

Global Justice and the Proposed Ban on Thimerosal-Containing Vaccines

Thimerosal is an ethyl mercury-containing compound that has been used safely for >60 years as a preservative in multidose vials of vaccines to prevent bacterial and fungal contamination of those vials when they are repeatedly entered to withdraw doses.^{1,2} In the late 1990s, preservative-free single-dose vials were widely introduced into high-income countries (HICs). This was a precautionary move in response to theoretical concerns, now known to be unfounded, that ethyl mercury in thimerosal could build up in vaccine recipients' bodies at a rate to similar methylmercury (a known toxin) causing toxicity.³ For low- and middle-income countries (LMICs), where the burdens of vaccine-preventable deaths are most profound, multidose vials of thimerosal-preserved vaccines are a critical part of immunization programs. Extensive additional resources associated with increased manufacturing, shipping, cold-chain storage, administration, and waste-handling infrastructure would be required by a move away from multidose vaccines; for example, a shift to single-dose vials would increase the annual cost of Pan American Health Organization- or UNICEF-supplied vaccines by >\$300 million.⁴

In January 2013, governments are set to finalize the products and processes that will be prohibited in a multilateral environmental treaty, backed by the United Nations Environment Programme, which aims to restrict human and environmental exposure to mercury.⁵ As a mercury derivative, thimerosal could potentially be included within the treaty. Although supportive of the objectives of reducing human and environmental exposure to mercury, the World Health Organization's Strategic Advisory Group of Experts on Immunization⁶ and much of the broader scientific and public health community⁷ have recommended that thimerosal be exempt from the treaty to avoid disruption to the global vaccine supply. In contrast, some nongovernmental organizations oppose such an exemption, arguing that it would be unjust to allow thimerosal to be used in LMICs when its use has been all but phased out of wealthier nations.^{8,9} This 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 in LMICs.

DIFFERENCE DOES NOT SIGNAL INJUSTICE

Although vaccines containing thimerosal are more widely used in LMICs than in HICs, a difference in immunization practice that would persist if thimerosal use were to continue in LMICs, the charge of injustice is misguided. Different practices, in and of themselves, do not

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ABBREVIATIONS

HICs—high-income countries

LMICs—low- and middle-income countries

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make for injustice; they are morally problematic only if they are unjustified and compromise the interests of the affected parties. The moral intuition at work here is one of equality, that each life must be treated with equal respect and regard. Treating individuals with equal regard, however, does not mean that all people are treated the same in all respects. Indeed, promoting equality in 1 sphere, such as health, often requires that people be treated differently in response to their unique needs and circumstances. It is only when differences in practice are not justified by differences in the needs and circumstances of the target individual or group, leading to avoidable harms, that concerns of injustice and inequality arise. Thus, the use of thimerosal-containing vaccines in some jurisdictions but not others would only be unjust if this practice were harmful and unjustified. Neither is true.

There is no credible scientific evidence that the use of thimerosal in vaccines presents any risk to human health. Extensive pharmacologic and epidemiological research has shown early, theoretical concerns about links to autism or other neurodevelopmental disorders to be false.^{10–15} Indeed, the exculpatory strength of the data now available on thimerosal is well evidenced by recent statements from the Global Advisory Committee on Vaccine Safety,¹⁶ US Institute of Medicine,¹⁷ and American Academy of Pediatrics,¹⁸ all of which have concluded that thimer-

osal exposure through vaccination is not harmful to human health.

THE INJUSTICE OF A THIMEROSAL BAN

In the absence of risk to human health, the use of thimerosal in vaccination programs in LMICs presents no threat of injustice. Rather, it is banning thimerosal that would cause an injustice to those living in LMICs and relying on these vaccines for effective protection against many harmful infectious diseases. Currently, multidose vaccines containing thimerosal are used in >120 countries to immunize ~84 million children every year,¹⁹ saving the lives of ~1.4 million people annually.²⁰ They are also used throughout the world, including the United States and other HICs, for pandemic influenza vaccines, because it allows for more rapid production and easier dissemination of the vaccines.²⁰ And yet, banning thimerosal would amount to banning such multidose vaccines, including tetanus toxoid, diphtheria-tetanus-whole cell pertussis, and hepatitis B vaccines.

