

FDA Says Viral Contamination Found in Second Rotavirus Vaccine

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Review

GAITHERSBURG, Md. -- DNA from a pig virus has been detected in Merck's RotaTeq rotavirus vaccine, an FDA official announced during the opening session of a hearing on rotavirus vaccines.

The announcement means that both rotavirus vaccines on the market have been found to harbor the contaminant, although officials said there was no immediate health hazard.

Merck researchers detected "very low levels" of porcine circovirus 1 and 2 (PCV1 and PCV2) DNA in RotaTeq and immediately shared the results with the FDA, according to Merck and the FDA.

"There is no evidence at this time that DNA from PCV causes any disease in humans," said a statement posted on Merck's website. "We remain confident in the safety profile and quality of RotaTeq."

In March, the FDA reported that PCV1 had been detected in Rotarix, a rotavirus vaccine manufactured by GlaxoSmithKline. Although the FDA said the virus didn't appear to be harmful to humans, with an alternative vaccine available, the agency recommended that clinicians discontinue use of Rotarix.

In the latest action, the FDA did not say whether RotaTeq should be avoided, but a top FDA official again stressed that the virus doesn't appear dangerous to humans.

"There is no evidence PCV1 poses a safety risk," said Norman Baylor, PhD, of the FDA's Center for Biologics Evaluation and Research (CBER) at a Friday meeting of the FDA's Vaccine and Related Biologics Advisory Committee (VRBAC).

Data on PCV2 is less robust, and the agency only became aware of the PCV2 contamination shortly before Friday's meeting.

Researchers with GlaxoSmithKline said Friday that their data prove the virus is benign, but that the company is committed to revamping its vaccine manufacturing process in order to produce Rotarix that is not contaminated with PCV1.

"This is a complex process and will take time," said Barbara Howe, MD, vice president of North American Vaccine Development.

Howe said the company is prepared to make the vaccine available again in the U.S.

Merck is the main provider of the rotavirus vaccine in the U.S. The company has distributed 30 million doses of RotaTeq here, and another seven million in other parts of the world.

GlaxoSmithKline's Rotarix meanwhile, is twice as widely-used as RotaTeq in foreign countries, but the company has provided just 2.5 million doses in the U.S., according to David Martin, MD, MPH, acting chief of CBER.

The VRBAC, which is a panel of outside experts, is meeting to discuss the contamination in Rotarix and the benefits and drawbacks of using new, more sensitive tests to check for viruses in the human vaccines. Those advanced detection methods were responsible for finding PCV1 in both rotavirus vaccines.

Both rotavirus vaccines are given orally to infants to prevent rotavirus disease, which can cause severe diarrhea and dehydration and is deemed responsible for the deaths of more than 500,000 infants around the world each year, primarily in low- and middle-income countries.

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