FDA Panel Opposes Pure Hydrocodone Painkiller

WASHINGTON (AP) — Government health experts overwhelmingly voted against a stronger version of hydrocodone on Friday, questioning the need for a new form of one of most widely abused prescription painkillers.

The Food and Drug Administration's panel of pain specialists voted 11-2 with one abstention against Zohydro for moderate to severe chronic pain. The drug was developed as a long-acting pain reliever by San Diego-based Zogenix Inc.

The FDA is not required to follow the group's recommendation, though it often does so. It is scheduled to make its decision on the drug by March 1.

The panelists acknowledged that the pill would likely reduce pain, but worried it would exacerbate the national epidemic of prescription painkiller abuse.

"I think the sponsor fulfilled the expectations of FDA, however I think the entire class is problematic in terms of abuse and safety issues," said Professor James Ware of the Harvard School of Public Health.

If approved, Zohydro would be the first pure hydrocodone medication available in the U.S. Currently available products combine the drug with lower-grade painkillers such as acetaminophen.

Hydrocodone is prescribed to treat pain from injuries, surgery, arthritis, migraines and a variety of other ailments.

Hydrocodone-containing pills consistently rank as the first or second most-abused medicines in the U.S., according to the Drug Enforcement Administration.

The drug belongs to a family of medicines known as opiates or opioids because they are chemically similar to opium. They include morphine, heroin, oxycodone, codeine, methadone and hydromorphone.

Opiates block pain but also unleash intense feelings of well-being and can create physical dependence. Several panelists said the risks of fatal overdose with opioids swayed their vote against Zohydro.

"I have traveled around the country and I have seen the repercussions of opioids — they are a threat to public health," said consumer panelist, Rodney Mullins, of the Health Promotion and Advisory Council.

In 2011, the Centers for Disease Control estimated 14,800 deaths were related to opioids.

Zogenix has touted the benefits of its long-lasting pill, which only needs to be taken once every 12 hours, compared with every four to six hours for combination drugs like Vicodin. The company also notes that patients taking pure hydrocodone would not be at risk for acetaminophen-related liver side effects.

Panel Chairman Randall Flick of the Mayo Clinic abstained from voting, but suggested Zogenix might reformulate the drug to make it more difficult to abuse. Drug abusers often crush or dissolve pills in liquid to unlock their extended release mechanism and get an intense high.

"It is my view that tamper-resistant formulations are likely to reduce the incidence of morbidity and mortality associated with this class of drugs," Flick said.

In recent years the FDA has begun prodding drugmakers to develop more sophisticated pain relievers that are harder to abuse, but such measures are not a requirement.

Zogenix said it would focus sales on 15 percent of the 330,000 U.S. health professionals who prescribe high-strength prescription painkillers. The company said it would to monitor prescribing patterns and visit physicians who appear to be writing more prescriptions than normal.

Shares of San Diego-based Zogenix were halted ahead of the meeting and last traded at $2.36.