

## US-India partner to fill Rotavirus Vaccine Gap

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Seattle, Washington, USA—Key medical researchers from the United States are partnering with Indian colleagues and an Indian pharmaceutical company to replace a vaccine pulled from the market nearly three years ago because of safety concerns in the U.S.

Experts estimate that 125,000 Indian children die each year from diarrhea caused by rotavirus. A safe, effective rotavirus vaccine would prevent these deaths, and would reduce rotavirus diarrhea hospitalizations for millions more. The vaccine would also save lives in other countries where rotavirus is a serious threat.

The world's first rotavirus vaccine, Rotashield, was used in the United States for about nine months in 1998-1999, after passing safety and effectiveness trials involving more than ten thousand patients. But once the vaccine was used more broadly, careful surveillance of vaccinated children showed a higher than expected incidence of intussusception, a rare bowel obstruction. Follow up studies seemed to confirm that 1 of every 12,000 vaccinated children might have that reaction. Because children in the U.S. tend not to die from rotavirus, the manufacturer decided that the benefits of rotavirus immunization might not outweigh other considerations in the U.S. market. This led to their decision to withdraw Rotashield from all markets.

"But the rotavirus picture is different in India than in the United States," says Dr. James Maynard of The Program for Appropriate Technology in Health, or PATH, "and what may be appropriate for one country creates serious problems in another. Nearly 1 out of every 250 children born in India die from diarrhea caused by rotavirus—meaning that it is nearly 50 times more dangerous for them not to be immunized than to receive the vaccine. Because the vaccine is no longer being sold anywhere, Indian parents do not have a chance to make that choice."

PATH, a non-profit organization headquartered in Seattle, helped broker the new partnership. Funded by the Bill & Melinda Gates Foundation, PATH's Children's Vaccine Program works to improve access to immunization in the poorest countries of the world. As part of that mission, PATH brought together the U.S. Centers for Disease Control and Prevention, the Indian Institute of Science, the All-India Institute of Medical Sciences, Stanford University, other partners in the Indo-U.S. Vaccine Action Program, and an Indian vaccine manufacturer, Bharat Biotech International to produce a safer, more effective vaccine especially for India. The viral components used to produce the new vaccine are thought to be much less likely to cause health problems than those used to create Rotashield. However, special measures will be put in place to quickly alert researchers to any cases of intussusception.

Dr. Krishna Ella, head of Bharat Biotech, expects to have the new vaccine ready for use by 2006. PATH will play an important role, working closely with Bharat Biotech to ensure that sufficient quantities are made available to the government at the lowest possible cost so that they can offer it to their poorest families. Wealthier Indians would likely pay more to get the vaccine through private physicians.

India, with growing numbers of highly capable scientists and a burgeoning high-tech infrastructure, is an emerging producer of world-class pharmaceutical and biological products. Because multi-national companies are losing interest in the low-profit vaccine business—resulting in global shortages of lifesaving vaccines—producers in the developing world are becoming increasingly important.

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About PATH: PATH is an international public health organization, dedicated to improving the health and well being of people living in those parts of the world with insufficient preventive health resources. PATH forges partnerships with other non-governmental organizations, the private sector, governments, and international agencies in order to develop and adapt health technologies, and design and initiate health communication interventions, media and social change campaigns, and advocacy.

The Children's Vaccine Program at PATH, funded by the Bill & Melinda Gates Foundation, works to assure that all children receive the full benefits of immunization without undue delay. It also supports development and introduction of crucial new vaccines.