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Pain-Pill Guidelines for Children Spark a Fierce Debate

Some lawmakers say an FDA move welcomed by patients' families will create more young addicts

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Maya Nelson, a 17-year-old with sickle cell anemia, has been hospitalized more than 60 times. Because her pain sometimes feels like being stabbed by a knife, her doctors periodically prescribe OxyContin, a painkiller she has taken since she was about 11.

Like other pediatric patients, Maya was taking OxyContin even though it wasn't approved for children—an authorized practice known as off-label use. The drug has allowed her to avoid hospitalization in some instances and stay on track to graduate from high school next year.

"Our lives would be a complete mess if she didn't have something like OxyContin to turn to," said her mother, Dawn Nelson, of Mount Pleasant, Mich.

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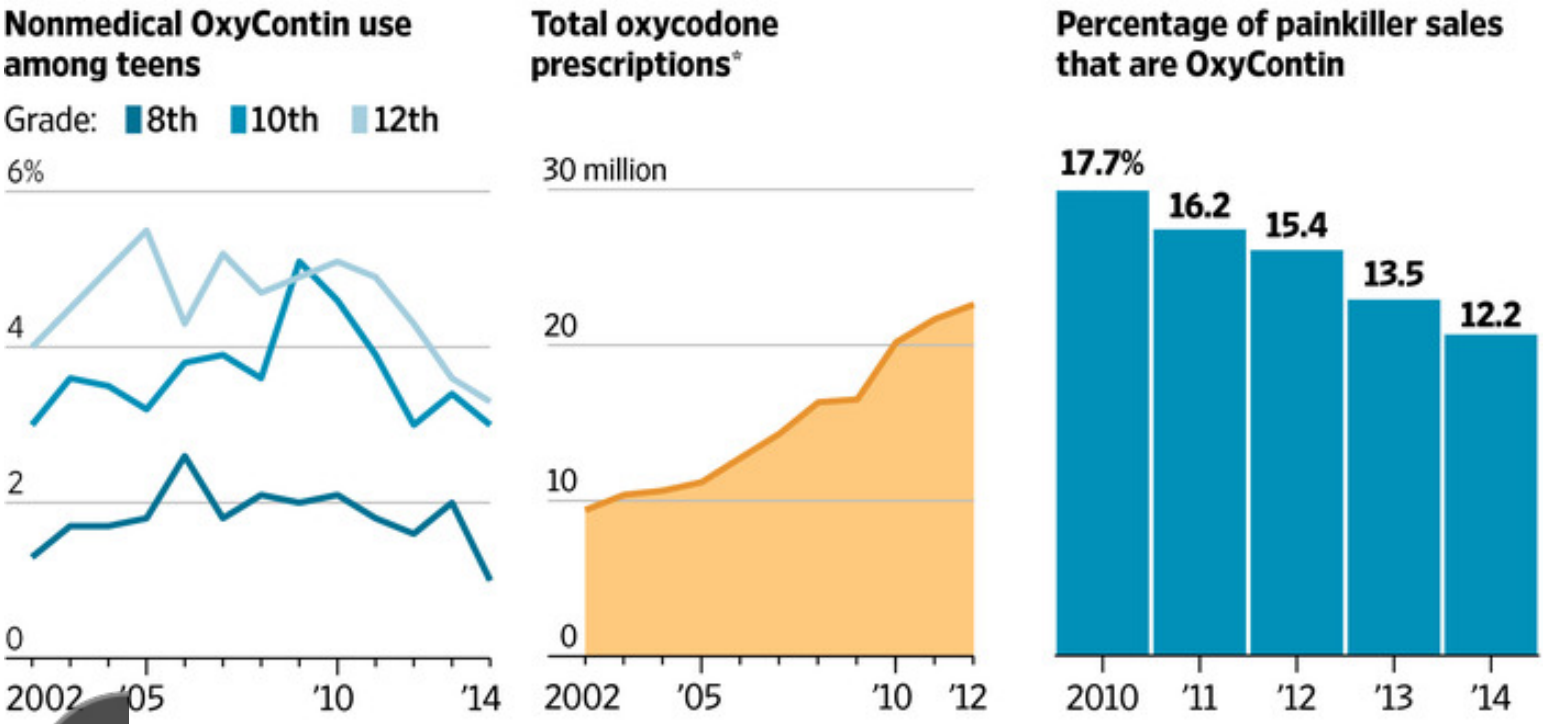
But the Food and Drug Administration's decision in August to officially approve use for certain children as young as 11, meaning doctors wouldn't have to prescribe it off label, has triggered fierce debate.

On one side are some elected officials and addiction specialists who say the move could expand access to a drug at the center of an epidemic of painkiller and heroin abuse in the U.S. that was responsible for 24,000 overdose deaths in 2013.

On the other are some physicians and families like the Nelsons who say the FDA move provides necessary guidance to doctors treating children with serious conditions. Doctors have had to rely on adult dosing information when prescribing the painkiller to children off label.

