



Philadelphia Department of Public Health
Division of Disease Control

DONALD F. SCHWARZ, MD, MPH
Deputy Mayor, Health & Opportunity
Health Commissioner

NAN FEYLER, JD, MPH
Chief of Staff

CAROLINE C. JOHNSON, MD
Director, Division of Disease Control

Health Alert

Immediate Temporary Suspension of Rotarix® (GSK) Vaccine

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Today, the FDA announced a temporary suspension of the use of the rotavirus vaccine Rotarix®, manufactured by GlaxoSmithKline (GSK). Components of a virus called porcine circovirus type 1 (PCV-1) were found in the vaccine. Although this virus is not known to cause illness in humans or animals, and can be found in common substances (such as food), it is not intended to be in the vaccine. Therefore, FDA is taking this precautionary measure to temporarily suspend use of Rotarix so that the agency can gather more information.

Is this a recall?

No. The vaccine is not being recalled at this time. Temporarily suspending Rotarix use will give FDA more time to gather information, including **1)** how the contamination occurred, and **2)** the next steps to take with the vaccine.

Which lots are affected?

The temporary suspension affects all Rotarix product (all lot numbers).

What should we tell parents of patients who have questions about Rotarix?

Parents should be reassured that the virus found in the vaccine is harmless, and that its presence in the vaccine does not affect the vaccine's effectiveness. There is no evidence at this time that having received Rotarix presents a safety risk.

What should providers do with Rotarix in stock?

1. Identify your entire Rotarix inventory, and stop using the vaccine immediately.
2. Bag the vaccine inventory, label it "**Do Not Use,**" but **keep it in your refrigerator.**
3. If you have separated your diluent from your vaccine, you will need to bag your Rotarix diluent and label it "**Do Not Use**" as well.
4. VFC providers should make sure to keep VFC and privately funded doses separate.

Has the virus been found in the other rotavirus vaccine, RotaTeq® (Merck)?

No. Preliminary testing of the Merck product by FDA scientists and an independent team of U.S. academic researchers has found no components of PCV-1 in RotaTeq.

Will there be enough RotaTeq to make up for the temporary Rotarix suspension?

There should be enough of Merck's RotaTeq for sufficient rotavirus vaccine coverage for U.S. infants. If you would like to order RotaTeq for VFC-eligible infants, please submit an order form immediately (you do not need to submit temperature logs).

For more information on:

- Rotavirus, Circovirus, and the Rotarix Vaccine, from the FDA:
<http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm205539.htm>

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Division of Disease Control • 500 South Broad Street, Philadelphia, PA 19146
215-685-6740 (phone) • 215-686-4514 (after hours) • 215-545-8362 (fax) • www.phila.gov/health/units/ddc • hip.phila.gov