

Infant Cold Medications Pulled From Drugstores

By Rob Stein
Washington Post Staff Writer
Friday, October 12, 2007; A01

Drugstores began clearing their shelves of over-the-counter cough and cold medicine designed for infants yesterday after leading manufacturers announced they were withdrawing the products amid rising concerns about the safety of the popular remedies.

The decision to pull 14 products, including well-known brands such as [Dimetapp](#) Decongestant Plus Cough Infant Drops, [Tylenol](#) Concentrated Infants' Drops Plus Cold and Robitussin Infant Cough DM Drops, came one week before the [Food and Drug Administration](#) plans to hold a hearing on nonprescription cough and cold medications for children.

The hearing is part of a broad evaluation of the products the agency launched in light of doubts about their effectiveness and mounting evidence the medications can cause serious complications, including severe hallucinations and agitation, seizures, high blood pressure, and heart and breathing problems that can be fatal in rare cases.

The companies maintain that the products are safe and effective when used properly but said they acted because of the risk of complications when misused, with most complications apparently occurring in children younger than 2.

"These medicines are -- and always have been -- safe at the recommended doses," said Linda A. Suydam, president of the [Consumer Healthcare Products Association](#), the industry group that announced the withdrawal. "These voluntary actions are being taken out of an abundance of caution."

The companies withdrawing the products -- [McNeil Consumer Healthcare](#), [Novartis Consumer Health](#) and Wyeth -- represent at least 95 percent of the market, the association said.

Critics of the products welcomed the move but called for the FDA to take further action, saying the products pose a hazard even when used at the proper doses.

"Today's action is an important step in the right direction, but FDA must do more to protect children," said Joshua M. Sharfstein, [Baltimore](#)'s health commissioner, who led a petition to the FDA after four children died in Baltimore after taking the medications. "Clearly, the products don't work and are unsafe."

Sharfstein said the FDA should institute a formal ban on the products for children age 2 and younger to make sure no other companies begin offering them.

"You don't want another manufacturer coming along and saying, 'Hey, this looks like a good market for me,' " he said.

In addition, Sharfstein said the agency should strengthen warning labels on the dozens of products still on the market that advise against their use in children younger than 6, and bar packaging that includes terms such as "toddler" that might encourage parents to use the medications in children that young.

"There is no evidence that the products are effective for young children, and there is evidence they can be unsafe, even at the usual doses. This is not just about misuse," he said, noting that the dosages typically used are untested estimates based on studies in adults. "That's why we are asking FDA to clearly label these products against use by children under age 6."

Some of the agency's reviewers recommended that step in documents prepared for next week's meeting of outside experts. FDA officials said the agency would await the recommendations of the panel. "All potential actions are on the table," said Joel Schiffenbauer, the FDA's deputy director of the division of nonprescription clinical evaluation.

Industry representatives defended plans to continue marketing products designed for children older than 2, saying they offer parents useful medications.

"We think they can be used safely," Suydam said. "When we looked at these cases, we found the biggest problem was accidental ingestion. We think that can be addressed with an education program about storing these products safely."

The organization did, however, favor adding new label warnings advising parents against using antihistamines to help their children sleep, which can be dangerous.

"This is a practice that has become more common, and we want to put a stop to it," Suydam said.

Over-the-counter cough and cold medications have long been a mainstay for parents trying to comfort children fighting common colds, coughs and other upper respiratory infections. Although many leading medical groups, including the [American Academy of Pediatrics](#), have long questioned their effectiveness and recommended against their use, they remain popular, especially for parents desperate to help a sick child.

Critics have long argued that there is virtually no good evidence that they work as drugmakers claim and good evidence that they can be dangerous.

"Given that there are serious consequences, including death, associated with the use of these products without compelling reason to use them, why are they being marketed for children?" Sharfstein asked. "The contrast between the state of the evidence and the displays in drugstores could not be more stark."

Sharfstein noted that some of the medications have been sold in packages that depict babies and toddlers and include droppers designed to administer doses supposedly safe for infants. The Prescription Project, a private nonprofit research group in [Boston](#), estimated that companies spend at least \$50 million a year marketing these products.

No one knows how many children have had adverse reactions to over-the-counter cough and cold medications, but the federal [Centers for Disease Control and Prevention](#) reported earlier this year that an investigation it launched found that at least 1,500 children younger than 2 suffered complications in 2004 and 2005. An FDA review prepared for next week's meeting describes dozens of cases of convulsions, heart problems, trouble breathing, neurological complications and other reactions, including at least 54 deaths involving decongestants and 69 deaths involving antihistamines.

Many doctors say they advise their patients against using the products and instead suggest they try Tylenol to alleviate pain, use humidifiers and saltwater solutions to alleviate congestion, and give plenty of fluids to keep the child hydrated. But distressed parents can be persuaded by heavy marketing, some say.

"When your kid is sick, you get a little desperate and think you have to do something," said Daniel J. Levy, a pediatrician in [Owings Mills](#), Md.

Sales of nonprescription cough and cold remedies marketed toward children rose 20 percent, to \$311.3 million, in the year that ended Sept. 8 (excluding sales at [Wal-Mart](#) stores), according to [ACNielsen](#), a [New York](#)-based market research company. About 15 percent of U.S. households bought these products in the year ended June 30, ACNielsen said.

Several major drugstore chains said they immediately began pulling the products from their shelves and blocking sales of the medications at their registers, along with any store-brand equivalents.