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Ban Is Advised on 2 Top Pills for Pain Relief

By [GARDINER HARRIS](#)

ADELPHI, Md. — A federal advisory panel voted narrowly on Tuesday to recommend a ban on Percocet and Vicodin, two of the most popular prescription painkillers in the world, because of their effects on the liver.

The two drugs combine a narcotic with acetaminophen, the ingredient found in popular over-the-counter products like Tylenol and Excedrin. High doses of acetaminophen are a leading cause of liver damage, and the panel noted that patients who take Percocet and Vicodin for long periods often need higher and higher doses to achieve the same effect.

Acetaminophen is combined with different narcotics in at least seven other prescription drugs, and all of these combination pills will be banned if the [Food and Drug Administration](#) heeds the advice of its experts. Vicodin and its generic equivalents alone are prescribed more than 100 million times a year in the United States.

Laureen Cassidy, a spokeswoman for Abbott Laboratories, which makes Vicodin, said, "The F.D.A. will make a final determination and Abbott will follow the agency's guidance."

The agency is not required to follow the recommendations of its advisory panels, but it usually does.

The panel's 20-17 vote to recommend a ban on the combination drugs was one of 11 it took at a meeting called to advise the F.D.A. on problems arising from the extraordinary popularity of acetaminophen. In 2005, American consumers bought 28 billion doses of products containing the ingredient.

While the medicine is effective in treating headaches and reducing fevers, even recommended doses can cause liver damage in some people. And more than 400 people die and 42,000 are hospitalized every year in the United States from overdoses.

In hopes of reducing some of these accidents, the committee voted 24 to 13 to recommend that the F.D.A. reduce the highest allowed dose of acetaminophen in over-the-counter pills like Tylenol to 325 milligrams, from 500. And members voted 21 to 16 to reduce the maximum daily dosage to less than 4,000 milligrams.

But they voted 20 to 17 against limiting the number of pills allowed in each bottle, with members saying such a limit would probably have little effect and could hurt rural and poor patients. Bottles of 1,000 pills are often sold at discount chains.

"We have no data to show that people who overdose shop at Costco," said Dr. Edward Covington, a panel member from the Cleveland Clinic Foundation.

Dr. Lewis S. Nelson, a toxicologist from the [New York University](#) School of Medicine who served as the panel's acting chairman, said experts had been warning of the dangers of combination painkillers like Percocet, which is

made by Endo Pharmaceuticals, and Vicodin for years.

Still, the recommendation is likely to come as a shock to many patients, who may be unaware of the dangers of high doses of acetaminophen — even if they know the drugs contain the ingredient.

Some doctors already avoid prescribing pills that combine acetaminophen with narcotics like oxycodone (found in Percocet) and hydrocodone (in Vicodin).

“It ties the doctor’s hands when you put the two drugs together,” said Dr. Scott M. Fishman, a professor of anesthesiology at the [University of California, Davis](#), and a former president of the American Academy of Pain Medicine. “There’s no reason you can’t get the same effect by using them separately.”

Dr. Fishman said the combinations were prescribed so often for the sake of convenience, but added, “When you’re using controlled substances, you want to err on the side of safety rather than convenience.”

Still, some doctors predicted that the recommendation would put extra burdens on physicians and patients.

“More people will be suffering from pain,” said Dr. Sean Mackey, chief of pain management at [Stanford University Medical School](#). “More people will be seeing their doctors more frequently and running up health care costs.”

In a statement, Johnson & Johnson, Tylenol’s maker, said it “strongly disagrees” with the proposed restrictions on acetaminophen, adding that they would be likely to “lead to more serious adverse events as consumers shift to other over-the-counter products,” like Advil and aspirin.

Linda A. Suydam, president of the Consumer Healthcare Products Association, said the committee had ignored studies showing that doses sold by her members — two pills of 500 milligrams, up to four times a day — were safe. “I think this is a very effective dose and one needed for individuals who experience chronic pain,” she said.

The committee also turned its attention to over-the-counter children’s medicines containing acetaminophen, voting 36 to 1 to limit them to a single formulation. Right now the liquids are sold in two different concentrations, leading to confusion among doctors and parents.

“I don’t think it’s safe to have two formulations out there,” said Dr. Nelson, the acting chairman.

The members were divided over which formula to recommend, the concentrated or the less concentrated one. F.D.A. officials suggested that they would likely settle on the less concentrated formula so that if parents make a mistake, they would be less likely to overdose.

Acetaminophen is included in a vast array of over-the-counter [cough](#) and cold products, including Nyquil, Excedrin and many others. A small share of accidental poisonings result when people take two or more of these combination products without understanding the risk.

The F.D.A. asked the committee whether it should ban combination products that include acetaminophen. The vote was 24 to 13 against such a ban, with many members saying consumers saw the products as valuable.

“Based on the data provided, the combination O.T.C. medications really contributed very little to overall poisonings,” said Dr. Osemwota A. Omoigui, a panel member from the Los Angeles Pain Clinic.

A 2005 study found that most poisonings resulted from patients’ taking Vicodin and similar products that combine

a narcotic with acetaminophen.

“I think this is the one place where we can engineer in safety,” said Dr. Judith M. Kramer, a panel member and an associate professor of medicine from Duke University Medical Center who voted to ban the combination prescription medicines. “We’re here because there are inadvertent overdoses that are fatal, and this is our one opportunity to have a big impact.”

Consumers need to be better educated about the risks of popular medicines, most panel members agreed.

“If you keep track of what you’re taking, none of this is an issue for you,” Dr. Jan Engle, a panel member and head of the Department of Pharmacy Practice at the [University of Illinois](#) in Chicago, said in an interview after the meeting.

Donald G. McNeil Jr. contributed reporting from New York.

An earlier version of this article misspelled, in one instance, the surname of Dr. Scott M. Fishman.

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