



## FDA Advisory Committee Recommends US Approval of Rotavirus Vaccine *Vaccine has the Potential to Save Thousands of Lives in Poor Countries*

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Gaithersburg, MD, February 20, 2008—The US Advisory Committee on Vaccines and Related Biological Products issued a positive recommendation today on the use of rotavirus vaccines, potentially bringing greater protection to children in the US from this common and sometimes fatal cause of severe diarrhea. After reviewing data from clinical trials on the safety and efficacy of Rotarix®, manufactured by GlaxoSmithKline Biologicals (GSK), the committee recommended that the US Food and Drug Administration (FDA) approve the company’s application for licensure. The FDA should make its ultimate decision on Rotarix® licensure in the US within the coming weeks. Another rotavirus vaccine, RotaTeq® manufactured by Merck & Co., Inc., received FDA approval in 2006.

Globally, rotavirus accounts for more than 500,000 deaths and two million hospitalizations annually. Ready access to good medical care means that children in industrialized countries rarely die from rotavirus infection. Children in the poorest countries, however, suffer the greatest burden: more than 90 percent of deaths due to rotavirus occur in the developing world, where access to simple, lifesaving treatment is severely limited.

“Vaccines against rotavirus remain the most effective way to prevent this deadly disease,” notes Dr. John Wecker, director of PATH’s Rotavirus Vaccine Program. “Making rotavirus vaccines available to the children in poor countries who face the greatest risk of dying must be a high priority.”

Every child in the world will contract rotavirus at least once before the age of three, regardless of income level or geographic location. Because vaccination is the only way to prevent hospitalizations from severe rotavirus infection in industrialized countries and the mortality it causes in low-resource settings, the World Health Organization (WHO) strongly recommends the inclusion of rotavirus vaccination into the national immunization programs of countries where clinical trials have shown rotavirus vaccines to be safe and effective. In January 2007, the WHO granted “prequalification” to Rotarix®, allowing it to be purchased through United Nations procurement systems.

Because rotavirus vaccines represent the best hope to save thousands of children's lives in poor countries, PATH's Rotavirus Vaccine Program is working in partnership with Merck and GSK to conduct large-scale clinical trials of their vaccines in Africa and Asia. These data will provide valuable information for developing countries considering the use of rotavirus vaccines to reduce rotavirus mortality.

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*PATH is an international nonprofit organization that creates sustainable, culturally relevant solutions enabling communities worldwide to break longstanding cycles of poor health. By collaborating with diverse public- and private-sector partners, PATH helps provide appropriate health technologies and vital strategies that change the way people think and act. PATH's work improves global health and well-being. For more information, please visit [www.path.org](http://www.path.org).*

*The PATH Rotavirus Vaccine Program is working with the GAVI Alliance, the World Health Organization, and the US Centers for Disease Control and Prevention to help countries make informed decisions about the use of rotavirus vaccines, and to access and afford the currently licensed vaccines.*