

**2015 HOUSE HUMAN SERVICES**

**HCR 3038**

# 2015 HOUSE STANDING COMMITTEE MINUTES

**Human Services Committee**  
Fort Union Room, State Capitol

HCR 3038  
2/23/2015  
Job #24253

- Subcommittee  
 Conference Committee

Committee Clerk Signature



## Explanation or reason for introduction of bill/resolution:

Legislative Management study on Zohydro.

## Minutes:

Testimony 1, 1b

Chairman Weisz opened the hearing on HCR 3038.

Rep. Ben Hanson: Introduced and supported the bill. (See Testimony # 1)

5:03

Rep. Mooney: The acetaminophen, isn't it Tylenol?

Rep. Hanson: It is in Tylenol.

**NO OPPOSITION**

Chairman Weisz closed the hearing.

Chairman Weisz took up HCR 3038.

Rep. Oversen: I Move a Do Pass on HCR 3038.

Rep. Mooney: Second.

Rep. Porter: I don't think I will support the motion. I think we have worked diligently with our board of pharmacy in putting together the programs for the prescription drug monitoring program in place. We have licensed physicians prescribing and we are monitoring all of that. I don't know what we as a legislative body would do with this type of study. I don't think this legislature could make an informed decision about this and that is why we have the board of pharmacy. This is as addictive as OxyContin and others like it and it is just timed released.

House Human Services Committee

HCR 3038

February 23, 2015

Page 2

Rep. Overseen: If there are other states who have taken action to make this a prescription of a last resort, I think it would be responsible to study it.

ROLL CALL VOTE: 5 y 8 n 0 absent

MOTION FAILED

Rep. Porter: I Move a Do Not Pass on HCR 3038.

Rep. Hofstad: Second.

ROLL CALL VOTE: 8 y 5 n 0 absent

MOTION CARRIED

Bill Carrier: Rep. Porter

Date: 2-23-15  
Roll Call Vote #: 1

2015 HOUSE STANDING COMMITTEE  
ROLL CALL VOTES  
BILL/RESOLUTION NO. 3038

House Human Services Committee

Subcommittee

Amendment LC# or Description: \_\_\_\_\_

Recommendation:  Adopt Amendment  
 Do Pass  Do Not Pass  Without Committee Recommendation  
 As Amended  Rerefer to Appropriations  
 Place on Consent Calendar  
Other Actions:  Reconsider  \_\_\_\_\_

Motion Made By Rep. Oversen Seconded By Rep. Mooney

Representatives	Yes	No	Representatives	Yes	No
Chairman Weisz	✓		Rep. Mooney	✓	
Vice-Chair Hofstad		✓	Rep. Muscha	✓	
Rep. Bert Anderson		✓	Rep. Oversen	✓	
Rep. Dick Anderson		✓			
Rep. Rich S. Becker		✓			
Rep. Damschen		✓			
Rep. Fehr					
Rep. Kiefert	✓				
Rep. Porter		✓			
Rep. Seibel		✓			

Total (Yes) 5 No 8

Absent 0

Floor Assignment \_\_\_\_\_

If the vote is on an amendment, briefly indicate intent:

Date: 2-23-15  
Roll Call Vote #: 2

2015 HOUSE STANDING COMMITTEE  
ROLL CALL VOTES  
BILL/RESOLUTION NO. 3038

House Human Services Committee

Subcommittee

Amendment LC# or Description: \_\_\_\_\_

Recommendation:  Adopt Amendment  
 Do Pass  Do Not Pass  Without Committee Recommendation  
 As Amended  Rerefer to Appropriations  
 Place on Consent Calendar  
Other Actions:  Reconsider  \_\_\_\_\_

Motion Made By Rep. Porter Seconded By Rep. Hofstad

Representatives	Yes	No	Representatives	Yes	No
Chairman Weisz		✓	Rep. Mooney		✓
Vice-Chair Hofstad	✓		Rep. Muscha		✓
Rep. Bert Anderson	✓		Rep. Oversen		✓
Rep. Dick Anderson	✓				
Rep. Rich S. Becker	✓				
Rep. Damschen	✓				
Rep. Fehr	✓				
Rep. Kiefert		✓			
Rep. Porter	✓				
Rep. Seibel	✓				

Total (Yes) 8 No 5

Absent \_\_\_\_\_

Floor Assignment Rep. Porter

If the vote is on an amendment, briefly indicate intent:

