

US panel opposes pure hydrocodone painkiller

December 9 2012, by Matthew Perrone

(AP)—U.S. 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 U.S. 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.

In 2011, the U.S. 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.

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.

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

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