

FDA NEWS RELEASE

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Components of Extraneous Virus Detected in Rotarix Vaccine; No Known Safety Risk

FDA Recommends Clinicians Temporarily Suspend Use of Vaccine as Agency Learns More

FDA is recommending that healthcare practitioners temporarily suspend use of the Rotarix vaccine for rotavirus immunization in the United States while the agency learns more about components of an extraneous virus detected in the vaccine. There is no evidence at this time that this finding poses a safety risk.

The agency recently became aware that an independent U.S. academic research team, using a novel technique, has found DNA from porcine circovirus 1 (PCV1) in Rotarix, which is manufactured by GlaxoSmithKline. PCV1 is not known to cause illness in humans or other animals. In addition, Rotarix has been studied extensively, before and after approval, and found to have an excellent safety record.

Follow-up tests by GlaxoSmithKline and FDA scientists confirmed the academic team's findings and confirmed that viral components have been present since the early stages of the vaccine's development, including during clinical studies. Preliminary testing by both the academic researchers and FDA scientists of another licensed vaccine against rotavirus infection, RotaTeq, has not detected components of PCV1.

"We are making clinicians aware of information recently received by FDA about the Rotarix vaccine," said Dr. Margaret A. Hamburg, Commissioner for Food and Drugs. "There is no evidence at this time that there is a safety concern. FDA is recommending that clinicians temporarily suspend use of Rotarix until we can learn more about the situation. We will keep the public and the clinical community updated on our findings."

Rotarix and RotaTeq are given by mouth to young infants to prevent rotavirus disease, which can cause severe diarrhea and dehydration and is estimated to be responsible for the deaths of more than 500,000 infants around the world each year, primarily in low- and middle-income countries. Before the introduction of a rotavirus vaccine, rotavirus resulted in more than 50,000 hospitalizations and several dozen deaths in the United States each year. FDA licensed RotaTeq in 2006 and Rotarix in 2008. Most children vaccinated in the United States received RotaTeq.

"In many countries, rotavirus causes so much severe illness and death that the known benefits of continued use of Rotarix far outweigh any theoretical risk of harm from the vaccine," said Dr. Thomas Frieden, Director of the Centers for Disease Control and Prevention. "We anticipate

that many countries will decide to continue vaccinating with Rotarix while more information becomes known.”

FDA will continue to gather more information about the PCV1 components in Rotarix, including whether intact virus, as opposed to DNA fragments, is present. The agency is assessing current vaccine testing methods. In four to six weeks, FDA will convene an expert advisory committee and make additional recommendations on the use of rotavirus vaccines.

FDA will provide updates to patients, providers, and the general public as more information becomes available. The agency will also continue to communicate with the World Health Organization and counterpart regulatory agencies in other countries.

For more information visit [FDA's Update on Rotarix Vaccine](#)¹ page