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A warning on kids' cold doses

FDA cautions against giving common medicines to the young

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Sun reporters

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Responding to safety concerns from Baltimore health officials, the FDA is recommending that common cough and cold medicines never be given to infants and toddlers, and that children under 6 should not be given antihistamines.

In a 356-page report released yesterday, the agency also proposes that warnings about the dangers of overdosing children be added to the labels of these widely used over-the-counter medications.

But the Food And Drug Administration's preliminary recommendations appeared to stop short of the blanket warning proposed by a national pediatricians' group and a group of doctors led by Baltimore's health commissioner, Dr. Joshua M. Sharfstein. They want the agency to advise against giving cold medicines to any child under 6.

Sharfstein said the evidence presented by the FDA suggests that the agency will adopt his more aggressive stance on the medications when it makes a final decision this year.

"You have hundreds of pages of review here, and no one is saying these products are safe or effective," he said. "That's nowhere in here - and if that's the case, they shouldn't be used."

An FDA advisory panel will take up those issues at hearings next month. The pediatric dosage guidelines currently used were approved more than 30 years ago. Critics point out that they were based on doses approved for adults, because few studies had been conducted on children.

"The whole idea was, if a disease is the same in adults and in children, you can normally extrapolate a dose for children," said FDA spokeswoman Susan Cruzan. "That is what's happened over the years. ... With all these issues being raised - safety concerns - we're going to go back and look at it."

In their petition to the FDA, Sharfstein and other doctors pointed to the deaths of four Baltimore children under age 4 in the past six years that were linked to cough and cold medications.



The FDA's review found that from 1969 through the fall of 2006, there were 54 reported deaths involving decongestants, and 69 with antihistamines - mostly in children younger than 2 years.

As their name suggests, decongestants are drugs designed to relieve stuffy noses by reducing swelling of the mucous membranes in nasal passages.

Antihistamines relieve runny noses, itching, sneezing, and watery eyes. They can also cause drowsiness.

The two types of drugs are often combined, sometimes with cough suppressants, in cold remedies.

In 2005, the U.S. Toxic Exposure Surveillance System, a national database of poisoning cases, recorded as many as 88,000 calls about young children overdosing or having adverse reactions to cough and cold medicines and antihistamines.

Critics say they're not just concerned about the medications being dangerous. In a strongly worded letter to the FDA, Dr. Jay E. Berkelhamer, president of the American Academy of Pediatrics, wrote that they have "been found not to be effective in this population at all."

"This is not a situation in which pediatric data are lacking, and we are unable to say one way or the other whether or not these products work in children," he wrote. "Multiple peer-reviewed studies concluded these medications and combinations are not effective at the currently recommended doses in children."

In papers filed with the FDA, the Consumer Healthcare Products Association, which represents the makers of over-the-counter medications, defended its products.

"Years of practical application by both doctors and parents using these medicines demonstrates that these ingredients are effective in relieving symptoms of cough and cold in children," the group wrote.

Still, the CHPA said it would recommend that labels be changed on all over-the-counter cough and cold medicines to warn against use in children under 2.

It would also recommend that antihistamine labels carry the warning "Do not use to sedate children."

Currently, the labels advise consumers to "consult your physician" for the dosage of cold and cough medicines in children under 2, and for antihistamine dosage in children under 6.

The FDA's preliminary recommendations suggest doing away with the consultation advice.

"They say 'Under age 2 consult your doctor,' which implies the doctor has information that's not on the label. But the doctor does not," said Dr. Wayne Snodgrass, a professor of pediatrics at University of Texas Medical Branch at Galveston and chairman of the American Academy of Pediatrics Committee on Drugs.

Sharfstein said he was surprised to see that the CHPA is willing to advise consumers not to use products in infants and toddlers, calling it "a significant shift" in the industry's position.

But it raised new concerns for him.

"If they think they should not be used, why are they selling products specifically for infants?" he said. "You walk into ... any pharmacy. You'll find multiple products marketed to children under age 2."

The medication makers said in their report to the FDA that they would like to see more research into the ingredients of these drugs and how they're metabolized by children ages 2 through 12.

Dr. Jay Gopal, chief of pediatrics at Union Memorial Hospital, said parents sometimes give the drugs to youngsters unwisely.

Children benefit from antihistamines such as Benadryl when they have an allergic reaction, but many parents give the medications inappropriately for colds and flu.

"It depends on what condition the child has," he said. "If it's for a cold, it's not a good idea to give it."

Even so, Dr. Janet Serwint, a Johns Hopkins pediatrician who signed Sharfstein's petition, said she understands why so many parents give these medications to their sick kids.

"They want to do something," she said. "In our society, to do something is often equated with giving a medication."

Common children's medicines and the drugs they contain

The FDA is recommending that common cough and cold medicines not be given to infants and toddlers, and that antihistamines should not be given to children under age 6. Here's a list of common children's remedies and the drugs in them:

- **Children's Benadryl**

Diphenhydramine (antihistamine)

- **Children's Dimetapp Cold and Allergy**

Bromopheniramine (antihistamine)

Phenylephrine (decongestant)

- **Toddler's Dimetapp Decongestant Drops**

Phenylephrine (decongestant)

- **Children's Tylenol Plus Cold**

Acetaminophen (pain relief, fever reduction)

Phenylephrine or Pseudoephedrine (decongestants)

- **Concentrated Tylenol Infant Drops Plus Cold**

Acetaminophen (pain relief, fever reduction)

Phenylephrine or Pseudoephedrine (decongestants)

- **Delsym**

Dextromethorphan (cough suppressant)

• **Neo-Syneprine Mild Formula Nasal Spray**

Phenylephrine (decongestant)

• **Pediacare Infant Decongestant Plus Cough**

Pseudoephedrine (decongestant)

Dextromethorphan (cough suppressant)

• **Pediacare Multi-Symptom Cold**

Phenylephrine (decongestant)

Dextromethorphan (cough suppressant)

• **Robitussin Pediatric Cough and Cold CF**

Phenylephrine (decongestant)

Dextromethorphan (cough suppressant)

Guaifenesin (expectorant)

• **Robitussin Pediatric Cough and Cold Nighttime**

Phenylephrine (decongestant)

Dextromethorphan (cough suppressant)

Chlorpheniramine (antihistamine)

• **Triaminic Daytime Cold and Cough**

Phenylephrine (decongestant)

Dextromethorphan (cough suppressant)

• **Triaminic Nighttime Cold and Cough**

Phenylephrine (decongestant)

Diphenhydramine (antihistamine)

Source: U.S. Food and Drug Administration

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