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Judge blocks Massachusetts ban on painkiller

By **STEVE LeBLANC**

Associated Press

APRIL 15, 2014 3:08 PM

BOSTON (AP) — A federal judge has blocked Massachusetts from banning the powerful new painkiller Zohydro.

U.S. District Court Judge Rya Zobel on Tuesday issued a preliminary injunction after the maker of the drug, Zogenix, argued in a lawsuit that the ban ordered by Gov. Deval Patrick last month is unconstitutional.



Zobel said in issuing the injunction that Massachusetts appears to have overstepped its authority in banning the prescription medication, which had been approved by the federal Food and Drug Administration, and that Zogenix was likely to succeed in its pursuit of a court order to lift the ban permanently.

The San Diego-based drugmaker hailed the ruling, saying that allowing states to essentially overturn decisions of the FDA would “set an alarming precedent.”

Patrick said he was disappointed, arguing that the ruling places commercial interests above the public’s health.

“Addiction is a serious enough problem already in Massachusetts without having to deal with another addictive narcotic painkiller sold in a form that isn’t tamper proof,” Patrick said in a statement. “We will turn our attention now to other means to address this public health crisis.”

The ban is believed to be the first attempt by a state to block a federally approved drug, according to the National Alliance for Model State Drug Laws.

Patrick ordered the ban after declaring a public health emergency in



crisis” because the narcotic can be easily crushed, then snorted or injected to create an immediate and potentially lethal high.

In her decision, Zobel noted the FDA’s approval of the drug in October and said federal law pre-empts Patrick’s emergency order.

“When the Commonwealth interposed its own conclusion about Zohydro ER’s safety and effectiveness by virtue of the ... emergency order, did it obstruct FDA’s Congressionally-given charge? I conclude that it did,” Zobel wrote.

She said allowing the ban would “undermine the FDA’s ability to make drugs available to promote and protect the public health.” She said Patrick’s suggestion that the ban might be lifted if Zogenix created a non-crushable “abuse-resistant” version of the prescription medication would force Zogenix to return to the FDA to seek approval for a drug different from the one that the FDA has already deemed safe.

Zogenix has also been able to show injury to its reputation by the highly publicized ban, Zobel said.

The judge said the state’s concerns can’t trump the legitimate use of the drug.

“Although the ban may prevent someone from misusing the drug, the ban prevents all in need of its special attributes from receiving the pain relief Zohydro ER offers,” she wrote.

Roger Hawley, chief executive officer of Zogenix, called the decision “a positive step forward for Massachusetts patients.”



seeking to ban or restrict one specific treatment,” Hawley said in a written statement.

Lawyers for the state had argued that the Massachusetts ban wouldn’t affect the federal approval process or the company’s ability to sell the drug elsewhere in the United States, but simply represented “another hurdle” the company must surpass in order to market the drug in Massachusetts.



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What do you think?



LeonTBone APRIL 15, 2014 — 03:47 PM

Thank you judge for letting doctors make decisions on medicine and healthcare rather than political zealots misguided by self-importance and tyrannical ambitions .



REPLY

Report



Rodalex APRIL 15, 2014 — 04:29 PM

It's not doctors, it's Big Pharm.



Report



LeonTBone APRIL 15, 2014 — 04:39 PM

I trust my doc, wouldn't be here if it wasn't for her. And I trust Mass General without question.

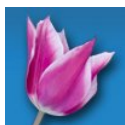


Report

[VIEW 1 REPLIES](#)

BUCKTHIS APRIL 15, 2014 — 03:48 PM

Well, bravo! See, Gov, you are NOT the all powerful. Fraud.

**andiejen** APRIL 15, 2014 — 03:53 PM

Since this drug was approved by the FDA, MA had no legal standing to try and ban it in our state.

I want my doctors free to prescribe what is available to them without interference from our state government.

[REPLY](#)[Report](#)**Rodalex** APRIL 15, 2014 — 04:34 PM

A concern is that many doctors very freely prescribe narcotics without fully considering the risk. Plenty are already available and this one does not have the safeguard against abuse that oxycontin was reformulated to have.

