VERBATIM

'I think it's especially important for pediatricians to remind parents that they are modeling safety to their children. Do they buckle up? Wear a bicycle helmet? Drink and drive? The closer the age of the child is to the potential behavior (riding a bike, driving, dating), the more direct is the connection between parental behavior and the child's likely actions.'

Dr. Michael S. Jellinek, p.28

Kawasaki Cases Lead to RotaTeq Label Changes

BY ELIZABETH MECHCATIE
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Several postmarketing reports of Kawasaki disease in recipients of the RotaTeq vaccine have prompted changes in the vaccine's label, but to date there is no known cause-and-effect relationship between the vaccine and these reports, according to the Food and Drug Administration.

Last month, the FDA approved the labeling changes, which add information to the adverse reactions and postmarketing sections of the vaccine's label. The information added includes six cases of Kawasaki disease that were observed in the phase III clinical trial of RotaTeq—five cases among 36,150 infants who received RotaTeq and one case among 35,536 infants who received the placebo.

There have been three additional cases of Kawasaki disease reported to the Vaccine Adverse Event Reporting System (VAERS) since RotaTeq was approved in February 2006 for preventing rotavirus infection—information that has also been added to the postmarketing section of the label. The three cases were identified through routine monitoring of VAERS and were reported in children receiving routine pediatric vaccines, including RotaTeq, according to an FDA statement on the Center for Biologics Evaluation and Research Web site.

The three reports of Kawasaki disease to VAERS do not exceed the number of cases that would normally be expected in children.

The three reports to VAERS do not exceed the number of cases that would normally be expected in children, and there is "not a known cause-and-effect relationship between receiving RotaTeq, or any other vaccine, and the occurrence of Kawasaki disease," the statement said. No changes to the indication for RotaTeq have been made, and no new warnings or precautions have been issued, and "health-care practitioners and parents should remain confident in using RotaTeq." As of June 8, about 6 million RotaTeq doses had been distributed in the United States, according to the FDA.

The FDA and the Centers for Disease Control and Prevention are continuing to monitor the safety of all vaccines, and encourage health care providers to report to VAERS any cases of Kawasaki disease and other serious adverse events in recipients of RotaTeq and other vaccines.

The CDC's Vaccine Safety Datalink (VSD) project also is monitoring for Kawasaki disease in RotaTeq vaccinees. In early June, the VSD project reported one case of Kawasaki disease that occurred within 30 days of RotaTeq vaccination, which was not confirmed.

This case is among 65,000 RotaTeq doses administered to children under age 1 year who are enrolled in the project, which is monitoring the safety of vaccines among patients enrolled in eight managed care organizations.

Kawasaki disease affects about 4,000 children annually in the United States; 80% are younger than age 5. RotaTeq is manufactured by Merck. ■