



Battling the Opioid Epidemic: FDA Seeks to Tighten Opioid Rules to Make New Drugs Less Addictive

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The US Food and Drug Administration (FDA) is proposing to tighten the rules for opioid manufacturers by requiring companies to prove their drugs may be less addictive. This is in light of the current opioid epidemic that is now being considered the worst drug crisis in US history.

If their proposal pushes through, drug makers will be asked to provide information on whether their drug has any characteristics that would mitigate the risks of overdose, abuse or the development of addiction?

The FDA already withdrew its previous guidance. Acting FDA Commissioner Ned Sharpless laid out a tougher new regulatory framework for evaluating applications for new opioids coming to the US market. Under the proposal, drug makers would have to say whether their drug has properties that could potentially get a person hooked or addicted. The drug makers would have to describe the risk of overdose, abuse, or the development of addiction.

Companies should also indicate whether their drugs have novel or greater risks compared to other opioids on the market and also note the public health implications of their products in terms of risks to non-patients,

including members of the patient's household, visiting relatives, friends, and others," said the FDA.

The Trump administration has so far struggled with dealing with the opioid epidemic. The opioid epidemic has been a major issue in all states all over the country and thousands of lawsuits are being filed against drug companies such as Teva Pharmaceuticals, Johnson & Johnson, and Purdue Pharma, for their alleged role in spreading the epidemic.

These companies are being sued in various courts for allegedly using misleading marketing strategies to significantly downplay the addictive qualities of their opioid products. They also allegedly convinced doctors to prescribe more opioids, creating the opioid problem that is killing more than 130 Americans every day.

About 47,000 people died of an opioid-related overdose in 2017, according to data from the US Centers for Disease Control and Prevention. The Trump administration has vowed to crack down on illicit use, although the country is still struggling with these overdoses. Click the link to see San Antonio's top rehab placement programs.

"Addressing the crisis of opioid addiction is an issue of great concern for our nation and remains a top public health priority for the FDA," Sharpless said in a statement. "The agency continues to take new steps to confront this crisis, while also paying careful attention to the needs of patients in accessing appropriate pain management."

OxyContin maker Purdue Pharma is facing around 1,600 civil cases because of their opioid product. The company is owned by the Sackler family. Some members of the Sackler family are individually named in certain lawsuits. These civil cases are being consolidated and transferred to a judge in the Northern District of Ohio.

In April, a former CEO of Rochester Drug Cooperative, one of the nation's largest drug distributors, was indicted on what prosecutors say are the first criminal charges against an executive of a drug company to stem from the opioid epidemic.

The FDA also acknowledged that opioids "present unique challenges" because the drugs help patients in pain but can also "cause enormous harm when misused and abused".

If someone in the family is struggling with opioid or alcohol addiction, it is important to seek help. A combination of medical detox and behavioral therapy can go a long way in the fight against drug abuse. But because every individual is affected by addiction differently, a comprehensive program tailored to their specific needs is necessary. Look for a nearby addiction treatment facility today and find out how drug treatment programs work.

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