**REPORT OF STANDING COMMITTEE**

**HCR 3038: Human Services Committee (Rep. Weisz, Chairman) recommends DO NOT PASS (8 YEAS, 5 NAYS, 0 ABSENT AND NOT VOTING). HCR 3038 was placed on the Eleventh order on the calendar.**

**2015 TESTIMONY**

**HCR 3038**



# NORTH DAKOTA HOUSE OF REPRESENTATIVES

STATE CAPITOL  
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## Representative Ben Hanson

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#1  
**COMMITTEES:**  
Industry, Business and Labor  
Transportation

## HCR 3038 Testimony; Rep. Ben Hanson

### House Committee on Human Services:

*February 18<sup>th</sup>, 2015 testimony in regards to HCR 3038; A concurrent resolution directing the Legislative Management to study Zohydro to determine if proper measures are in place to make the prescription of this drug a last resort.*

Mr. Chair, fellow committee members, for the record my name is Ben Hanson and I am a representative from District 16 in Fargo and West Fargo. I stand before you today to testify in favor HCR 3038.

First a little defining. Zohydro is newly FDA-approved opioid (think Oxycontin, Percocet, Vicodin, etc.) painkiller. The big difference with Zohydro is the absence of acetaminophen. Acetaminophen is what reduces the addictive nature of the opioids in similar prescription drugs. The unfortunate side effect is (sometimes severe) damage to the liver. Zohydro's manufacturer, Zogenix, is attempting to provide pain relief with those in severe pain who also have liver conditions. In doing so they have made the first ever long-acting product pain killer with a single ingredient: hydrocodone.

The potential for addiction and abuse is high. Since 1999 deaths from prescription drug overdoses have quadrupled. Over prescription of products such as Oxycontin are well-documented and other states have begun looking into how and when Zohydro should be prescribed. The intent of this study is to monitor its use in North Dakota during the interim and see whether we want to impose our own restrictions as to when the product is prescribed.

part of #16 HCR 3038  
2-23-15

AP / September 24, 2014, 3:50 AM

# Anti-addiction activists to FDA head: Quit



FDA Commissioner Margaret Hamburg during daily White House briefing on June 21, 2011 / ALEX WONG, GETTY IMAGES

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**WASHINGTON** -- Anti-addiction activists are calling for the Food and Drug Administration's top official to step down, saying the agency's policies have contributed to a national epidemic of prescription painkiller abuse.

In a letter released Wednesday, more than a dozen groups ask the Obama administration's top health official to replace FDA Commissioner Dr. Margaret Hamburg, who has led the agency since 2009. The FDA has been under fire from public health advocates, politicians and law enforcement officials since last October, when it approved a powerful new painkiller called Zohydro against the recommendation of its own medical advisers.

The new letter is the first formal call for new leadership at the FDA over the issue.

"We are especially frustrated by the FDA's continued approval of new, dangerous, high-dose opioid analgesics that are fueling high rates of addiction and overdose deaths," states the letter, which is addressed to Health and Human Services Secretary Sylvia Burwell, who oversees the FDA and other health agencies. The groups signing the letter include Physicians for Responsible Opioid Prescribing, a 900-member advocacy group that petitioned the FDA to drastically restrict opioid use. The FDA rejected that petition last year.

A spokeswoman for the Department of Health and Human Services said opioid abuse "is a serious issue and one that the secretary is focused on."

"Secretary Burwell appreciates hearing from stakeholders on the important issue of prescription opioid abuse, and looks forward to responding to their letter," spokeswoman Tait Syc said in a statement.

Deaths linked to the addictive medications, including OxyContin and Vicodin, have more than tripled over the last 20 years to an estimated 17,000 in 2011, the

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most recent year for which the Centers for Disease Control and Prevention reports figures.

The CDC has called on doctors to limit their use of the medications to the most serious cases of pain, such as cancer patients and end-of-life care. But the vast majority of prescriptions written in the U.S. are for more common ailments like arthritis and back pain.

Hamburg has supported broad use of the drugs, noting that 100 million Americans reportedly suffer from chronic pain.

The letter to HHS says the commissioner and the FDA are out of step with efforts by the CDC and other parts of the federal government.

"Dr. Hamburg's support for using opioids to treat chronic non-cancer pain is squarely at odds with efforts by the CDC to discourage this widespread practice," states the letter, which is signed by the National Coalition Against Prescription Drug Abuse and 15 other groups.

