FDA panel to vote on painkiller restrictions

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FILE - In this Dec. 12, 2007 file photo, Tylenol drugs are shown in the drug department at Costco in Mountain View, Calif. During a two-day meeting that started Monday June 29, 2009, the FDA is asking more than 35 experts what additional steps can be taken to reduce accidental overdose with the over-the-counter and prescription pain relievers.(AP Photo/Paul Sakuma, File)

(AP) -- Government experts are scheduled to vote on whether Nyquil and other combination cold medications should be pulled from the market to help curb deadly overdoses.

The Food and Drug Administration has assembled more than 35 experts for a two-day meeting to discuss and vote on ways to prevent overdose with acetaminophen - the pain-relieving, fever-reducing ingredient in Tylenol and dozens of other prescription and over-the-counter medications.

Despite years of educational campaigns and other federal actions, acetaminophen remains the leading cause of liver failure in the U.S., sending 56,000 people to the emergency room annually, according to the FDA. There are about 200 acetaminophen-related deaths each year.

"It can happen to anybody, but it's very rare," said Dr. Lee Simon, an associate professor at Harvard Medical School, who attended Monday's meeting. "Obviously it's important that we improve the communication about these products because they are ubiquitous, and we still see people inadvertently overdosing."

The drugs that could be pulled off shelves are combination medications, such as Procter & Gamble's NyQuil or Novartis' Theraflu, which mix acetaminophen with other ingredients that treat cough and runny nose.

The FDA is not required to follow the advice of its panels, though it usually does. The panel vote is scheduled for Tuesday afternoon.

Manufacturers could lose hundreds of millions of dollars in sales if combination drugs are pulled from the market. Total sales of all acetaminophen drugs reached $2.6 billion last year, with 80 percent of the market comprised of over-the-counter products.

The FDA says patients often pair the cold medications with pure acetaminophen drugs, like Tylenol, exposing themselves to unsafe levels of the drug.

But the industry group that represents Johnson & Johnson, Advil-maker Wyeth and other companies defended the products Monday, saying they pose a relatively small risk to patients.

Only 10 percent of deaths linked to acetaminophen medications involved over-the-counter combination cold medications, according to the

Consumer Healthcare Products Association.

The majority of deaths were caused by either single-ingredient drugs or prescription strength combination drugs like Endo Pharmaceutical's Percocet, which combines oxycodone and acetaminophen.

"We believe there is a clear health benefit of over-the-counter combination products containing acetaminophen," said Linda Suydam, the group's president.

Tylenol-maker Johnson & Johnson also pushed back against a proposal to lower the maximum daily dose of acetaminophen, which is currently 4 grams daily, or eight pills of a medication like Extra Strength Tylenol.

While taking more than 4 grams per day can cause liver injury, J&J argued that taking the exact dose is proven to treat osteoarthritis pain.

The FDA panel also will vote on a series of other proposals, including changes to the packaging and labeling of medications. Both ideas are designed to prevent patients from taking more than the recommended dose of the drug.