

New York Times
September 20, 2002

Warnings Sought for Popular Painkiller

By SHERYL GAY STOLBERG

SILVER SPRING, Md., Sept. 19 — Citing evidence that thousands of Americans unwittingly take toxic — and potentially fatal — doses of acetaminophen, a panel of expert scientists today urged stronger warning labels for the painkiller, the main ingredient in nearly 200 over-the-counter cold and headache remedies, including Tylenol. The committee voted nearly unanimously, 21 to 1, to advise the Food and Drug Administration to adopt the stronger warnings, and the agency typically follows such advice. The vote came after F.D.A. officials presented evidence that 100 people die and more than 2,000 are hospitalized each year as a result of liver damage from unintentional overdoses of acetaminophen.

Those numbers are relatively small compared with the billions of doses of acetaminophen taken each year, and manufacturers insist that the drug, which is also in prescription painkillers like Percocet and Vicodin, is safe when taken as directed.

But the committee's chairman, Dr. Louis Cantilena, said the panel was convinced of the need to reduce the risk further. Committee members were "particularly disturbed," Dr. Cantilena said, to hear that many consumers mistakenly mixed more than one acetaminophen product because they failed to realize, for instance, that their prescription painkiller and cold medicine both contained the drug.

The advisers called for every package of acetaminophen to say in bold type that it contained the ingredient and suggested warnings that taking more than the recommended dose could cause liver damage, steps the manufacturer of Tylenol is already taking.

In addition, the committee asked for warnings to consumers not to use more than one product containing acetaminophen at the same time.

The dry statistics of today's session gave way to emotion when a Pennsylvania mother told the panel how her 23-year-old son had died of an unintentional overdose of acetaminophen, which he had taken to alleviate wrist pain.

"You cannot allow more innocent men, women and children to suffer," the woman, Kate Trunk, said, adding, "Death is not an acceptable side effect."

Today's meeting was part of a long-awaited review by the Food and Drug Administration of over-the-counter painkillers. On Friday, the panel will reconvene to consider possible labeling changes for aspirin and ibuprofen, the main ingredient in drugs like Advil.

The drug agency first issued its proposal for labeling requirements for painkillers in 1988. Once the review is complete, it can issue final regulations.

Acetaminophen has been on the market since 1955 and is thought to be the most widely used pain reliever in the world. The current recommended dose is no more than four grams a day, or eight extra-strength pills of 500 milligrams each. Experts say anything beyond that is potentially dangerous, and also advise patients to take the lowest effective dose.

Yet in some people, particularly those who consume alcohol, even the recommended dosage can be risky. So acetaminophen labels warn people who consume three or more alcoholic beverages a day to consult their doctors before taking the drug.

That is "imperfect advice," said Dr. Sandra Kweber, a food and drug official involved in the acetaminophen review.

But after a lengthy discussion, panel members decided against changing it, saying there was not enough evidence to substitute a new recommendation.

"We can't completely tell who is at risk," Dr. Kweber said. "We don't have enough information to really help us understand what it is about alcohol and this drug that makes it a potentially bad combination."

Some people take acetaminophen to commit suicide; indeed, the food and drug agency says more people die of intentional overdoses of acetaminophen than of unintentional ones. In addition, some babies and young children die every year because their parents confuse recommended dosages of infant drops, which are highly concentrated, with other liquid forms of the drug, despite package warnings that the two cannot be interchanged. The various liquid formulations of the drug are so confusing that pediatricians say it is difficult to advise patients over the phone. Even Dr Cantilena, the panel chairman, said he had trouble with them.

"In my own household," he said, "we have four different concentrations. I have to use a calculator when I dose my kid."

Dr. William M. Lee, a professor at the University of Texas Southwestern Medical Center at Dallas, said acetaminophen caused three times as many cases of liver failure as all other drugs combined.

Dr. Lee told the panel he had reviewed 308 cases of liver failure at 25 medical centers around the country and found that 40 percent were due to acetaminophen toxicity. In an interview, he said, "It is the most common cause of liver failure, and these cases should be preventable."

Already, some labeling changes are under way. McNeil Consumer and Specialty Pharmaceuticals, the manufacturer of Tylenol, is voluntarily remaking labels on its product, which will now carry the word "acetaminophen" in bold type on the packaging. McNeil also intends to place new warnings on all its acetaminophen products to say that "taking an overdose may cause liver damage."

McNeil is not the only company marketing acetaminophen; there are 10 others, said Linda Suydam, president of the Consumer Healthcare Products Association, which represents over-the-counter drug manufacturers.

"All of the industry is anxious to cut down on the number of unintentional overdoses, and clear up any confusion, if there is any," Ms. Suydam said.