FDA spokeswoman Erica Jefferson said Hamburg has been "a tireless public health advocate" for over 20 years.

"Preventing prescription opioid abuse and ensuring that patients have access to appropriate treatments for pain are both top public health priorities for the FDA," Jefferson said in a statement.

The calls for Hamburg's resignation come almost a year after the FDA approved Zohydro, the first extended-release, pure form of hydrocodone ever cleared for the U.S. market. Hydrocodone was previously only available in immediate release, combination pills that contain smaller amounts of the drug.

Commissioner Hamburg has defended the drug's approval by saying that it fills an important medical niche. Older combination pills like Vicodin mix hydrocodone with other drugs like acetaminophen, which can cause liver damage at high levels.

Members of Congress from West Virginia, Massachusetts and Kentucky have introduced bills to ban the drug. And attorneys general from 28 states asked the FDA to revoke the drug's approval or require that the pills be reformulated to prevent users from crushing them for snorting or injection.

But Wednesday's letter also criticizes the FDA for approving drugs that are actually designed to be harder to abuse.

The groups take issue with the agency's July approval of a new painkiller called Targiniq, which combines oxycodone with the ingredient naloxone. The addition of naloxone is designed to block the euphoric effects of oxycodone when it is snorted or injected. But the groups point out that Targiniq tablets can still be abused by simply chewing them - the most common approach to abusing painkillers.

The FDA has faced criticism from lawmakers representing states that have been hardest hit by opioid abuse, including Sen. Joe Manchin of West Virginia, Sen. Charles Schumer of New York and Congressman Hal Rogers of Kentucky.

Media representatives for all three lawmakers declined to comment on the letter. The American Pain Society, which represents physician pain specialists, also declined to comment for this story.

AP

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Published on FiercePharma (<http://www.fiercepharma.com>)

## Hamburg called on to resign for FDA's approval of Zohydro

September 24, 2014 | By Eric Palmer

The FDA approved opioid painkiller Zohydro nearly a year ago as a med to provide relief for those with chronic pain. But the drug has been nothing but 11 months of aggravation for the agency and its leader, Commissioner Margaret Hamburg, who is now being called on to resign by organized anti-addiction groups who say the FDA has contributed to an epidemic of abuse in the country.



*FDA Commissioner  
Margaret Hamburg*

"We are especially frustrated by the FDA's continued approval of new, dangerous, high-dose opioid analgesics that are fueling high rates of addiction and overdose deaths," says a letter to Hamburg's boss, Health and Human Services Secretary Sylvia Burwell, according to *CBS News*. The letter is signed by about 15 groups.

An HHS spokesperson said Burwell would respond, adding that opioid abuse "is a serious issue and one that the secretary is focused on."

The approval of Zohydro and other painkillers has turned into a political hot potato for Hamburg, who has pointed out that 100 million people who suffer from chronic pain are looking for relief. But some doctors, prosecutors and politicians have pointed to rising rates of opioid addiction and overdose deaths, and the attendant crime, and called on the agency to stop approving new drugs in the category. Overdose deaths from painkillers tripled in the 20 years leading up to 2011.

The groups claim the agency is not in sync with a country overwhelmed by a drug problem and point to the U.S. Centers for Disease Control and Prevention (CDC) recommendation that doctors reserve high-powered painkillers for use on cancer patients and for end-of-life care. Most prescriptions are written, instead, for back pain and arthritis.

The letters says, "Dr. Hamburg's support for using opioids to treat chronic non-cancer pain is squarely at odds with efforts by the CDC to discourage this widespread practice." But FDA spokeswoman Erica Jefferson responded that "[p]reventing prescription opioid abuse and ensuring that patients have access to appropriate treatments for pain are both top public health priorities for the FDA."

In testimony this year before a Senate committee, Hamburg said, "We recognize that this is a powerful drug, but we also believe that if appropriately used, it serves an important and unique niche with respect to pain medication and it meets the standards for safety and efficacy." The FDA has also approved some drugs that are formulated in ways to make them more difficult to abuse, but Hamburg has also acknowledged that abuse-deterrent technology so far has been unable to foil dedicated abusers.

The approval last October of Zohydro, the first extended-release uncut form of hydrocodone, provided a rallying point for building frustration. The issue has also been a media magnet for some politicians, like Massachusetts Gov. Deval Patrick, who drew national attention for his failed effort to ban its use in Massachusetts.

