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FDA NOTE TO CORRESPONDENTS

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FDA Revises Recommendations for Rotavirus Vaccines

The U.S. Food and Drug Administration today revised its recommendations for rotavirus vaccines for the prevention of the disease in infants and has determined that it is appropriate for clinicians and health care professionals to resume the use of Rotarix and to continue the use of RotaTeq.

The agency reached its decision based on a careful evaluation of information from laboratory results from the manufacturers and the FDA's own laboratories, a thorough review of the scientific literature, and input from scientific and public health experts, including members of the FDA's Vaccines and Related Biological Products Advisory Committee that convened on May 7, 2010 to discuss these vaccines.

The FDA also considered the following in its decision:

- Both vaccines have strong safety records, including clinical trials involving tens of thousands of patients as well as clinical experience with millions of vaccine recipients.
- The FDA has no evidence that PCV1 or PCV2 pose a safety risk in humans, and neither is known to cause infection or illness in humans.
- The benefits of the vaccines are substantial, and include prevention of death in some parts of the world and hospitalization for severe rotavirus disease in the United States. These benefits outweigh the risk, which is theoretical.

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