

FDA considers lowering nicotine levels in cigarettes (Update)

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(HealthDay)—In an unprecedented move, the U.S. Food and Drug

Administration on Thursday said it plans to cut the amount of addictive nicotine in the nation's cigarettes.

The goal is to lower the amount of nicotine to minimally or non-addictive levels, the agency said.

"We see a historic opportunity here to use that product standard to potentially more rapidly migrate smokers off of combustible cigarettes, that we know cause a lot of death and disease related to tobacco use, and potentially onto products that can provide adults with access to nicotine without all the harms associated with combustion," FDA Commissioner Dr. Scott Gottlieb said during a media briefing.

But e-cigarettes "and other products that could offer a bridge to quitting need to be properly evaluated," he noted.

One lung health expert applauded the move.

"Exploring a product standard to lower nicotine content in cigarettes to minimally or non-addictive levels is an exciting concept," said Andrea Spatarella, from the Center for Tobacco Control at Northwell Health, in Great Neck, N.Y. "Any and all efforts to reduce or eliminate the health burdens and tobacco-related deaths to millions of Americans deserves consideration."

Tobacco use—mainly cigarette smoking—kills more than 480,000 Americans a year and costs nearly \$300 billion a year in direct health care and lost productivity, the FDA noted.

Mitch Zeller, director of the FDA's Center for Tobacco Products, said at the briefing, "Given their combination of toxicity, addictiveness, prevalence and effect on non-users, cigarettes are the category of tobacco product that causes the greatest public health burden. In fact,

cigarettes are the only legal consumer product that when if used as intended will kill half of all long-term users prematurely."

Reducing nicotine levels in cigarettes and other policy measures could help prevent millions of tobacco-related deaths in the United States, Gottlieb added.

The proposal on reducing nicotine levels includes a review of current science about how nicotine creates and sustains addiction to cigarettes, and asks for public input and review.

Gottlieb said answers will be sought on questions such as, "What potential maximum nicotine level would be appropriate for the protection of public health? Should a product standard be implemented all at once or gradually?"

Also, he added, there could be "unintended consequences" to making cigarettes less addictive, for example, the growth of a black market in high-nicotine cigarettes.

Still, Gottlieb said a new analysis, published online March 15 in the *New England Journal of Medicine*, has suggested that millions could benefit from the proposed move.

"If this scenario were implemented, this analysis suggests that approximately 5 million additional adult smokers could quit smoking within one year of implementation," Gottlieb said.

"And with this scenario, an even greater impact could be felt over time: by the year 2100, the analysis estimates that more than 33 million people—mostly youth and young adults—would have avoided becoming regular smokers. And smoking rates could drop from the current 15 percent to as low as 1.4 percent," he added.

"All told, this framework could result in more than 8 million fewer tobacco-caused deaths through the end of the century— an undeniable public health benefit," Gottlieb said.

Young people would benefit hugely from the proposed move, one lung health expert said.

"The benefits the FDA cites for this proposal are extraordinary," said Matthew Myers, president of the Campaign for Tobacco-Free Kids.

"Given these enormous public health benefits and the millions of lives that would be saved, it is critical that the FDA move as quickly as possible to turn this plan into reality," Myers said. "There is no other single action our country can take that would prevent more young people from smoking or save more lives."

Still, another expert said the move could backfire.

"Lowering the nicotine level in cigarettes may simply lead to more cigarettes smoked by current smokers," said Dr. Len Horovitz, a pulmonary specialist at Lenox Hill Hospital in New York City. He believes that to really put an end to the scourge of smoking, "tobacco and nicotine—in other words, cigarettes—must be eliminated as a threat to health."

Spatarella agreed the nicotine-lowering strategy could fail.

"It is feasible that the end user may react to the decrease in the addictive chemical nicotine by smoking more. What they perceive as a lack in quality, or the amount of nicotine needed to satisfy their nicotine craving, they may make up for in quantity, the number of products consumed," she suggested.

"The smoking behaviors may remain unchanged and the smoker may seek other tobacco products to fill that nicotine gap," Spatarella added. "They may seek to purchase traditional cigarettes with higher nicotine content from illegal sources."

In its proposal, the FDA said that it also plans to examine the role that flavors—including menthol—play in people starting, continuing and quitting smoking, to assess regulation of premium cigars, and to update how it deals with the development and regulation of nicotine-replacement products, such as nicotine gums, patches and lozenges that help smokers quit.

More information: The American Cancer Society offers a [guide to quitting smoking](#).

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