The companies that make some of the most abused painkillers have also come in for criticism and, more recently, legal action. The city of Chicago and two California counties have filed lawsuits against 5 manufacturers of prescription painkillers, accusing them of conspiracy and fraud in an effort to alter public perceptions about narcotic painkillers. The suits are seeking millions of dollars to pay for the public's costs. The 5 companies include Actavis (\$ACT), Endo (\$ENDP), Johnson & Johnson's (\$JNJ) Janssen Pharmaceuticals, Purdue Pharma and Teva (\$TEVA).

**Source URL:** <http://www.fiercepharma.com/story/hamburg-called-resign-fdas-approval-zohydro/2014-09-24>

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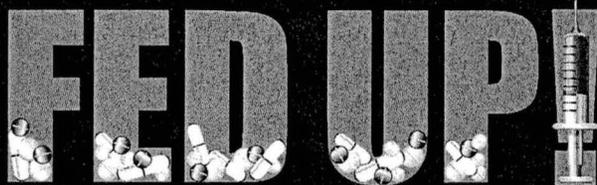
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**A COALITION TO END  
THE OPIOID EPIDEMIC**  
*'Opioids are narcotic painkillers & heroin*

February 26, 2014

Margaret A. Hamburg, M.D.  
Commissioner  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

RE: New Drug Application NDA 202880, Zohydro ER

Dear Dr. Hamburg,

We are writing to echo concerns raised in letters written by Members of the United States Congress and by State Attorneys General regarding the Food and Drug Administration's (FDA) approval of Zohydro, a high-dose, single-entity hydrocodone formulation. We join them in asking you to adopt the recommendation of the FDA-appointed scientific advisory panel, which voted 11-2 against approval of Zohydro.

On behalf of consumer safety organizations, health care agencies, addiction treatment providers, community-based drug and alcohol prevention programs, professional organizations, and other groups on the front-line of our nation's opioid addiction epidemic, we ask you to put the public's health ahead of industry interests. In the midst of a severe drug addiction epidemic fueled by overprescribing of opioids, the very last thing the country needs is a new, dangerous, high-dose opioid.

If your decision to approve Zohydro was based on adherence to existing FDA policies, then surely those policies require urgent revision. FDA must take into account recent history. After the release of similar high-dose opioid analgesics, thousands of lives were lost from overdose and hundreds of thousands of medical and non-medical users became addicted. We implore you to take these painful lessons into account.

Over the past 15 years, prescriptions for opioids have skyrocketed. The United States, with about 5% of the world's population, is now consuming more than 84% of the world's entire oxycodone supply and more than 99% of the hydrocodone supply.<sup>1</sup> According to the United States Centers for Disease Control (CDC), the sharp increase in opioid prescribing has led to parallel increases in opioid addiction and overdose deaths. Since 1999, overdose deaths have skyrocketed, especially among middle-aged individuals prescribed opioids for chronic pain. Opioid analgesic overdose deaths have increased by 415% in women and 265% in men.<sup>2</sup>

Zohydro's maker has claimed that it is safer than existing hydrocodone products because it does not contain acetaminophen. Zohydro is not safer. The highest available dosage of Zohydro will contain 5 to 10 times more hydrocodone than Vicodin or Lortab. Someone unaccustomed to taking opioids could suffer a fatal overdose from just two capsules. A single capsule could be fatal if swallowed by a child. For patients unable to tolerate acetaminophen, many opioid formulations made without acetaminophen are already available. There is no need for another high-dose, single-entity opioid.

Too many people have already become addicted to similar opioid medications and too many lives have been lost. We urge you to exercise your authority and responsibility to protect the public's health by keeping Zohydro off the market.

Sincerely,

<sup>1</sup> United States hydrocodone and oxycodone consumption statistics as reported by the International Narcotics Control Board in 2012.

<sup>2</sup> CDC. Vital signs: Overdoses of prescription opioid pain relievers and other drugs among women—United States, 1999–2010. MMWR 2013; 62:537-542

**A call for immediate, coordinated and comprehensive federal action  
to end the epidemic of opioid addiction and overdose deaths**

5

G Caleb Alexander

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Sam Ball

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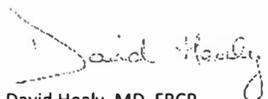
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Stuart Gitlow

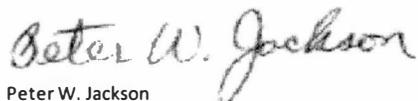
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Amy Graves