[Report](#)**LeonTBone** APRIL 15, 2014 — 04:44 PM

Don't know what kind of doctor's you go to....well...judging from the pic, I think I can figure it out. I'll take my doc's advise of DeValue et als, and other quasi-medical-professional-wanna-be's-and-nuts until proven otherwise.

[Report](#)[VIEW 1 REPLIES](#)**W1GYF** APRIL 15, 2014 — 03:59 PM

Just what we need - another drug of abuse that will be over-prescribed.

[REPLY](#)[Report](#)**Rodalex** APRIL 15, 2014 — 04:37 PM

MA DPH should start keeping track of people treated for Zohydro abuse and keep the judge updated.

[Report](#)**LeonTBone** APRIL 15, 2014 — 04:47 PM

...A Government Datab: [VIEW 1 REPLIES](#) none think of that before.

**GeneralSterlingPrice** APRIL 15, 2014 — 04:56 PM

What next DeVille? Who can get what medical procedure?

You need to go away.... Far away.....



REPLY

Report

**jimmytaxes** APRIL 15, 2014 — 05:17 PM

Too bad it takes the Feds to put our Communist governor in his place.



REPLY

Report

**jeffcutt72** APRIL 15, 2014 — 07:40 PM

You have no idea what the word communist means, do you?



Report

**jimmytaxes** APRIL 15, 2014 — 07:48 PM

jeff: Yes, someday I'll explain it to you in simple terms that even you can understand.



Report

**frank57** APRIL 15, 2014 — 05:29 PM

@Roladex News flash: Such a database already exists - it's called the prescription monitoring program. That's exactly why it was created - to catch the pill mills. It does a pretty good job. Any other great ideas?



REPLY

Report

**Rodalex** APRIL 15, 2014 — 05:40 PM

No---I mean stats on overdoses and patients treated for Zohydro dependence. Zohydro can be modified just as oxycontin was and becomes abuse-proof. They intend to do this, but want to market Zohydro while developing the modified version. If they were being responsible, they could have modified it BEFORE marketing it---or hold off on marketing it until it has been modified.



2 0

Report



jimmytaxes APRIL 15, 2014 — 05:30 PM

The governor is in no position to determine Federal pharmaceutical policy with the compounding crime resulting in several deaths under his watch.

6 -2 REPLY

Report



KocaniBill APRIL 15, 2014 — 05:37 PM

Morons celebrating this decision as if it is some kind of victory for freedom. Wake up!... It is a bought and paid for win for BIG PHARMA. New drugs are their lifeline...safe or not. Blind faith in your doctor knowing the effects of the thousands of drugs out there is more than moronic!

Oxycontin has lead to a surge in heroin use. Why? Heroin is cheaper.

3 -3 REPLY

Report



GeneralSterlingPrice APRIL 15, 2014 — 05:42 PM

BIG GOVERNMENT is so wonderful. We should all be humbled by its presence and pay tribute to our leaders.....

Get a life.

7 -2

Report



curocity APRIL 15, 2014 — 08:17 PM

Lets no forget that more people now die annually from accidental drug overdose than in auto accidents. I'm confident Zohydro will drive that number even higher,

2 -2

Report



AguaCaliente APRIL 15, 2014 — 05:47 PM

Zohydro is simply extended-release hydrocodone (aka Vicodin). However, unlike all prior hydrocodone formulations, it contains no acetaminophen (Tylenol) or other drug, such as ibuprofen or aspirin. It should provide effective analgesia for those who continuously require an opioid, but a less-powerful one than OxyContin (ER oxycodone). That's my layman's take on it. I just think it's good to know exactly what's being discussed.

That said, I think the government has no right at all to tell anyone what they may be prescribed for pain. It's unfortunate that some dependence and abuse sometimes accompany these substances, but that is an [adult] individual's choice to make for him/her self and should not be the decision of



kind of a different topic.



REPLY

Report

COMMENT BLOCKED

**Ralphie** APRIL 15, 2014 — 05:50 PM

Did you expect Patrick to win this legal argument? It only took him three tries to pass the bar exam.



