

States revolt against powerful new painkiller

April 4 2014, by Beth Garbitelli



In this Wednesday, Jan. 8, 2014 file photo, Vermont Gov. Peter Shumlin delivers the State of the State Address at the Statehouse in Montpelier, Vt. On Thursday, April 3, 2014, Shumlin announced an emergency order that would make it harder for physicians to prescribe a new class of drugs that includes Zohydro. Many feel the extended-release pill is prone to abuse, because it's not tamper resistant and contains up to five times more of the narcotic hydrocodone than previously available in other pills. (AP Photo/Andy Duback, File)

State officials fighting a well-publicized battle against heroin and prescription drug abuse are revolting against a powerful new painkiller

that law enforcement and public health officials fear could worsen an already acute drug problem.

On Thursday, Vermont Gov. Peter Shumlin announced an emergency order that would make it harder for physicians to prescribe a new class of drugs that includes Zohydro. Many feel the extended-release pill is prone to abuse, because it's not tamper resistant and contains up to five times more of the narcotic hydrocodone than previously available in other pills.

The Food and Drug Administration approved the drug last fall and it hit the market last month.

Prescription drug abuse is the fastest growing drug problem in the U.S. with more than 4.5 million Americans abusing pain relievers, according to a 2013 Drug Enforcement Administration report.

Law enforcement and public health officials say for many people, prescription painkiller abuse can pave the way to heroin addiction. In January, Shumlin devoted the bulk of his State of the State address to Vermont's "full blown heroin crisis."

Shumlin didn't go as far as Massachusetts Gov. Deval Patrick, who last week ordered an outright ban on prescribing and dispensing Zohydro until it is marketed in a form that is difficult to abuse. But Shumlin and Vermont Health Commissioner Dr. Harry Chen both questioned the FDA approval.



In this Jan. 22, 2014 file photo, Mass. Gov. Deval Patrick gestures during a news conference at the Statehouse in Boston. Patrick last week ordered an outright ban on prescribing and dispensing Zohydro until it is marketed in a form that is difficult to abuse. Zohydro belongs to a family of medicines known as opiates or opioids. Others include morphine, heroin and oxycodone, the painkiller in OxyContin. (AP Photo/Charles Krupa, File)

"It's not like we don't have painkillers in America," Shumlin said. "So you know, we're just saying 'Hey, we understand we don't control the FDA, but we do have some influence in Vermont,'" he said.

The backlash against Zohydro has been growing since last year, when the FDA approved the drug against the recommendation of an internal advisory committee.

Late last year, 28 state attorneys general signed a letter asking the FDA to revoke the drug's approval or require the manufacturer to reformulate

the drug so it is more difficult for abusers to crush for snorting or injection.

U.S. Sen. Joe Manchin and Rep. Stephen Lynch introduced legislation that would compel the FDA to withdraw the drug.

Zohydro belongs to a family of medicines known as opiates or opioids. Others include morphine, heroin and oxycodone, the painkiller in OxyContin.

Its painkilling power comes from hydrocodone. Other medications, such as Vicodin, contain the same narcotic but also include acetaminophen, the active ingredient in Tylenol.

San Diego-based Zogenix, which makes Zohydro, said the drug is no more potent, per milligram, than other hydrocodone medications. The company also said it set up a board of experts to guard against abuse and that its sales representatives are not being paid based on the volume, but rather on their efforts to ensure prescribers, pharmacists and patients understand the medication's risks and benefits.

The FDA said Zohydro meets its standards and provides an important treatment option for patients with chronic pain. The agency, which in 2010 approved a crush-resistant version of OxyContin to try to discourage abuse, also points out that abuse-deterrent formulations of Zohydro are in the early stages of development.

Shumlin said he chose strict regulation over an outright ban, at least in part to avoid what could be expensive litigation.

"I expect that Massachusetts is likely to confront that and we really wanted to get something done quickly," Shumlin said.

Vermont's emergency rule to prescribe Zohydro includes requirements that prescribers conduct a thorough medical evaluation and risk assessment.

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