After rigorous review by health regulators of its safety and efficacy, thimerosal, in accordance with World Health Organization standards, is approved for use in multidose vials of vaccines. Although there are other preservatives on the market, none are yet viable alternatives to thimerosal.^{21,22} In addition, substituting other yet-to-

be-developed preservatives for thimerosal has the potential to alter vaccine stability, safety, and efficacy, and would require resource-intensive and time-consuming reformulation and testing of the vaccines.²³ Complying with a thimerosal ban, then, would require all countries party to the treaty to exclusively use single-dose vials of vaccines, which would result in enormous strain on the resources and public health infrastructure of many LMICs.²⁴ Even if cost and distribution challenges could be met in at least some LMICs, it is projected that countries would face interruptions to vaccine supply, particularly for the most basic, routine vaccines.²⁰ The result would be millions of people, predominantly in LMICs, with significantly restricted access to lifesaving vaccines for many years.

Not surprisingly, during the course of negotiations, LMIC governments have questioned whether thimerosal should be exempted from the treaty.²⁵ The resistance to its continued use comes entirely from nongovernmental organizations in HICs, the populations of which would not suffer the consequences of the potential ban. Where's the justice in that?

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REFERENCES

- Herman LM, Gerbert DA, Larson LW, et al. Vaccines, thimerosal, and neurodevelopmental outcomes. *JAAPA*. 2006;19(1):16, 18–19
- US Food and Drug Administration. Vaccines, Blood and Biologics: Thimerosal in Vaccines Questions and Answers. US Department of Health and Human Services. Available at: www.fda.gov/BiologicsBloodVaccines/Vaccines/QuestionsaboutVaccines/UCM070430 Published April 30, 2009. Accessed September 25, 2012
- American Academy of Pediatrics and US Public Health Service. Joint statement of the American Academy of Pediatrics (AAP) and the United States Public Health Service (USPHS). *Pediatrics*. 1999;104(3 pt 1):568–569
- World Health Organization. World Health Organization Immunizations, Vaccines and Biological, Immunization Practices Advisory Committee (IPAC). Final Meeting Report and Recommendations, April 17–18, 2012. Available at: www.who.int/immunization_delivery/systems_policy/IPAC_2012_April_report.pdf. Accessed September 25, 2012
- United Nations Environment Programme. Overarching Framework: UNEP Global Mercury Partnership. Available at: www.unep.org/hazardoussubstances/Portals/9/Mercury/Documents/Overarching%20Framework.pdf Published June 2009. Accessed September 25, 2012
- World Health Organization. Meeting of the Strategic Advisory Group of Experts on