REPLY

Report

**MisterBeasley** APRIL 15, 2014 — 07:16 PM

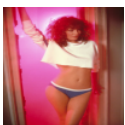
Remember the "tobacco settlement" money? It was supposed to be used to fight tobacco addiction. For a number of years, Massachusetts had a very successful anti-tobacco program in its schools, and it was extended to discuss the dangers of other forms of drug addiction as well. After a while, though, the pols saw all that money going to a good cause, and they began to deflect some of it into their favorite charity, the General Fund of the Commonwealth of Massachusetts, to be used for the same waste and corruption as so much of our tax money.

They took away millions from anti-drug education, and now we have an epidemic of addiction. What else would you expect?



REPLY

Report

**McDimmerson** APRIL 15, 2014 — 07:21 PM

It'll be even more popular now since it was banned.
Way to go, Politico



REPLY

Report

**workingman1** APRIL 15, 2014 — 07:27 PM

STAY OUT of my doctor's office DEVOID



REPLY

Report

raconte APRIL 15, 2014 — 07:29 PM

What a great day for people living with severe chronic pain! Thank you Judge Zobel for putting the needs of patients first over Gov. Patrick's wrong-headed decision to ban the sale of Zohydro in

 4  -1 [REPLY](#)[Report](#)**Nina0701** APRIL 15, 2014 — 07:38 PM


No one who needs a pain killer this strong should have to go without it because someone might abuse it.

 2  -2 [REPLY](#)[Report](#)**tahos** APRIL 15, 2014 — 07:46 PM

Once again Governor Patrick demonstrates his arrogance and incompetence.

 4  0 [REPLY](#)[Report](#)**curocity** APRIL 15, 2014 — 08:06 PM

Zogenix, the manufacturer of Zohydro could have taken a leading role for the pharmaceutical industry by reformulating its product into a tamper resistant formulation. As formulated it is a very safe bet it will rapidly become one of more sought after prescription drugs on the street. On-Line sales and promotion of the drug have already begun. Governor Patrick and the other states are correct that the abuse of prescription opioids has reached epidemic proportions. Its time the FDA require all formulations be tamper resistant and that those presently approved and on the market be given a set schedule to present a tamper resistant formulated product to them for approval. Its time for social responsibility and public safety to be given greater consideration than corporate profits.

 2  -1 [REPLY](#)[Report](#)**mjk22061** APRIL 15, 2014 — 09:19 PM

The state of MA can override the FDA and authorize medical marijuana...but they can't ban a much more dangerous drug ?

 0  0 [REPLY](#)[Report](#)**jkgdhgadhgyagdhgaj** APRIL 15, 2014 — 10:18 PM

Of course the Liberals have drugged 2 generations of boys with their gender equity projects aimed at making girls scientists and mathematicians. Aderall, Ritalin and other so called ADHD drugs lead to OXY and them to heroin or meth.

How dare they ruin these kids and then pontificate about the latest painkiller.

 0  -1 [REPLY](#)



Grantiville01886 APRIL 16, 2014 — 07:57 AM

The judge ruled that Duhval blatantly broke the law.

She did not "block Massachusetts" as the Globe headline states.



Report

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Two killed in Mass. Turnpike accident

The accident happened about 5 a.m. on the eastbound side of the turnpike and caused delays in both directions.

News 10 min ago Share



Weather Wisdom: Winter apparently not quite done with us

Some commuters have to use their winter driving skills one more time today, thanks to a spring storm that's dumped sleet and snow across the region.

News 3 hours ago Share



A real-life toy story: Nebraska toddler found inside bowling alley claw machine

A missing child was found safely surrounded by stuffed animals inside a vending machine across the street from his home.



Russian Flag

SLOVYANSK, Ukraine (AP) — An Associated Press reporter says he saw a column of combat vehicles in an eastern Ukrainian city, occupied by pro-Russian insurgents and flying Russian flags.

