

New powerful painkiller has abuse experts worried

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In this Dec. 22, 2011 photo, the sun slowly sets on the empty parking lot at the Zogenix headquarters in San Diego. The pharmaceutical maker is one of at least four companies working on purer, more powerful versions of the nation's second most-abused medicine, hydrocodone, a trend that has addiction experts worried that it could spur a new round of abuse. (AP Photo/Lenny Ignelzi)

Drug companies are working to develop a pure, more powerful version of the nation's second most-abused medicine, which has addiction experts worried that it could spur a new wave of abuse.

The new pills contain the highly addictive painkiller hydrocodone, packing up to 10 times the amount of the drug as existing medications such as Vicodin. Four companies have begun patient testing, and one of them - Zogenix of San Diego - plans to apply early next year to begin marketing its product, Zohydro.

If approved, it would mark the first time patients could legally buy pure hydrocodone. Existing products combine the drug with nonaddictive painkillers such as acetaminophen.

Critics say they are especially worried about Zohydro, a timed-release drug meant for managing moderate to [severe pain](#), because abusers could crush it to release an intense, immediate high.

"I have a big concern that this could be the next OxyContin," said April Rovero, president of the National Coalition Against Prescription Drug Abuse. "We just don't need this on the market."

OxyContin, introduced in 1995 by Purdue Pharma of Stamford, Conn., was designed to manage pain with a formula that dribbled one dose of oxycodone over many hours.

Abusers quickly discovered they could defeat the timed-release feature by crushing the pills. Purdue Pharma changed the formula to make OxyContin more tamper-resistant, but addicts have moved onto generic oxycodone and other drugs that do not have a timed-release feature.

Oxycodone is now the most-abused medicine in the United States, with hydrocodone second, according to the Drug Enforcement Administration's annual count of drug seizures sent to police drug labs for analysis.

The latest drug tests come as more [pharmaceutical companies](#) are getting into the \$10 billion-a-year legal market for powerful - and addictive - opiate narcotics.

"It's like the wild west," said Peter Jackson, co-founder of Advocates for the Reform of Prescription Opioids. "The whole supply-side system is set up to perpetuate this massive unloading of opioid narcotics on the

American public."

The pharmaceutical firms say the new hydrocodone drugs give doctors another tool to try on patients in legitimate pain, part of a constant search for better painkillers to treat the aging U.S. population.

"Sometimes you circulate a patient between various opioids, and some may have a better effect than others," said Karsten Lindhardt, chief executive of Denmark-based Egalet, which is testing its own pure hydrocodone product.

The companies say a pure hydrocodone pill would avoid liver problems linked to high doses of acetaminophen, an ingredient in products like Vicodin. They also say patients will be more closely supervised because, by law, they will have to return to their doctors each time they need more pills. Prescriptions for the weaker, hydrocodone-acetaminophen products now on the market can be refilled up to five times.

Zogenix has completed three rounds of patient testing, and last week it announced it had held a final meeting with Food and Drug Administration officials to talk about its upcoming drug application. It plans to file the application in early 2012 and have Zohydro on the market by early 2013.

Purdue Pharma and Cephalon, a Frazer, Pa.-based unit of Israel-based Teva Pharmaceuticals, are conducting late-stage trials of their own hydrocodone drugs, according to documents filed with federal regulators. In May, Purdue Pharma received a patent applying extended-release technology to hydrocodone. Neither company would comment on its plans.

Meanwhile, Egalet has finished the most preliminary stages of testing aimed at determining the basic safety of a drug. The firm could have a

product on the market as early as 2015 but wants to see how the other companies fare with the FDA before deciding whether to move forward, Lindhardt said.

Critics say they are troubled because of the dark side that has accompanied the boom in sales of narcotic painkillers: Murders, pharmacy robberies and millions of dollars lost by hospitals that must treat overdose victims.

Thousands of legitimate pain patients are becoming addicted to powerful prescription painkillers, they say, in addition to the thousands more who abuse the drugs.

Prescription [painkillers](#) led to the deaths of almost 15,000 people in 2008, more than triple the 4,000 deaths in 1999, the Centers for Disease Control and Prevention reported last month.

Emergency room visits related to hydrocodone abuse have shot from 19,221 in 2000 to 86,258 in 2009, according to data compiled by the [Drug Enforcement Administration](#). In Florida alone, hydrocodone caused 910 deaths and contributed to 1,803 others between 2003 and 2007.

Hydrocodone belongs to family of drugs 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. The withdrawal symptoms are also intense, with users complaining of cramps, diarrhea, muddled thinking, nausea and vomiting.

After a while, opiates stop working, forcing users to take stronger doses

or to try slightly different chemicals.

"You've got a person on your product for life, and a doctor's got a patient who's never going to miss an appointment, because if they did and they didn't get their prescription, they would feel very sick," said Andrew Kolodny, president of Physicians for Responsible Opioid Prescribing. "It's a terrific business model, and that's what these companies want to get in on."

Under pressure from the government, Purdue Pharma last year debuted a new [OxyContin](#) pill formula that "squishes" instead of crumbling when someone tries to crush it.

But Zogenix, whose drug is time-released but crushable, says there is not enough evidence to show that such tamper-resistant reformulations thwart abuse.

"Provided sufficient effort, all formulations currently available can be overcome," Zogenix said in a written response to questions by The Associated Press.

At a conference for investors New York on Nov. 29, Zogenix chief executive Roger Hawley said the FDA was not pressuring Zogenix to put an abuse deterrent in Zohydro.

"We would certainly consider later launching an abuse-deterrent form, but right now we believe the priority of safer hydrocodone - that is, without acetaminophen - is a key priority for the FDA," Hawley said.

FDA spokeswoman Erica Jefferson said the agency would not comment on its discussions with drug companies, citing the need to protect trade secrets.

Drug control advocates say they're worried the U.S. government is too lax about controlling addictive pain medications. The United States consumes 99 percent of the world's hydrocodone and 83 percent of its oxycodone, according to a 2008 study by the International Narcotics Control Board.

One 41-year-old loophole in particular has fed the current problem with hydrocodone abuse, critics say. The federal Controlled Substances Act, passed in 1970, puts fewer controls on combination pills containing hydrocodone and another painkiller than it does on the equivalent [oxycodone](#) products.

A Vicodin prescription can be refilled five times, for example, while a Percocet prescription can only be filled once.

The Drug Enforcement Administration and Food and Drug Administration have been studying whether to close this loophole since 1999 but have made no decision. Congress is now considering a bill that would force the agencies to tighten the controls.

"This is a problem that is fundamentally an oversupply problem," said Jackson, the drug-control advocate. "The FDA has kind of opened the floodgates, and they refuse to recognize the mistakes made in the past."

Pure hydrocodone falls into the stricter drug-control category than hydrocodone-acetaminophen medications, meaning patients would have to go to their doctors for a new prescription each time they needed more pills. But Jackson said that's no guarantee against abuse, noting that dozens of unscrupulous doctors have been caught churning out prescriptions in so-called "pill mills."

The [Drug](#) Enforcement Administration, which enforces controls on medicines along with the FDA, said it could not comment on drugs that

have not yet been approved for sale.

However, Zogenix has acknowledged the abuse issue could become a liability.

"Illicit use and abuse of hydrocodone is well documented," it said in a filing with the Securities and Exchange Commission in September.

"Thus, the regulatory approval process and the marketing of Zohydro may generate public controversy that may adversely affect regulatory approval and market acceptance of Zohydro."

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