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**Region IV Public Health**  
Clark, Cowlitz, Skamania, Wahkiakum counties  
and Cowlitz Tribe

# Health Alert

Please deliver a copy of the accompanying alert to each provider in your organization.

Thank you

**Questions regarding this alert may be directed to the office of:**

**Alan Melnick, MD, MPH**  
Health Officer

**Jennifer Vines, MD, MPH**  
Deputy Health Officer

**Clark County Public Health**  
**Cowlitz County Health Department**  
**Skamania County Health Department**  
**Wahkiakum County Department of Health and Human Services**  
**(360) 397-8412**  
**Please Distribute**

Categories of Health Alert messages:

**Health Alert:** conveys the highest level of importance; warrants immediate action or attention.

**Health Advisory:** provides important information for specific incident for situation; may not require immediate action.

**Health Update:** provides updated information regarding an incident or situation; no immediate action necessary.



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## **HEALTH ALERT**

### **22 March 2010**

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

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.

Fortunately, the Washington's childhood vaccine program does not include the GlaxoSmithKline product. However, some providers in SW Washington may have privately purchased the vaccine. If providers have privately purchased the GlaxoSmithKline product, they should take the following steps:

- **Stop using the Rotarix Vaccine, mark the vaccine “do not use,” and keep it refrigerated until further notice.**

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.

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.

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).