



March 22, 2010

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Distributed via Health Alert Network  
Monday, March 22, 2010, 15:54 EDT (03:54 PM EDT)  
CDCHAN-00311-2010-03-22-ALT-N

### **Recommendation to Temporarily Suspend Usage of GlaxoSmithKline Rotarix (Rotavirus) Vaccine**

**Summary:** The U.S. Food and Drug Administration (FDA) has learned that DNA from porcine circovirus type 1 (PCV1), a virus not known to cause disease in humans, is present in the Rotarix vaccine. All available evidence indicates that there has been no increased risk to patients who have received this vaccine. PCV1 is not known to cause any disease in animals or humans; therefore, it has not been routinely tested for in vaccine development. Rotarix has been extensively studied, before and after approval, and found to have an excellent safety record (i.e., no unusual adverse events). However, FDA is recommending that healthcare practitioners temporarily suspend usage of the Rotarix vaccine for rotavirus immunization in the United States while the agency learns more about the detection of components of the virus found in the vaccine.

#### **Background**

FDA has learned that DNA from porcine circovirus type 1 (PCV1) is present in the Rotarix vaccine. This finding was reported to FDA by GlaxoSmithKline on March 15<sup>th</sup>, 2010, based on work originally performed by an academic research team using a novel technique to look for viruses. GlaxoSmithKline then conducted additional studies and confirmed that PCV1 DNA is present in the finished Rotarix vaccine, as well as in the cell bank and seed from which the vaccine is derived. This finding suggests that the PCV1 DNA has likely been present since the early stages of the vaccine's development.

Rotavirus vaccines are given by mouth to young infants to prevent rotavirus disease, which can cause severe diarrhea and dehydration. Each year, rotavirus disease causes more than 500,000 deaths in infants globally, and more than 50,000 hospitalizations and several dozen deaths in the United States. There are two licensed rotavirus vaccines in the United States: RotaTeq (Merck) and Rotarix (GlaxoSmithKline).

#### **Recommendations**

While FDA is learning more about the situation, the agency is recommending that clinicians temporarily suspend the use of Rotarix. This recommendation applies to all lots of the Rotarix vaccine. RotaTeq vaccine is available for rotavirus immunization during this period. For children who have received one dose of Rotarix, CDC advises that clinicians complete the series with RotaTeq for the next two doses.

Since RotaTeq was licensed in 2006 and Rotarix in 2008, most children vaccinated in the United States received RotaTeq. The RotaTeq vaccine is made using a different process from the Rotarix vaccine. Preliminary studies by FDA on the RotaTeq vaccine have not shown the presence of PCV1 DNA. FDA is working with Merck to confirm these results.

FDA is obtaining additional information about the presence of PCV1 DNA in Rotarix, including whether intact virus (as opposed to DNA components) is present. FDA is also investigating how the PCV1 DNA came to be present in the vaccine.

Within the next four to six weeks, FDA will convene an advisory committee to review the available data and make recommendations on the licensed rotavirus vaccines. FDA will also seek input on the use of new techniques for identifying viruses in vaccines. The agency anticipates that following the advisory committee meeting, based on expert input and additional review, FDA will make further recommendations on the use of the two licensed rotavirus vaccines in the United States.

The recommendations detailed above are for the United States, where there is less rotavirus disease and an alternative vaccine is available. Other countries may decide to continue vaccinating with Rotarix while more information becomes known. Available evidence suggests that the benefits of continued use of Rotarix in countries where rotavirus disease is common and severe far outweigh any potential risk from the vaccine.

Clinicians are requested to report any suspected adverse events following Rotarix vaccination to the Vaccine Adverse Event Reporting System (VAERS) via phone 800-822-7967 or on-line: <http://vaers.hhs.gov>.

**For More Information:**

FDA intends to provide frequent updates to patients, providers, and the general public as its understanding evolves. Additional information is available at: [www.fda.gov](http://www.fda.gov).

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