

Panel Tells FDA to Keep Rotavirus Vaccines Available

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Review

GAITHERSBURG, Md. -- Members of an FDA advisory panel agreed that the two approved rotavirus vaccines -- Merck's RotaTeq and GlaxoSmithKline's Rotarix -- should continue to be used, despite known contamination with a pig virus.

The FDA -- which advised clinicians in March to temporarily [stop using Rotarix](#) after it was found to be contaminated with porcine circovirus 1 (PCV1) -- is expected to offer updated guidance soon.

The FDA does not have to follow the advice of its advisory committees, but it usually does.

RotaTeq and Rotarix are administered orally to millions of infants worldwide to prevent rotavirus, which can cause severe diarrhea and dehydration and is deemed responsible for the deaths of more than 500,000 infants each year, primarily in low- and middle-income countries.

The vaccines offer a clear public health benefit that far outweighs a "theoretical" risk from PCV, which does not appear to be harmful to humans, said Philip LaRussa, MD, a professor of pediatric infectious diseases at Columbia-Presbyterian Hospital in New York City.

LaRussa is a member of the Vaccine and Related Biologics Advisory Committee (VRBAC), which met Friday to discuss what the agency should do about the finding that Rotarix is contaminated.

But plans changed when the FDA learned last week that the only other rotavirus vaccine, [RotaTeq](#), was also contaminated with not only PCV1, but PCV2 as well.

It seems unlikely that the FDA's warning to avoid Rotarix will stand given that no data indicate the virus is harmful to people and that Merck's vaccine also contains the virus.

GlaxoSmithKline scientists presented data to the panel indicating the PCV1 virus is not harmful to humans, at least in the short term.

"PCV1 infection is widespread but does not cause any disease in pigs or other animal species including humans," said X.J. Meng, MD, PhD, of the Virginia-Maryland College of Veterinary Medicine in Blacksburg, Va., who spoke on behalf of GSK.

There was less information on PCV2, but an FDA official said it has been known to cause illness in pigs, although not in humans.

Even though the committee members were not comfortable with the PCV2 data, they still agreed that the vaccines should remain in wide use. A [recent study](#) found 72% of infants under five months received the vaccine in eight test sites across the U.S.

"Based on the fact that the data really strongly suggests there's not a substantive risk in the short term, we have to go with the benefit and accept the risks," said panel member Stephen Hughs, PhD, director of the National Cancer Institute's HIV Drug Resistance Program.

"This is one of those situations where you're given two bad choices," he added.

Most of the panel members said they would like data on whether PCV is harmful in the long term, but understood that the vaccines are highly effective and serve an important public health role, particularly in underdeveloped countries where infants can die from dehydration associated with rotavirus.

RotaTeq has only been in use since 2006, and Rotarix since 2008, so long-term U.S. data aren't available.

Representatives from GlaxoSmithKline told the panel that while the data prove PCV1 is benign, the company is committed to revamping its vaccine manufacturing process in order to produce a PCV1-free version of Rotarix.

"That is a Herculean amount of work," remarked VRBAC panelist Harry Greenberg, MD, a microbiology and immunology professor at Stanford University.

Karen Midthun, MD, acting director of the Center for Biologics Evaluation & Research (CBER), said the agency needs "to consider this very expeditiously," but declined to predict when the agency will provide further guidance on the rotavirus vaccines.

Representatives of Merck did not address the panel.

In both cases, PCV was detected using a new and more sensitive test than was previously used, and the panel warned that more contaminants will likely be found as labs start to implement advance detection methods to test vaccines for viruses and other contaminants.

"There are some very difficult times ahead," warned panel chairman Jack Stapleton, MD, director of infectious diseases at the University of Iowa Hospital Clinic.

Norman Baylor, director of CBER's Office of Vaccines Research Review, agreed.

"Using these technologies, we are going to find unknowns, and it's going to be very difficult for the agency to convene an advisory committee every time we find one of these agents," he said.

The panelists suggested the agency should come up with some alternative to advisory committee meetings to analyze the safety of agents that might be uncovered in vaccines in the future.

The panel's consumer representative said the FDA needs to be transparent if other contaminants are detected in vaccines and biologics in the future.

"The public has a right to know whatever you learn," said the panel's consumer representative, Vicky Debold, PhD, RN, director of patient safety at the National Vaccine Information Center.

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