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# Vaccines and Related Biological Products Advisory Committee Meeting Background Material

## Porcine Circovirus and Rotavirus Vaccines

May 6, 2010

The Vaccines and Related Biological Products Advisory Committee meeting on May 7th will discuss the findings shared with the public on March 22, 2010, that porcine circovirus type 1 (PCV1) DNA was found in GlaxoSmithKline Biologicals' Rotarix Vaccine. Additional data pertaining to the Rotarix vaccine will also be presented to the committee.

FDA recently received information from Merck & Co, Inc. that its preliminary studies have identified fragments of DNA from PCV1 and from a related porcine circovirus type 2 (PCV2) in its RotaTeq vaccine. Merck's findings suggest that the number of PCV DNA fragments in its vaccine may be smaller than what has been found in Rotarix. These preliminary findings will be included in discussions with the Committee.

FDA has been working closely with manufacturers of the two licensed rotavirus vaccines, has consulted with experts inside and outside of the federal government, and has considered issues related to the novel testing that led to the identification of PCV.

FDA has no evidence to date that these findings pertaining to Rotarix and RotaTeq pose a safety risk. Both vaccines have strong safety records, including clinical trials involving tens of thousands of patients and clinical experience with millions of patients.

PCV1 and PCV2 are both small, circular viruses composed of a single strand of DNA. PCV1 and PCV2 are common in pigs. Neither PCV1 nor PCV2 are known to cause illness in humans, however PCV2 may cause illness in pigs.

Rotarix and RotaTeq are the two U.S. licensed vaccines indicated for the prevention of rotavirus disease in infants. Rotavirus disease causes the deaths of more than 500,000 infants around the world each year, primarily in low and middle-income countries. Before the introduction of vaccination, the disease caused more than 50,000 hospitalizations and several dozen deaths in the United States each year. Rotavirus vaccines are given by mouth to infants to prevent rotavirus disease, which can cause severe diarrhea and dehydration.

FDA will continue to work with both GSK and Merck as additional testing is conducted by both the manufacturers and FDA to further assess the findings of PCV DNA in rotavirus vaccines.

After considering the input of the Committee's experts and the available scientific information, FDA will make further recommendations on the use of the licensed rotavirus vaccines in the United States. FDA will provide updates to the public and clinical community through [www.fda.gov](http://www.fda.gov) (<https://wayback.archive-it.org/7993/20170113080519/http://www.fda.gov/>) and other communications.

### Resources for You

- [Update on Rotavirus Vaccine \(/7993/20170113080519/http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm205539.htm\)](http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm205539.htm) [ARCHIVED]
- [2010 Meeting Materials, Vaccines and Related Biological Products Advisory Committee \(/7993/20170113080519/http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/BloodVaccinesandOtherBiologics/VaccinesandRelatedBiologicalProductsAdvisoryComr\)](http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/BloodVaccinesandOtherBiologics/VaccinesandRelatedBiologicalProductsAdvisoryComr) [ARCHIVED]

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