Amy Graves  
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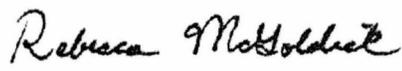
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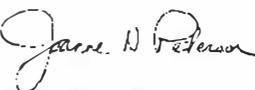
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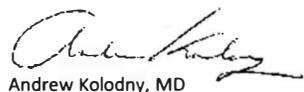


Joanne Peterson  
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BlueShield of Northeastern New York (Albany)

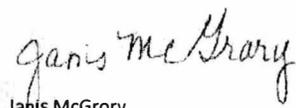
Avi Israel  
Avi Israel  
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Save the Michaels of the World  
Buffalo, NY



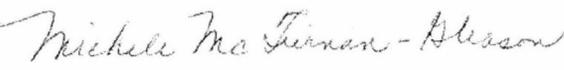
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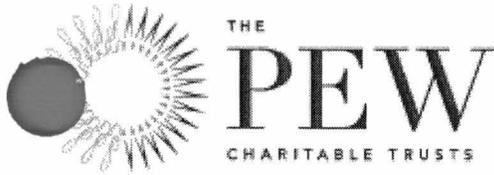
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## State and Consumer Initiatives

Scott Davis - Indian Affairs

April 28, 2014

# S Fearing Abuse, States Challenge FDA on Painkiller Approval

By [Michael Ollove](#), Staff Writer

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Notwithstanding a court order, Massachusetts and other states plan to restrict use of a new painkiller drug, setting up a showdown with the federal government over who gets to decide the best way to protect public health.

In the case of Zohydro, the argument pits the needs of millions of chronic pain sufferers against the urgent desire of states to combat an already catastrophic epidemic of prescription drug abuse. Although there haven't been specific cases of Zohydro abuse in

Massachusetts, Democratic Gov. Deval Patrick fears the powerful new drug will make the painkiller abuse crisis even worse.

In the first round earlier this month, U.S. District Court Judge Rya W. Zobel came down on the side of Washington, ruling that Massachusetts could not ban a drug deemed to be safe and effective by the Food and Drug Administration. In thwarting Patrick's move—perhaps the first time a state has ever tried to ban a drug approved by the FDA—Zobel emphasized that federal law trumps state law.

But Patrick responded to his loss in court by slapping other restrictions on Zohydro, beyond those mandated by the federal government. Whether those steps will invite another court challenge remains to be seen.



Kentucky Attorney General Jack Conway and a woman whose daughter died from a prescription pill overdose share a hug in front of a billboard warning of the dangers of prescription drug abuse. Kentucky and other states want the FDA to overturn its approval of Zohydro, a powerful new painkiller. (AP)

Next door in Vermont, Democratic Gov. Peter Shumlin has already taken similar steps. Meanwhile, the GOP-controlled Ohio legislature is considering its own ban on Zohydro.

There also has been action in Washington, D.C. Members of Congress from Massachusetts, Kentucky and West Virginia have introduced bills to ban the drug, and 29 state attorneys general – representing both parties – have asked the FDA to reconsider its October approval of Zohydro.

And in February, nearly four dozen consumer and anti-addiction groups signed a letter to FDA Commissioner Margaret Hamburg urging her to overturn the approval of Zohydro.

“We’re in the context of a very serious epidemic of opioid drug addictions and opioid deaths and that’s a public health crisis that has been growing over the last decade and half,” said Michael Carome, director of the Health Research Group at the consumer organization Public Citizen, which signed the letter to Hamburg. “The last thing we needed was another extended release opioid for treating chronic pain.”

### No Liver Damage

Zohydro is in the class of naturally occurring or synthetic chemicals containing the psychoactive chemical opioid, as are a number of legal prescription pain medications such as Vicodin, Percocet and OxyContin. Heroin is also an opioid. The opioid painkillers not only are easily abused, but they often prompt users to try heroin, which is far cheaper.

According to a 2013 report by the Trust for America’s Health, 6.1 million Americans abuse or misuse prescription drugs. Overdose deaths involving prescription painkillers have quadrupled since 1999, and now outnumber those from heroin and cocaine combined.

**6.1 Million**  
AMERICANS ABUSE OR MISUSE  
PRESCRIPTION DRUGS

Zohydro is the first single-ingredient, long-acting product containing the semi-synthetic opioid hydrocodone. Until Zohydro, which

 TWEET THIS FACT

is just reaching the market now, all the other painkillers on the market containing hydrocodone were combined with the anti-inflammatory analgesic acetaminophen. The use of acetaminophen, which is not addictive, allows patients to take less potent opioids which are both addictive and can cause nausea, constipation and dangerously shallow breathing. Acetaminophen is a common ingredient in over-the-counter painkillers, such as Tylenol and Excedrin, as well as opioid medications like Percocet and Vicodin.

