Dynamic Chiropractic

CDC Pulls the Plug on Rotavirus Vaccine

Editorial Staff

The CDC's Advisory Committee on Immunization Practices has withdrawn its recommendation that infants receive a vaccine to protect them from rotavirus, a disease that causes severe diarrhea and vomiting, citing concerns that the vaccine may cause a rare and potentially fatal side effect in some children.

The committee released a statement saying that it "no longer recommends immunization of infants" with the rotavirus vaccine and voted unanimously to withdraw its recommendation that it be given to infants at two, four and six months of age. Their decision comes a week after American Home Products, the manufacturer of the vaccine (marketed under the name "RotaShield"), voluntarily pulled its product from the market.

The announcement also comes nearly four months to the day after the Food and Drug Administration recommended a halt to further vaccinations due to a possible association between the vaccine and intussusception, a potentially fatal bowel disorder, in children who had recently been inoculated.

"We felt that the risk of an adverse reaction to the vaccine, in this case intussusception, outweighed the potential benefit the parents would likely see in their individual child," said Dr. John Livengood, director of epidemiology and surveillance at the CDC's National Immunization Program.

When it was introduced in this country last summer, the vaccine was hailed as a way to fight rotavirus, the leading cause of childhood diarrhea in the United States. Every year, rotavirus afflicts three million American children, resulting in approximately 500,000 physician visits, 55,000 hospitalizations and between 20 to 30 deaths annually.

While the actual number of deaths resulting from the disease is extremely low in the U.S., rotavirus is much more deadly in developing countries that have poorer diets and less adequate health care, killing up to a million children worldwide each year. Doctors - and drug manufacturers - therefore had high hopes of introducing the vaccine to a much larger audience in the coming months.

But questions surrounded the efficacy and safety of the vaccine even before it was approved by the FDA. Prelicensure trials conducted in the U.S. and Finland showed the vaccine to be no more than 68% effective against any form of rotavirus and only 69% effective against cases of severe diarrhea caused by rotavirus. Natural infections, in comparison, leave a child between 75-88% immune from the disease.

Prelicensure trials also showed the incidence of intussusception to be one in approximately every 2,000 vaccine recipients. An uncommon condition with no known cause, intussusception occurs when one section of a child's intestine becomes enfolded within another. The condition causes vomiting, bloody stools and abdominal pain and can require surgery if it isn't detected early enough. As a result, it was listed as a potential adverse reaction both on the vaccine's label and as an insert in the vaccine's packaging.

Despite the known side effects, the RotaShield vaccine gained approval from the Food and Drug Administration and was licensed on August 31, 1998. Concerns began to arise almost immediately after the drug was put into use, however, as the Centers for Disease Control's Vaccine Adverse Events Reporting System began receiving reports of intussusception in children who had recently been vaccinated.

On July 15th, less than a year after gaining approval, the CDC and the American Academy of Pediatrics recommended that administration of the rotavirus vaccine be postponed until November after receiving nearly two dozen reports of intussusception in children who had received the vaccine. Two months later, an FDA medical officer put the number of suspected rotavirus/intussusception cases at 99, including two deaths that were caused by the disorder.

In a press release issued on October 16th, American Home Products said that it had evaluated cases of intussusception reported to the Vaccine Adverse Events Reporting System, as well as preliminary data from studies currently being conducted by the CDC. Based on those findings, "These data continue to suggest a temporal association between the use of RotaShield and the development of intussusception.

"While additional studies are planned or in progress to better understand this relationship, the company believes that the use of RotaShield should not be resumed during the upcoming rotavirus season. Therefore... it is in the best interest of the public and our customers for the company to withdraw all remaining supplies of the vaccine."

Even as American Home Products announced a recall of the vaccine, the number of intussusception cases continued to mount. When the ACIP finally released their decision on October 22nd, according to Dr. Livengood, a total of 102 cases of intussusception had been reported among infants who were vaccinated, between eight and nine times the number of cases the committee had expected to see.

Livengood also cited a recent Centers for Disease Control survey which found a "strong, significant" causal relationship between vaccination and the bowel disorder. The CDC is still conducting postlicensure trials with the rotavirus vaccine and is expected to release more comprehensive findings later this year.

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