

# FDA to target addictive levels of nicotine in cigarettes

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In this Thursday, Nov. 10, 2016 photo, test cigarettes sit in a smoking machine in a lab at the Centers for Disease Control and Prevention in Atlanta. On Friday, July 28, 2017, the U.S. Food and Drug Administration announced that it wants to lower nicotine levels in cigarettes so they aren't so addictive. (AP Photo/Branden Camp)

For the first time, the federal government is proposing cutting the nicotine level in cigarettes so they aren't so addictive.

U.S. Food and Drug Administration chief Scott Gottlieb on Friday directed the agency's staff to develop new regulations on nicotine. The FDA has had the power since 2009 to regulate nicotine levels but hasn't done so. Stocks of cigarette makers plunged after the announcement.

Gottlieb also said the FDA is giving e-cigarette makers four more years to comply with a review of products already on the market. The agency needs to concentrate on nicotine regulation and not be distracted by the debate on whether e-cigarettes help smokers quit, he said.

"A renewed focus on nicotine can help us to achieve a world where cigarettes no longer addict future generations of our kids," Gottlieb said in a speech to staff in Silver Spring, Maryland.

Tar and other substances inhaled through smoking make cigarettes deadly, but the nicotine in tobacco is what makes them addictive. Tobacco use is the leading cause of preventable heart disease, cancer and death in the United States, causing more than 480,000 deaths annually.

Gottlieb said he has asked the FDA's Center for Tobacco Products to explore whether lowering nicotine could create a black market for higher nicotine products and what role e-cigarettes and others forms of nicotine delivery may play in reducing harm from smoking. Battery-powered e-cigarettes turn liquid nicotine into an inhalable vapor.

Gottlieb also wants new rules to address flavored tobacco products and kids.

U.S. smoking rates have been falling for decades. They dropped from about 17 percent in 2014 to 15 percent in 2015, and held about steady at that level last year.

The FDA announcement is great news, said Eric Donny, a University of

Pittsburgh researcher who has studied what happens when smokers puff on cigarettes with lower levels of nicotine. Donny and other researchers found that reducing nicotine substantially—by around 90 percent—leads to smokers being less dependent on cigarettes and smoking fewer of them.

There have been concerns that smokers might react to lower nicotine levels by smoking more of them to compensate. But the research shows that's not what happens—not if enough nicotine is taken out, Donny said.

"If you just reduce it a little, people might smoke more to make up the difference. They need to reduce it a lot," said Donny, who said regulators should consider a 95 to 97 percent reduction.

"Most of the harm associated with smoking is related not to the nicotine but everything else in the smoke. Reducing nicotine doesn't make a cigarette safe, it just makes it less addictive," said Donny, director of Pitt's Center for the Evaluation of Nicotine in Cigarettes.

There's additional research underway to see how often people who smoke lower-nicotine cigarettes switch to e-cigarettes or other, less harmful tobacco products, he said.

Kenneth Warner, a retired University of Michigan public health professor who is a leading authority on smoking and health, said he was pleasantly surprised to learn of the FDA announcement.

"If you can separate the nicotine people are craving from the smoke that's killing them, then you may be doing something very important," Warner said.

Campaign for Tobacco-Free Kids president Matthew Myers praised the overall approach as "a bold and comprehensive vision" but called the e-

cigarettes delay "a serious error."

"This long delay will allow egregious, kid-friendly e-cigarettes and cigars, in flavors like gummy bear, cherry crush and banana smash, to stay on the market with little public health oversight," Myers said in a statement.

Altria Group, which sells Marlboro and other cigarettes in the U.S., said it would be "fully engaged" in FDA's rule-making process. Altria also makes e-cigarettes.

"It's important to understand that any proposed rule such as a nicotine product standard must be based on science and evidence, must not lead to unintended consequences and must be technically achievable," the company said in a statement.

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