STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH
IMMUNIZATION PROGRAM

PLEASE COPY THIS FOR ALL HEALTH CARE PROVIDERS IN YOUR PRACTICE

TO: **All Users of State Supplied Vaccines**

FROM: **Mick Bolduc**
Vaccine For Children (VFC) Coordinator

DATE: **March 22, 2010**

SUBJECT: **Temporary Suspension of Rotarix vaccine**

The primary purpose of this communication is to notify you on a recommendation from the U.S. Food and Drug Administration (FDA) to temporarily suspend Rotarix vaccine while the agency learns more about components of an extraneous virus detected in the vaccine.

Rotarix Vaccine

The FDA is recommending that healthcare providers temporarily suspend use of Rotarix brand Rotavirus vaccine manufactured by Glaxo SmithKline. Independent testing has found DNA from porcine circovirus 1 in Rotarix. **Porcine circovirus 1 is not known to cause illness in humans or other animals. Although there is no evidence at this time to suggest that Rotarix is unsafe to adminster, the FDA is recommending that the vaccine not be used until further information becomes available.** Preliminary testing of Merck's RotaTeq vaccine has not detected components of porcine circovirus 1. The FDA will convene an expert advisory committee and make additional recommendations on the use of rotavirus vaccines in 4-6 weeks. Updates will be posted at **www.fda.gov**

RotaTeq Vaccine

Until the FDA puts forth additional Rotavirus recommendations the Immunization Program will supply RotaTeq vaccine. Rotateq is administered in a 3 dose series so children who have already received one dose of Rotarix should receive 2 additional doses of RotaTeq. We are working with CDC on trying to provide you with doses of RotaTeq as quickly as possible. We will be sending out additional information to you as soon as it becomes available. Thank you in advance for your patience and understanding during this evolving situation.

Attached is a Question & Answer document for healthcare providers as well as the official health alert from CDC. As always, if you have any questions please call the State Immunization Program at (860) 509-7929.

Information for Healthcare Providers and Public Health Professionals

I have a supply of Rotarix in my medical practice. What should I do with it?
FDA recommends that clinicians temporarily suspend the administration of Rotarix, until the temporary hold on vaccination with Rotarix is lifted. Because new recommendations are expected in four to six weeks, clinicians should keep Rotarix for possible future use.

Is there any medical follow-up needed for children who have received the Rotarix vaccine?
No. FDA does not believe medical follow-up is warranted for children who have been vaccinated with Rotarix. Extensive studies, including placebo-controlled, randomized clinical studies involving tens of thousands of vaccine recipients, support the safety and effectiveness of the vaccine. FDA's recommendation to temporarily hold on the use of Rotarix is a precaution taken while more is learned about the situation.

Will FDA's recommendation that clinicians temporarily suspend using Rotarix lead to a shortage of rotavirus vaccine in the United States?
FDA does not anticipate significant shortages of rotavirus vaccine in the United States. RotaTeq represents the majority of the rotavirus vaccine market in the United States.

If a child has received one dose of Rotarix, what should I do for the next dose?
For children who have received one dose of Rotarix, the Centers for Disease Control and Prevention advises that clinicians can complete the series with RotaTeq for the next two doses.

How can I find out more?
FDA will keep healthcare providers and public health professionals updated on its review of the situation at www.fda.gov.

This is an official

CDC HEALTH ALERT

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Monday, March 22, 2010, 15:54 EST (3:54 PM EST)
CDCHAN-00311-10-03-22-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 15th, 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.

Categories of Health Alert Messages:	
Health Alert	Conveys the highest level of importance; warrants immediate action or attention.
Health Advisory	Provides important information for a specific incident or situation; may not require immediate action.
Health Update	Provides updated information regarding an incident or situation; unlikely to require immediate action.

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