

# Potent new painkiller stokes alarm in US

March 8 2014, by Kerry Sheridan

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A potent new painkiller hit the US market this week, despite warnings from top experts that the drug may deliver a deadly setback in America's battle with opioid addiction.

Zohydro ER can contain 10 times the amount of hydrocodone as the most popular prescription painkiller, Vicodin, and is easily crushable so it could be snorted, bearing none of the recent safeguards added to pills like OxyContin (oxycodone).

In a nation where some 15,000 people die annually from prescription painkiller use, the drug's approval has raised alarm among doctors, lawmakers and relatives of those lost to overdose.

Two senators have launched an investigation into practices by the US Food and Drug Administration, amid allegations that pharmaceutical companies eager for a chunk of the \$9 billion painkiller market may have paid to influence regulators' decisions.

"It's almost unheard of," said Andrew Kolodny, president of the group Physicians for Responsible Opioid Prescribing.

"For FDA to approve a drug that is going to make a serious problem worse, it is pretty shocking."

Zohydro was approved in October 2013, even though a panel of FDA-convened experts voted against 11-2. The FDA is not obligated to follow the advice of its advisory committees, but it typically does.

An FDA spokesman told AFP the decision was made "after careful consideration," and "the product's benefits outweigh its risks when used as intended."

Zohydro contains pure hydrocodone in a range of doses, including time-release options that are much stronger than competitor products.

It does not contain acetaminophen, which can cause liver damage and death in high doses and is included in most other prescription opioids.

The drugmaker, California-based Zogenix, said in a statement that the "acetaminophen-free formulation of extended release hydrocodone is an important therapeutic option for certain [chronic pain patients](#)."

## **A mother's story**

Musician and financial adviser Steve Rummler was one of the 100 million people in the United States who suffer from [chronic pain](#).

He was prescribed narcotic painkillers in 2005 for a lingering back injury.

"The doctor kept increasing the amounts that he would give to Steve," his mother, Judy Rummler, told AFP.

By 2009, Steve's family learned he was seeking painkillers from multiple sources. He tried to learn other ways of coping. He tried rehab for addiction.

"He seemed great for a very short period of time, then he relapsed because of his pain," said Rummler.

When his last refills ran out, he scored some heroin, and overdosed on

July 1, 2011, at the age of 43.

"He was a totally different person the last few years of his life," said his mother, who now chairs a coalition of activists called Fed Up.

The group has held rallies and met with lawmakers in an effort to curb the [prescription painkiller](#) epidemic, which public health experts say is also fueling a rise in heroin and street drug use.

One hundred people in the United States die each day from drug overdose, according to the Centers for Disease Control and Prevention.

Regulators have introduced some tighter rules, and drugs like Zohydro fall under Schedule II, which means the pills can only be dispensed with a written prescription.

But plenty of people, including kids as young as 10, find ways to get opioids, said Janina Kean, president and CEO of High Watch Recovery Center in Connecticut.

"They are being overly prescribed. They end up in people's medicine cabinets," she said in an interview.

"We have a huge crisis in our country."

## **Pay to play?**

The Washington Post and Milwaukee Journal Sentinel reported in October that hundreds of emails released in a public records request showed pharmaceutical companies paid tens of thousands of dollars to attend FDA advisory panel meetings.

The FDA denied any impropriety, but US lawmakers have launched a

probe into whether the payments influenced regulators' decisions to approve drugs like Zohydro.

"If these allegations are true, there is a clear, illegal conflict of interest between the FDA and these [pharmaceutical companies](#) that puts consumer safety at risk," said Louisiana Senator David Vitter in a letter to the FDA last week.

Senator Chuck Schumer of New York has urged the Department of Health and Human Services to override the FDA and remove Zohydro from the market until protections to prevent abuse are added.

But that seems unlikely. The drug is already available in select US pharmacies, a spokeswoman for Zogenix said.

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