The problem is that in high dosages, acetaminophen is highly toxic to the liver and can cause irreparable, even fatal damage to the organ. One University of Pennsylvania study found that half of the deaths caused by acetaminophen overdose were unintentional. That explains why the FDA last year began limiting the amount of acetaminophen in painkilling medications to 325 milligrams. But even that amount may be too much for those with compromised livers. Until now, many of them were forced to either do without hydrocodone painkillers, risk further damage to their livers, or take other opioids that do not contain acetaminophen.

That is why Zohydro represents a welcome advance to many. “It does have an advantage for some people in that it delivers hydrocodone without the risk of acetaminophen,” said Lynn Webster, immediate past president of the American Academy of Pain Medication.

10

## Potent—And Easily Abused

But it is the potency potential for illegal users that has opponents so worried and angry at the FDA, not only for its approval of the drug but also its failure to require the manufacturer, Zogenix, to develop a version that is more difficult to abuse. Critics have seized on the fact that the FDA's own advisory committee voted 11-2 against approving the drug. An FDA spokesperson, Sandy Walsh, said the agency often takes the counsel of its advisory committees, but not always.

Walsh acknowledged the potential for Zohydro's misuse. But she argued that revised labeling—including a boxed warning about the serious risks of addiction, abuse, and misuse—along with other safeguards would “support its safe and appropriate use.”

Unlike some other extended release opioids already on the market, Zohydro doesn't yet come in an abuse deterrent form, which would cut its potency when crushed for the purpose of smoking, snorting or injecting. Zohydro pills can come in dosages as high as 50 milligrams, which isn't unusual for a drug released over 12 hours. But when crushed by illicit users, the entire 50 milligrams can be delivered at once.

Zogenix argues that on a per milligram basis, Zohydro is no more potent than Vicodin and equally as potent as oxycodone. It also points out that when used appropriately, Zohydro is released into the body over 12 hours rather than two or three hours as is the case with quick-release medications.

The company also says it is developing an abuse deterrent version of Zohydro. In the meantime, it said it has implemented other safeguards, such as compensating sales representatives for educating doctors, pharmacists and patients on the risks and benefits of extended-release opioids. The company also says it is giving patients free locking pill bottle caps and discounted safe-storage units.

## Other Painkillers in Pipeline

Vermont's Shumlin was the first to slap restrictions on the use of Zohydro in his state. Earlier this month, he issued an emergency rule that, in addition to other measures, requires prescribers to ascertain that other pain medications have proven ineffective before prescribing Zohydro to a patient. Patients also are required to be observed and monitored for abuse potential by way of the state's prescription monitoring program. Such programs are designed to detect abusers who may be going to multiple prescribers to get painkillers.

“I didn't want to make the same mistake here that we made with OxyContin in the '90s,” said Harry Chen, commissioner of the Vermont Department of Health. “The reality is that it was given out like candy.” Chen does not believe the state's authority to regulate doctors and pharmacies gives it the ability to place restrictions on Zohydro. So far, however, no one has filed a legal challenge.

Chen said Vermont and Massachusetts conferred about what to do about Zohydro, but Vermont decided not to issue a ban, fearing that it would not stand up in court, which proved to be the case in Massachusetts.

Zogenix, not the FDA, asked Zobel for an injunction to overturn the Massachusetts ban. The company also objects to the restrictions Patrick placed on Zohydro last week in Massachusetts, which appear to resemble Vermont's. The company said it is being unfairly targeted.

Sherry Green, chief operating officer of The National Alliance for Model State Drug Laws, agreed with Zogenix that taking action against selective prescription drugs is the wrong approach.

“When we focus almost solely on an individual drug we tend not to put as much attention on the underlying problem which is the abuse and addiction. Obstructing illicit routes to one medication only creates pathways to another one,” Green said.

The issue isn't likely to fade away. The FDA is now considering approval of a combination of oxycodone and

morphine called Moxduo, which frightens anti-addiction advocates as much as Zohydro. As with Zohydro, an FDA advisory committee has recommended against approval.

"What crossed my mind is whether the FDA will again disregard its advisory board," said Vermont's Chen. "I hope not."

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12