- Immunization, April 2012—conclusions and recommendations. *Wkly Epidemiol Rec.* 2012;87(21):201–216
7. PATH et al. Open Letter to UNEP Chair Fernando Lúgrís. October 6, 2011. Available at: www.unep.org/hazardoussubstances/Portals/9/Mercury/Documents/INC3/PATH_Letter%20to%20Fernando%20Lugris-%20UNEP%20Mercury%20Treaty%20and%20Thiomersal%20in%20Vaccines.pdf Accessed September 25, 2012
 8. SafeMinds. Presentation to SAGE meeting of April 2012, Session: Information on Vaccines for an Intergovernmental Negotiating Committee on Mercury. Available at: www.who.int/immunization/sage/meetings/2012/april/sage_apr_2012_thiomersal_statement_safeminds.pdf Published 2012. Accessed September 25, 2012
 9. King PG. “Falsus in Uno, Falsus in Omnibus”—A Thimerosal-preserved Vaccine Conundrum. Presentation to SAGE meeting of April 2012, Session: Information on Vaccines for an Intergovernmental Negotiating Committee on Mercury. Available at: http://www.who.int/immunization/sage/meetings/2012/april/sage_apr_2012_thiomersal_statement_comeds.pdf Accessed September 25, 2012
 10. Hviid A, Stellfeld M, Wohlfahrt J, Melbye M. Association between thimerosal-containing vaccine and autism. *JAMA.* 2003;290(13):1763–1766
 11. Verstraeten T, Davis RL, DeStefano F, et al; Vaccine Safety Datalink Team. Safety of thimerosal-containing vaccines: a two-phased study of computerized health maintenance organization databases. *Pediatrics.* 2003;112(5):1039–1048
 12. Madsen KM, Lauritsen MB, Pedersen CB, et al. Thimerosal and the occurrence of autism: negative ecological evidence from Danish population-based data. *Pediatrics.* 2003;112(3 pt 1):604–606
 13. Stehr-Green P, Tull P, Stellfeld M, Mortenson PB, Simpson D. Autism and thimerosal-containing vaccines: lack of consistent evidence for an association. *Am J Prev Med.* 2003;25(2):101–106
 14. Pichichero ME, Cernichiari E, Lopreiato J, Treanor J. Mercury concentrations and metabolism in infants receiving vaccines containing thiomersal: a descriptive study. *Lancet.* 2002;360(9347):1737–1741
 15. Aschner M, Ceccatelli S. Are neuropathological conditions relevant to ethylmercury exposure? *Neurotox Res.* 2010;18(1):59–68
 16. Global Advisory Committee on Vaccine Safety; World Health Organization. Global Advisory Committee on Vaccine Safety, June 2012. *Wkly Epidemiol Rec.* 2012;87(30):281–287
 17. Immunization Safety Review Committee; Board on Health Promotion and Disease Prevention, Institute of Medicine. *Immunization Safety Review: Vaccines and Autism.* Washington, DC: The National Academies Press; 2004
 18. American Academy of Pediatrics. AAP publications reaffirmed and retired. *Pediatrics.* 2010;126(1):177
 19. Ban on all mercury-based products would risk global immunization efforts, says AAP, WHO. *AAP News.* June 1, 2012. Available at: <http://aapnews.aappublications.org/content/early/2012/06/01/aapnews.20120601-1.full?rss=1> Accessed September 25, 2012
 20. Siva N. Thiomersal vaccines debate continues ahead of UN meeting. *Lancet.* 2012;379(9834):2328
 21. Cirefice G. Alternatives to thimerosal as preservatives for vaccines. Presentation to SAGE meeting of April 2012, Session: Information on Vaccines for an Intergovernmental Negotiating Committee on Mercury. Available at: http://www.who.int/immunization/sage/meetings/2012/april/USFDA_perspective_thiomersal_alternatives.pdf Published 2012. Accessed September 25, 2012
 22. Bossche GV. Alternative preservatives for vaccines. Presentation to SAGE meeting of April 2012, Session: Information on Vaccines for an Intergovernmental Negotiating Committee on Mercury. Available at: http://www.who.int/immunization/sage/meetings/2012/april/alternative_preservatives_vaccines_bossche.pdf Accessed September 25, 2012
 23. Ball R. Substituting thimerosal preservative used in vaccines: FDA perspective. Presentation to SAGE meeting of April 2012, Session: Information on Vaccines for an Intergovernmental Negotiating Committee on Mercury. Available at: http://www.who.int/immunization/sage/meetings/2012/april/USFDA_perspective_thiomersal_alternatives.pdf Published 2012. Accessed September 25, 2012
 24. Drain PK, Nelson CM, Lloyd JS. Single-dose versus multi-dose vaccine vials for immunization programmes in developing countries. *Bull World Health Organ.* 2003;81(10):726–731
 25. United Nations Environment Programme. UNEP(DTIE)/Hg/INC.3/8. Report of the intergovernmental negotiating committee to prepare a global legally binding instrument on mercury on the work of its third session. Available at: www.unep.org/hazardoussubstances/Portals/9/Mercury/Documents/INC3/3_8_report_final.pdf. Accessed September 25, 2012

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