US approves more powerful, pure hydrocodone drug (Update)

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The U.S. Food and Drug Administration has approved a stronger, single-ingredient version hydrocodone, the widely-abused prescription painkiller.

The agency said Friday it approved the extended-release pill Zohydro ER for patients with pain that requires "daily, around-the-clock, long-term treatment" that cannot be treated with other drugs.

Hydrocodone is currently sold in combination pills like Vicodin to treat pain from injuries, surgery, arthritis and migraines. The new drug from Zogenix is the first pure hydrocodone drug approved in the U.S.

The approval came as a surprise since the agency's own panel of outside advisers gave the drug an overwhelmingly negative review last year. The panel of pain specialists voted 11-2, with one abstention, against approving the drug, questioning the need for a new form of one of most widely-abused prescription drugs in U.S.

Zohydro's approval was quickly criticized by patient safety advocates who had urged the FDA to reject the drug at the public panel last December.

"We're just going to kill more kids and then the FDA is going to come back and say, 'oh, we made a mistake,'" said Avi Israel. His son Michael committed suicide in 2011 while struggling with painkiller addiction. Israel is the founder of a group called, Save the Michaels of the World, which aims to combat painkiller abuse in young people.

In 2011, U.S. doctors wrote more than 131 million prescriptions for hydrocodone, making it the most prescribed drug in the country, according to government figures. Hydrocodone also consistently ranks among 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. Others include morphine, heroin, oxycodone, codeine and methadone.

Friday's news was also blasted by lawmakers in Congress who have been trying to rein in prescription drug abuse in their home states.

Rep. Bill Keating, a Democrat, said the FDA should have required the drug to contain anti-abuse design features that would make it harder for users to crush the pills and snort or inject them.

"FDA not only approves this dangerous drug, but does so without requiring any abuse-deterrent features. This is outrageous," Keating said in a statement. "Abuse-deterrent technologies should not be the anomaly, they must be the norm."

In recent years, Purdue Pharma, Pfizer Inc., Endo Health Solutions Inc. and other drugmakers have developed tamper-resistant versions of popular opioid drugs.

The timing of the FDA announcement also drew criticism from safety advocates and lawmakers. Only one day earlier the FDA said it would support stronger restrictions on combination drugs containing hydrocodone, including Vicodin and dozens of other generic formulations.

The drugs currently available mix hydrocodone with non-addictive pain relievers like aspirin and acetaminophen. For decades these drugs have been subject to less rigorous prescribing limits than other prescription painkillers like oxycodone.

Late Thursday, the FDA said it would recommend moving hydrocodone combination drugs from the schedule III class to the schedule II class of medications. The switch means that the drugs can only be prescribed by a physician and cannot be refilled. Currently the drugs can be refilled up to five times by the patient can be and prescribed by

nurses and other health care workers.

The DEA had first asked the agency to reclassify the drug a decade ago, and lawmakers and safety advocates had increased their pressure on the agency in recent years.

The FDA said in its announcement Friday that the newly-approved Zohydro would be regulated under the schedule II classification.

The agency is also requiring the drug's manufacturer to conduct studies of Zohydro's potential misuse and abuse when used longer than 12 weeks.

The most common side effects reported in company trials included constipation, nausea, drowsiness, fatigue, dizziness, dry mouth, vomiting and itching.

Shares Zogenix, Inc. jumped in trading Friday, climbing 80 cents, or 36 percent, to close at $3.04. Earlier shares set a 52-week high of $3.45.