FDA weighs options to reduce painkiller overdoses

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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) -- Tylenol, Excedrin, NyQuil. These household brands and others have come to symbolize safe, convenient relief from the aches and pains of everyday life. But this week the Food and Drug Administration is focusing on a seldom-discussed side effect of the medications: severe liver damage. Since the drugs first became widely available in the 1950s, the FDA has tried to minimize the risks of acetaminophen - the pain-relieving, fever-reducing ingredient in Tylenol and dozens of other prescription and over-the-counter medications.

Acetaminophen overdoses send an estimated 56,000 people to the emergency room each year, according to the FDA.

Despite decades of educational campaigns, bolstered warnings and other federal actions, acetaminophen continues to be the leading cause of liver failure in the U.S.

In documents posted online, the FDA said marketing of Tylenol and other medications emphasizes their safety, leading many consumers to assume they are "extremely safe and not likely to lead to serious injury."

But the 4 gram-per-day maximum dose listed on many medications is just below levels that can cause potentially fatal liver injury.

During a two-day meeting that started Monday morning, 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.

The FDA does not have to follow the group's advice, though it usually does. Individual companies already are sparring in an effort to influence the FDA's decision.

Panelists will be asked to vote on a range of options: adding a "black box" warning label to the products, lowering the drug dosage in some products, or pulling certain types of medications off the market - which could cost manufacturers millions in sales.

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

The FDA has focused on both prescription and nonprescription combination drugs because patients often pair them with a pure acetaminophen medication, like Tylenol, exposing themselves to unsafe levels of the drug.

Still, the agency acknowledges that such overdoses only account for a small number of deaths. According to FDA documents, only five of the 72 deaths reported with acetaminophen in 2005 involved combination drugs. Twenty-seven of the deaths involved single-ingredient over-the-counter acetaminophen products. The remaining 40 deaths were connected with prescription acetaminophen drugs.

Though pulling popular brand-name drugs off the market would be an unusually aggressive step by the government, the industry's trade group already is making a strong case for the products.

"These products provide consumers with effective pain relief and are safe and effective when used according to labeled direction," the Consumer Healthcare Products Association said in briefing documents posted online.

Acetaminophen is one of the most widely used drugs in the U.S., with more than 28 billion doses sold in 2005, according to the FDA.

Industry leaders have launched campaigns to try and sway the FDA's decision.

Tylenol-maker Johnson & Johnson warned panelists that any new restrictions on acetaminophen would force patients to switch to nonsteroidal anti-inflammatory drugs, which carry risks of gastrointestinal bleeding and kidney injury. Top-sellers in that market include Bayer AG's aspirin and Wyeth's Advil.

In response, executives from Wyeth scheduled a series of media briefings last week, arguing that there is no evidence that reduced use of acetaminophen would cause more negative side effects with their drug.

"There are major flaws in their arguments that are not born out in real world experience," said Dr. Paul Desjardins, a vice president with Wyeth.

Desjardins pointed out that the U.K. has put tighter safety measures in place for acetaminophen without causing increased problems with Advil and other nonsteroidal anti-inflammatory drugs.

For its part, the FDA has made clear it will not play king-maker in the market for over-the-counter medications. The agency says its only goal is to reduce liver injury, "not to decrease appropriate acetaminophen use or to drive people to use NSAIDS instead."