

Cold Drugs Put 7,000 Children A Year in ERs

Study Cites Access, Dosage in Ages 2-5

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More than 7,000 children get rushed to emergency rooms each year after suffering adverse reactions to cough and cold medicines, according to the first national estimate of the risks posed by the widely used remedies.

Most of the problems occur in children ages 2 to 5 who get into the medications on their own, researchers said. They based their conclusions on an analysis of data from a nationally representative sample of 63 emergency rooms in 2004 and 2005.

"Anytime a child ends up in the emergency department because they had access to a bottle of medication, that is a problem that could be prevented," said Daniel S. Budnitz of the federal Centers for Disease Control and Prevention, which conducted the research.

The report comes as the Food and Drug Administration considers whether to further restrict the use of the products because of concern about their risks and questions about their effectiveness. Critics and supporters of the products seized on the new report to support their positions.

"This is a lot of trips to the emergency room for products that have no known benefit," said Joshua M. Sharfstein, Baltimore's public health commissioner and the leader of a coalition of pediatricians that petitioned the FDA to restrict promotion of the products for use by children. "It's time to pull the plug on the marketing of these products."

But Linda A. Suydam of the Consumer Healthcare Products Association, an industry group, said the report shows that the problem stemmed primarily from parents giving the wrong dose or failing to make sure the products were out of the reach of children.

"These really are situations where parents were perhaps confused and gave the wrong dosage or inadvertently left out their medication in a way that children could get into them," she said. She defended the effectiveness of the products and their safety when used properly, saying parents want continued access to them.

Last fall, the industry voluntarily withdrew all products marketed for children younger than 2 but said the products were safe and effective for older children.

An FDA advisory panel, however, voted that there was no evidence that the products were effective and recommended against their use in children younger than 6.

On Jan. 16, the FDA formally urged parents not to use the products in children younger than 2, citing recent surveys showing that many parents continue to use them. Agency officials said they had not determined what to do about older children.

Sharfstein filed his petition after four children in Baltimore who had ingested the remedies died. The CDC said last year that at least 1,500 children younger than 2 had complications in 2004 and 2005 from the products, and an FDA review noted dozens of cases of convulsions, heart problems, trouble breathing, neurological complications and other reactions, including at least 123 deaths.

The new report, published online yesterday by the journal *Pediatrics*, is the first attempt to get a nationwide estimate of the extent of the problems.

Researchers analyzed data collected by a nationwide drug safety surveillance system that gathers information from 63 emergency rooms to provide a representative sampling of adverse drug events. The researchers identified 301 cases between Jan. 1, 2004, and Dec. 31, 2005. Extrapolated nationwide, that works out to 7,091 cases a year. Cold and cough drugs account for 5.7 percent of all medicine-related visits to the emergency room by children younger than 12, the researchers found.

In most of the cases, the researchers were unable to determine what symptoms the children experienced. But in those cases where that information was available, 19 percent had allergic reactions, and 13 percent had neurological symptoms such as sleepiness or problems walking.

Although the cases included prescription and over-the-counter products, the researchers said most of them involved nonprescription products.

Children ages 2 to 5 accounted for 64 percent of the cases, and nearly 80 percent of the cases in this age group involved situations where children got into the products without their parents' knowledge. But in the remaining cases, either the parents gave the wrong dose or a correct dose produced an adverse reaction.

Ninety-three percent of the cases did not require the children to be hospitalized, but about 7 percent required additional treatment. The researchers did not know whether any children died.

Based on the findings, the researchers recommended a number of steps to reduce the risk, such as encouraging parents to make sure products are kept capped and out of reach, designing better child-proof containers and avoiding colors that make the products look appealing to children.

"We have a wide range of options that we can do today and implement in the future," Budnitz said.