



Debate over cold meds for kids hinges on safety issue

Liz Hoffman

The first frost of the season hit Boston last week, and as every parent knows, the colds, coughs, stuffy noses and sore throats aren't far behind.

But when parents go to the medicine aisle this winter, they may find fewer options, the result of a new set of federal recommendations handed down late last month.

An advisory committee appointed by the Food and Drug Administration (FDA) voted to ban many pediatric cough and cold medicines amid growing concerns that the medications are generally ineffective and potentially unsafe, particularly for small children.

The committee voted 21-1 on Oct. 19 to ban the use of these drugs — which include staples like Dimetapp and Robitussin, as well as several products in the Tylenol line — in children under 2, who have suffered the majority of serious adverse effects over the past several decades. Side effects are rare, but with more studies supporting skeptics' claims that the drugs do not actually alleviate cold symptoms, many physicians and professional organizations consider them an unnecessary risk.

"The guiding principle here should be that if a drug is ineffective, then its risk, unless zero, will always exceed

its benefits," said Dr. Michael Shannon, chief of emergency medicine at Children's Hospital Boston and one of four pediatricians who addressed the advisory panel prior to its vote. "These drugs do not work."

The American Academy of Pediatrics and the American College of Chest Physicians have come out in

support of the ban. These drugs, now among the biggest over-the-counter sellers on the market, were approved as "generally regarded as safe" and placed on what is known in the industry as the GRAS list. Many hit shelves as early as the 1960s and have faced little scrutiny in the decades since; before last month, the FDA had conducted no review of their safety or effectiveness since 1976. Most of these drugs were not tested explicitly on children and dosing recommendations for children were extrapolated from adult dosages based on weight.

"You can't simply adjust the dose for child weight and assume that it is safe or that the effect will be the same," Shannon said. "Knowing what we know about pediatric pharmacology ... the GRAS list needs to be reexamined. Cough and cold preparations are just the most high-profile offenders." Adverse outcomes are rare, but serious. An FDA internal review in February 2007 found that from 1969 through 2006, 123 deaths were attributed to the active ingredients in most cough and cold medicines — 54 to decongestants and 69 to antihistamines. The majority of these occurred in children under 2. A report by the Centers for Disease Control and Prevention found that in 2004 and 2005, more than 1,500 children under the age of 2 experienced serious effects from cough and cold drugs. Some of these cases are the result of accidental overdoses. Acetaminophen, the active ingredient in Tylenol products, can cause liver failure in high doses, as can some antihistamines. To address that danger, many drug manufacturers have announced plans to standardize the measuring caps across the industry to prevent unintentional overdoses that occur when parents use a cap from one medicine to measure another. But many of the more serious cases are the result of dangerous drug interactions rather than overdose, Shannon said. Children with

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Shirley Austin (right) helps Sudanese refugee Zuruf Basher, 16, to write an essay on pyramids. Shirley — herself a refugee from Nigeria and now a third-year student at Boston University's

Goldman School of Dental Medicine — began visiting the Bashers in 2005, and has continued to help refugee families adapt to American life. (Daniela Caride photo)



Mayor Thomas M. Menino (left) and the Mayor's Office of New Bostonians held the second annual "We Are Boston" awards ceremony at the Boston Convention & Exhibition Center on Monday, honoring David Ortiz and other outstanding individuals and organizations who have made significant contributions in embracing Boston's diversity. (Photo courtesy of City of Boston Mayor's Office)

Mass. auto insurance overhaul is underway

Steve LeBlanc

Most drivers can look forward to a drop in their car insurance rates under the state's new competitive system, but insurance officials couldn't say how big the average decrease would be statewide.

Under the old system, where the state set one rate for all insurers, rates fell by 11.7 percent last year.

Consumer advocates have suggested that with the old system, car owners could have looked at another cut of at least 10 percent this year.

Under the new competitive system, most insurers are offering average rate cuts of less than 10 percent.

State Insurance Commissioner Nonnie S. Burnes said based on filings that rates fell by 11.7 percent last year.

Hub student helps U.S. newcomers find refuge

Daniela Caride

Shirley Austin has been through a lot.

Her family could have been killed during confrontations between Muslims and Christians in Jos, Nigeria, in the 1990s. For seven years, she couldn't see her mother, Josephine, who fled to the United States, afraid of local riots. She left Africa at 17 in search of safety and a chance to reunite her family.

And still, Shirley considers herself "very lucky."

"I have my entire family here, [and] we speak English. I was very lucky in that aspect. But not everyone is like that," she says. "It's nice to know you are in a new place, that you don't face the same dangers, but now there's a

whole new set of ... obstacles to go through."

So when Shirley got her green card in 2006, she decided to help other refugees.

"It just came to me. I want to help people who'd gone through the same thing, having to leave your country," says Shirley, 25, sitting on a brown couch at her carpeted apartment in Dorchester on a recent Saturday afternoon.

After a quick search on the Internet, Shirley found Catholic Charities, a nonprofit social services organization that offers nearly 140 programs in the greater Boston area and is always looking for volunteers.

As a refugee herself, Shirley was perfect for the job, according to Maurine ... Shirley, continued to page 8

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