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FDA Commissioner: Zohydro Offers Unique Option to Treat Pain

Food and Drug Administration (FDA) Commissioner Margaret Hamburg defended the agency's decision to approve the pure hydrocodone drug Zohydro ER (extended release).

At a Senate hearing, Hamburg said, "If appropriately used, it serves an important and unique niche with respect to pain medication and it meets the standards for safety and efficacy."

Speaking before the Senate Health, Education, Labor and Pensions Committee, Hamburg acknowledged Zohydro is a powerful drug.

She noted that unlike other hydrocodone drugs, Zohydro does not contain acetaminophen, which can be toxic to the liver.

Zohydro is designed to be released over time, and can be crushed and snorted by people seeking a strong, quick high. "I would love if we had abuse-deterrent formulations that were actually meaningful and effective at deterring abuse in all instances. We are moving in that direction," Hamburg said. "Right now, unfortunately, the technology is poor."

The FDA's decision to approve Zohydro has been criticized by some legislators and public health groups, Reuters reports. Hamburg has received letters protesting the decision from 28 state attorneys general and four senators, among others.

Law enforcement agencies and addiction experts predict approval of the drug will lead to an increase in overdose deaths.

Zohydro was approved for patients with pain that requires daily, around-the-clock, long-term treatment that cannot be treated with other drugs. In December 2012, a panel of experts assembled by the FDA voted against recommending approval of Zohydro ER. The panel cited concerns over the potential for addiction. In the 11-2 vote against approval, the panel said that while the drug's maker, Zogenix, had met narrow targets for safety and efficacy, the painkiller could be used by people addicted to other opioids, including oxycodone.

Taking prescription drugs not prescribed for you by a doctor or in a way that hasn't been recommended by a doctor, can be more dangerous than you think. In fact, it can be fatal. Click here to learn more.