

# FDA approves powerful new opioid in 'terrible' decision

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The Food and Drug Administration campus in Silver Spring, Maryland  
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The Food and Drug Administration approved a powerful new opioid Friday, despite strong criticism and accusations that it bypassed its own advisory process to do it.

The new drug, Dsuvia, is a tablet that goes under the tongue. It is designed for use in the battlefield and in other emergency situations to treat intense, acute pain.

Known generically as sufentanil, it's a new formulation of a drug currently given intravenously. Critics say it will be incredibly easy for health workers to pocket and divert the drug to the illicit drug market and because it is so small and concentrated, it will likely kill people who overdose on it.

"This is a dangerous, reckless move," said Dr. Sidney Wolfe senior adviser of Public Citizen's Health Research Group. He questions whether there's need for yet another synthetic opioid when the U.S. is in the throes of an opioid overdose crisis.

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FDA Commissioner Dr. Scott Gottlieb defended the decision in a lengthy statement.

“We understand the concerns about the availability of a high potency formulation of sufentanil and the associated risks,” he wrote.

“There are very tight restrictions being placed on the distribution and use of this product. We’ve learned much from the harmful impact that other oral opioid products can have in the context of the opioid crisis,” Gottlieb added.

“We’ve applied those hard lessons as part of the steps we’re taking to address safety concerns for Dsuvia.”

But Dr. Raeford Brown, chair of the FDA’s Anesthetic and Analgesic Drug Products Advisory Committee and a professor of anesthesiology and pediatrics at the University of Kentucky, said he did not think the FDA had taken enough care.

“I am very disappointed with the decision of the agency to approve Dsuvia,” Brown said in a statement.

“This action is inconsistent with the charter of the agency. As I discussed with representatives of the agency today, neither the lack of efficacy data, nor the sponsor’s response to safety concerns, have been answered,” he added.

“Clearly the issue of the safety of the public is not important to the commissioner, despite his attempts to obfuscate and misdirect.”

### **[The FDA says the risk of abuse outweighs the safety of this drug](#)**

Brown, who has issued statements critical of FDA in tandem with Public Citizen, said he was left out of the advisory process for Dsuvia. He was not present when his committee voted to recommend approval on October 12.

“It is certain that Dsuvia will worsen the opioid epidemic and kill people needlessly,” Wolfe said. “It will be taken by medical personnel and others for whom it has not been prescribed. And many of those will overdose and die.”

Opioids, including prescription opioids and heroin, killed 42,000 people in 2016, the CDC says. Provisional numbers for 2017 indicate they killed 49,000. Opioid overdose deaths are so bad that they have [helped lower U.S. life expectancy](#).

Synthetic opioids alone killed 27,000 people in 2017, the CDC says.

Gottlieb said the FDA considered the risks carefully. He noted that opioids require special care, both because of the overdose epidemic and because Congress has told the FDA to take special considerations into account when approving opioid products.

They include a plan to control their use, called a risk evaluation and mitigation strategy. “It can’t be dispensed to patients for home use and should not be used for more than 72 hours.

And it should only be administered by a health care provider using a single-dose applicator. That means it won't be available at retail pharmacies for patients to take home," Gottlieb said.

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"I believe that the unique aspects of Dsuvia, including those that make this drug a high priority for the Pentagon, differentiate this new formulation of sufentanil from other sufentanil products in a way that is consistent with population-based considerations for how it fits into the overall drug armamentarium," Gottlieb added.

The military had asked for the drug to be made available, he said.

"The FDA has made it a high priority to make sure our soldiers have access to treatments that meet the unique needs of the battlefield, including when intravenous administration is not possible for the treatment of acute pain related to battlefield wounds," he added.

Wolfe disagreed. "It's a terrible decision," he said.

The FDA has been accused of doing too little to control opioid prescriptions before. A [team of Johns Hopkins University researchers](#), including a former FDA official, published what they said was evidence the FDA did little to stop doctors who were over-prescribing opioids.