Youth Use

The Food and Drug Administration recently approved OxyContin for certain children as young as 11. Prescriptions for this type of painkiller have doubled over a decade.



*Data includes OxyContin and other forms of oxycodone. OxyContin is a brand of oxycodone.
Sources: University of Michigan (teen use); IMS Health (prescriptions, sales)

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OxyContin is an extended-release version of oxycodone, an opioid painkiller. Because of its formulation, it can smooth out peaks and valleys of pain. Patients 19 and younger represented about 1% of dispensed prescriptions for oxycodone in 2014, according to IMS Health Holdings Inc., a health-care data company.

After requesting that the maker of OxyContin, Purdue Pharma LP, perform studies of the drug's effects on children, FDA officials determined it was safe for youths 11 and older and established appropriate prescribing guidelines.

Expanded use of OxyContin in pediatric patients isn't the intent, FDA officials say. The agency approved the drug only for treating those with severe, long-term pain, such as cancer patients or those recovering from major spinal surgery, who were already taking an opioid painkiller.

The FDA is requiring Purdue to conduct more studies on the drug's use in children, and to report any adverse effects.

After marijuana, psychotherapeutics—a category that includes painkillers—are the most-abused group of drugs among children ages 12 to 17, according to the Substance Abuse and Mental Health Services Administration. Nonmedical use of OxyContin among 10th- and 12th-graders increased from 2002 to roughly 2009, but it has

declined since then, according to the annual Monitoring the Future survey, which tracks youth drug use.

Some elected officials in states grappling with rampant painkiller abuse are furious.

OxyContin is an extended-release version of oxycodone, an opioid painkiller. *PHOTO: TOBY TALBOT/ASSOCIATED PRESS*

"When we make it easier for kids to get this stuff, we are sentencing ourselves to more opiate addiction and more misery for America," Gov. Peter Shumlin of Vermont, a Democrat, said in an interview. He cited the example of Dustin Machia, a former addict from Franklin County who first tried OxyContin in 10th grade when his friends offered it to him. He quickly became addicted and wound up stealing $20,000 worth of goods from his parents to feed his habit.

OxyContin "is a pretty powerful drug to introduce to an 11-year-old," said Mr. Machia, now 27 and clean for seven years. "It's just putting them on a fast track to disaster."

But Donna Ludwinski, director of research programs at Solving Kids' Cancer, a research-advocacy group, said a child who starts taking OxyContin illicitly presents a separate issue—one she said she is familiar with, living in an area of West Virginia devastated by painkiller abuse. "I guarantee you that it would be hard to find an example" of a child

"who was actually prescribed OxyContin for an appropriate condition and got addicted," she said. Ms. Ludwinski's son died of cancer at age 24 in 2010 and required intensive pain management as a child.

On Sept. 18, eight U.S. senators, including Joe Manchin (D., W.Va.) and Kelly Ayotte (R., N.H.), signed a letter to the FDA "to express our dismay" and to call for a review of its decision.

"Children, whose brains are not yet fully developed, are especially vulnerable to drug dependency and abuse," the senators wrote.

Another group of lawmakers has requested a Senate hearing to examine the FDA's decision. And Mr. Manchin is promoting a bill that would require the agency to consult with an advisory committee before approving any opioid painkillers and, if it rejects the panel's advice, to explain before Congress why.

Maya Nelson, right, shown with her mother, Dawn, at Maya's dorm room at Great Lakes Adventist Academy in Cedar Lake, Mich. *PHOTO: LAURA MCDERMOTT FOR THE WALL STREET JOURNAL*

Some addiction specialists also criticize the FDA approval. It "gives Purdue Pharma a green light to promote the drug to be used in children," said Andrew Kolodny, chief medical officer at Phoenix House, a nonprofit addiction-treatment

provider.

In an August letter to Mr. Manchin, Purdue's chief medical officer, Gail Cawkwell, wrote that the company "will not promote to pediatricians or other physicians the new pediatric safety and dosing information for OxyContin." She added, "We are committed to combating the overuse, misuse and abuse of prescription opioids."

Dr. Kolodny also noted the FDA wording on severe pain is so broad that it could apply to conditions far less serious than cancer.

"We did not specify particular causes of pain that are appropriate to treat with OxyContin because it would be impossible to categorize all of those conditions," said Eric Pahon, an FDA spokesman.

Chris Feudtner, an attending physician at Children's Hospital of Philadelphia, said he supported the FDA's decision. OxyContin "can be an incredibly important treatment for children who are in severe chronic pain," he said.

Dr. Feudtner said he sympathizes with elected officials contending with painkiller abuse. "I would not want to in any way minimize the importance of coming up with effective strategies to curtail the prescription-opioid addiction problem," he said. But "trying to repeal the FDA labeling is not the way to do it."

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