

FDA panel recommends ban on the painkiller Darvon

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WASHINGTON - Government medical advisers Friday recommended a ban on Darvon, a prescription medicine that's been used to treat pain for more than 50 years but left a trail of problems such as addiction and suicide.

A Food and Drug Administration advisory panel voted 14-12 to recommend withdrawing Darvon after a daylong hearing examining its risks and benefits. The FDA is not required to follow the recommendations of its advisers, but often does so.

Darvon was first approved in 1957, when there were few alternatives for treating pain except aspirin and powerful narcotics. Now mainly marketed as Darvocet, which includes a dose of acetaminophen, the drug remains one of the top 25 most commonly prescribed medications. More than 20 million prescriptions were written in 2007.

The consumer group Public Citizen had petitioned the FDA to withdraw Darvon because the drug offers relatively weak pain relief and poses an overdose risk, with the potential to be used in suicides.

"With a drug that has almost no evidence of benefit, any risk is unacceptable," said Dr. Sidney Wolfe, a drug safety expert with Public Citizen who first sought a ban in the 1970s. "Hopefully the FDA will follow the vote of its advisers." Two companies that market the drug - Xanodyne Pharmaceuticals and Qualitest/Vintage Pharmaceuticals- say the medication is safe and effective when used as directed. In documents filed with the FDA, the companies said doctors need a range of options to treat pain, and noted that many other painkillers have become drugs of abuse - some with far worse consequences. Dr. Jerry Avorn, a professor of medicine at Harvard and a critic of the pharmaceutical industry commended the FDA for taking a hard look at Darvon. "I have been astonished at how widely used this drug is," Avorn said. "It's no longer the most abusable and most dangerous drug in its class, but the fact that there are worse drugs doesn't make Darvon a good drug."

The United Kingdom banned its version of Darvon in 2005. If the FDA decides not to follow suit, it may take other steps, such as requiring stiffer warnings, safety studies or special education efforts aimed at doctors and patients. Wolfe said he is recommending that the drug be withdrawn gradually, because some patients have become dependent on it.

In an analysis prepared for the hearing, the FDA's safety office said it had searched the agency's database of reported drug problems, but the result was

"insufficient" to allow reviewers to make a clear-cut recommendation. The safety office found more than 3,000 reports of serious problems. The top three were suicide, drug dependence and overdoses.

In a separate analysis, the FDA office that handles painkillers said Darvon is a weak pain reliever. Most studies show that in Darvocet, the widely used combination drug, the Darvon component appears to contribute "little or no" additional pain relief beyond that provided by the acetaminophen component, reviewers said.

Wolfe presented the advisory panel with new data from the government's Drug Abuse Warning Network, which tracks emergency room visits and deaths. It said that Darvon-related deaths rose to 503 in 2007, from 446 in 2006. In both years, about 20 percent were suicides. The network covers only about one-third of the U.S. population.

Data from Florida's medical examiner reporting system showed that in 2007 Darvon was present in the bodies of 341 people who died of any cause. Medical examiners identified it as the cause of death in 85 cases.

On the Net:

FDA meeting agenda: <http://tinyurl.com/cg5k5a>

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