

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

AUTHORS: Louis Z. Cooper, MD, FAAP,^a and Samuel L. Katz, MD, FAAP^b

^aDepartment of Pediatrics, College of Physicians and Surgeons, Columbia University, New York, New York; and ^bDepartment of Pediatrics, School of Medicine, Duke University, Durham, North Carolina

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.

Opinions expressed in these commentaries are those of the authors and not necessarily those of the American Academy of Pediatrics or its Committees.

www.pediatrics.org/cgi/doi/10.1542/peds.2012-1823

doi:10.1542/peds.2012-1823

Accepted for publication Oct 9, 2012

Correspondence to Louis Z. Cooper, MD, 80 Central Park W, Apt 11F, New York, NY 10023. E-mail: lzcooper@verizon.net

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

Copyright © 2013 by the American Academy of Pediatrics

FINANCIAL DISCLOSURE: The authors have indicated they have no financial relationships relevant to this article to disclose.

FUNDING: No external funding.

COMPANION PAPERS: Companions to this article can be found on pages 149 and 154, and online at www.pediatrics.org/cgi/doi/10.1542/peds.2012-1760 and www.pediatrics.org/cgi/doi/10.1542/peds.2012-2976.

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.

REFERENCES

1. Ban on mercury-based products would risk global immunization efforts, says AAP, WHO. Available at: <http://aapnewspublications.org/content/33/7/4>. Accessed June 1, 2012
2. Centers for Disease Control and Prevention (CDC). Thimerosal in vaccines: a joint statement of the American Academy of Pediatrics and the Public Health Service. *MMWR Morb Mortal Wkly Rep*. 1999;48(26):563–565
3. Orenstein WA, Paulson JA, Brady MT, Cooper LZ, Seib K. Global vaccination recommendations and thimerosal. *Pediatrics*. 2012;131(1):149–151
4. Ball LK, Ball R, Pratt RD. An assessment of thimerosal use in childhood vaccines. *Pediatrics*. 2001;107(5):1147–1154

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

Louis Z. Cooper and Samuel L. Katz

Pediatrics 2013;131;152

DOI: 10.1542/peds.2012-1823 originally published online December 17, 2012;

Updated Information & Services	including high resolution figures, can be found at: http://pediatrics.aappublications.org/content/131/1/152
References	This article cites 1 articles, 0 of which you can access for free at: http://pediatrics.aappublications.org/content/131/1/152#BIBL
Subspecialty Collections	This article, along with others on similar topics, appears in the following collection(s): Infectious Disease http://www.aappublications.org/cgi/collection/infectious_diseases_sub Vaccine/Immunization http://www.aappublications.org/cgi/collection/vaccine_immunization_sub
Permissions & Licensing	Information about reproducing this article in parts (figures, tables) or in its entirety can be found online at: http://www.aappublications.org/site/misc/Permissions.xhtml
Reprints	Information about ordering reprints can be found online: http://www.aappublications.org/site/misc/reprints.xhtml

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN®



PEDIATRICS[®]

OFFICIAL JOURNAL OF THE AMERICAN ACADEMY OF PEDIATRICS

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

Louis Z. Cooper and Samuel L. Katz

Pediatrics 2013;131;152

DOI: 10.1542/peds.2012-1823 originally published online December 17, 2012;

The online version of this article, along with updated information and services, is
located on the World Wide Web at:

<http://pediatrics.aappublications.org/content/131/1/152>

Pediatrics is the official journal of the American Academy of Pediatrics. A monthly publication, it has been published continuously since 1948. Pediatrics is owned, published, and trademarked by the American Academy of Pediatrics, 345 Park Avenue, Itasca, Illinois, 60143. Copyright © 2013 by the American Academy of Pediatrics. All rights reserved. Print ISSN: 1073-0397.

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN[®]

