recommendations. Given the complexity of the science involved in making guidelines, the polarity between vaccine advocates and those believing their children have been harmed, the media’s attraction to controversy, and, in retrospect, inadequate follow-up education about the issues to clinicians and the general public, it is not surprising that the steps taken left misunderstanding and anxiety in the United States and concerns in the global public health community.

Since 1999, studies to better understand the pharmacology and toxicology of ethyl mercury have documented the profound differences between ethyl and methyl mercury. In addition, efforts to find evidence of harm to children from TCVs, used globally for >60 years, have failed to reveal any such damage. This is in sharp contrast to experience involving methyl mercury, a documented serious neurotoxin.

Had the AAP (and, we suspect, the USPHS) known what research has revealed in the intervening 14 years, it is inconceivable to us that these organizations would have made the joint statement of July 7, 1999. The World Health Organization recommendation to delete the ban on thimerosal must be heeded or it will cause tremendous damage to current programs to protect all children from death and disability caused by vaccine-preventable diseases.

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