



COMMONWEALTH of VIRGINIA

Department of Health

P O BOX 2448
RICHMOND, VA 23218

March 26, 2010

KAREN REMLEY, MD, MBA, FAAP
STATE HEALTH COMMISSIONER

TTY 7-1-1 OR
1-800-828-1120

Dear Colleague:

I am writing to bring to your attention the temporary suspension of Rotarix, a rotavirus vaccine manufactured by GlaxoSmithKline (GSK) and to share recommended actions for you to take.

The Food and Drug Administration made the recommendation to suspend use of the vaccine on March 22 after receiving information that DNA material from porcine circovirus type 1 (PCV1) is present in Rotarix. Please be aware, however, that there is no evidence at this time that material from PCV1 in Rotarix poses a safety risk. PCV1 is not known to cause any disease in humans or other animals and the vaccine has been extensively studied, before and after approval, and found to have an excellent safety record.

There is no evidence at this time of any risk to patients who have received the Rotarix vaccine.

Currently, health care providers are encouraged to:

- Suspend the use of Rotarix rotavirus vaccine.
- Keep your inventory of Rotarix vaccine viable, continuing to store it under proper conditions and temperatures. This suspension of use is not a recall; it may be determined later that Rotarix vaccine is acceptable to use.
- Use RotaTeq, manufactured by Merck, for rotavirus vaccination. RotaTeq is made using a different process from Rotarix and preliminary studies have not shown the presence of PCV1 DNA.
- For infants who received only the first dose of Rotarix, complete the rotavirus vaccination by administering **TWO** doses of RotaTeq, for a total of three doses of rotavirus vaccine.
- Advise parents that infants who received the full two dose series of Rotarix are considered fully immunized and no action is needed.

Additional information on vaccine recommendations, including the timing and spacing of doses may be found at: http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5802a1.htm?s_cid=rr5802a1_e. The Virginia Department of Health will continue to closely monitor and review any new data that may become available and will provide an update once additional FDA recommendations are released in several weeks. Should you have any questions or concerns, please contact the Division of Immunization at 804-864-8055.

Sincerely,

A handwritten signature in cursive script, appearing to read "Karen Remley".

Karen Remley, MD, MBA, FAAP
State Health Commissioner