News 5 hours ago Share



South Korea Says 295 Missing in Ferry Disaster

A ferry carrying 477, most of them high school students, sank in cold waters off South Korea's southern coast, killing at least two and injuring seven, officials said.

News 5 hours ago Share



Court to Weigh Challenge to Ban on Campaign Lies

WASHINGTON (AP) — Negative campaigning and mudslinging may be a fact of life in American politics, but can false accusations made in the heat of an election be punished as a crime?

BDC 6 hours ago Share



cargo ship ran aground in the lower Chesapeake Bay on Tuesday in high winds gusting up to 70 mph, the Coast Guard said.

News 9 hours ago Share



Mike Napoli appears to have dislocated ring finger

The last thing the Red Sox need is another player going down with an injury but that's what happened Tuesday night in Chicago.

Sports 9 hours ago Share



Red Sox lose on a walkoff error

A throwing error credited to Xander Bogaerts led to a 2-1 White Sox walkoff win over the Red Sox.

BDC 9 hours ago Share

Rains in northern New England add to flood threat

MONTPELIER, Vt. (AP) — Heavy rains and melting snow and ice pushed rivers toward or above flood stage around Vermont, New Hampshire and Maine on Tuesday and flooded some roads in the region.

News 9 hours ago Share

NYPD Abandons Muslim Surveillance Unit

The controversial unit never generated a lead, according to the New York Times.



Tsarnaev Widow Subpoenaed in Waltham Slayings

Tamerlan Tsarnaev's widow, Katherine Russell, was asked to produce for a grand jury any items owned by one of the victims.

News 12 hours ago Share



Marathon Bombing Carjack Victim Reveals Face

"Danny" was shown during an interview on CBS Evening News.

News 13 hours ago Share

26.2 reasons for hope on this Marathon anniversary

On the anniversary of the 2013 Boston Marathon race and bombings, here are 26.2 reasons to feel good and have hope.

Obnoxious Boston Fan 13 hours ago Share

10 Reasons Why the Bruins Can Win the Stanley Cup

Boston is deep, has the best goaltender in North America, and home-ice throughout the playoffs. Other than that, no reason they should win, right?

Eric Wilbur's Sports Blog 13 hours ago Share

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Game 14: Red Sox at White Sox Live Updates

Follow along with updates and commentary on tonight's Red Sox-White Sox game, the first of a three-game series in Chicago. Game time is set for 8:10 p.m.

Extra Bases  13 hours ago  Share



Tonight's Red Sox Lineup: Bogaerts Bats Second With Pedroia Out

Here are the lineups for the first game of the Red Sox-White Sox series that gets underway at 8:10 p.m.

Extra Bases  13 hours ago  Share


MLB to Fine John Farrell For Replay Remarks

He was fit to be tied, now he'll be fined. Red Sox manager John Farrell will be fined by Major League Baseball for his criticism of the instant replay system last weekend at Yankee Stadium, MLB executive VP of baseball operations Joe Torre told the New York Daily News.

Extra Bases  13 hours ago  Share

Patriots mock draft 7.0: What if the Patriots don't pick in the first round?

It wouldn't be a surprise for the Patriots to move down the board to try to acquire more picks. Here's how it might look.

Extra Points  13 hours ago  Share



Bruins aren't too concerned with "target on their backs"

After their regular season success, the Boston Bruins think the "target on their backs" comment is only a perception heading into the Stanley Cup Playoffs.

Bruins Daily 13 hours ago Share



Cyrus Hospitalized, Cancels Show

Miley Cyrus canceled her show in Kansas City after being hospitalized for a "severe allergic reaction to antibiotics."

Entertainment 13 hours ago Share



Robot Sub Returns to Water After 1st Try Cut Short

PERTH, Australia (AP) — A robotic submarine looking for the lost Malaysian jet continued its second seabed search on Wednesday.

Business 14 hours ago Share



Marathon Finish Line Evacuated After Suspicious Packages Discovered

An adult male suspect was detained and is being questioned by police after two suspicious bags were found near the Boston Marathon finish line.

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Obama Congratulates UConn on NCAA




week's NCAA tournaments.

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