

Are reduced-nicotine cigarettes coming?

August 4 2022, by Kathy Katella



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The Food and Drug Administration (FDA) recently announced a plan to reduce nicotine in cigarettes, and addiction experts say such a plan could have a substantial impact on public health in the United States. Tobacco smoking remains the leading preventable cause of death and disease—at last count, there are 480,000 deaths a year related to smoking in this



country.

While the number of people who smoke has declined over the years—and many <u>young people</u> are turning to e-cigarettes rather than starting cigarette <u>smoking</u>—"we still have a lot of people with a very long history of cigarette smoking, who, despite all <u>tobacco public health</u> efforts, are not able to stop," says Lisa Fucito, Ph.D., director of the Tobacco Treatment Service at Smilow Cancer Hospital.

About 70% of the country's 31 million adult smokers say they would rather not smoke; each year, more than half of them try to quit, according to government statistics, but only 7.5% of those actually give up smoking.

Though there are several steps between the FDA's late June announcement and a new law, reducing <u>nicotine</u> in cigarettes could lead to major changes for people who smoke.

Fucito and other Yale Medicine experts shed light on the FDA's plan and its potential implications.

What is the nicotine-reduction plan and why is the FDA proposing it now?

Reducing nicotine in cigarettes is part of a Biden Administration Cancer Moonshot Initiative to cut cancer deaths by 50% in 25 years. (The FDA's June announcement followed a proposal in April to ban menthol cigarettes and flavored cigars.)

The more recent plan would require <u>tobacco companies</u> to slash nicotine in cigarettes to levels that would no longer be considered addictive. It does not affect other products that contain nicotine, such as <u>smokeless</u>



tobacco, e-cigarettes, oral nicotine pouches, or nicotine replacement therapies (such as nicotine lozenges and patches).

This is not a new idea—it has been discussed since 1994. A Family Smoking Prevention and Control Act in 2009 finally provided the FDA with regulatory control over tobacco, as well as the ability to reduce nicotine levels (although not to zero). But the agency still needed scientific evidence to back up taking action.

Since then, federally funded research has provided ample evidence to support the strategy. <u>A notable study</u> published in the *New England Journal of Medicine* in 2015 showed that reducing nicotine in cigarettes resulted in less smoking and more attempts to quit.

How fast will a nicotine-reduction plan happen?

Experts don't expect a nicotine-reduction mandate to come quickly. The FDA's intention is to propose a standard by May 2023. The agency must first publish a rule, allow for public comments, then publish a final rule. Tobacco companies that don't agree with the rule could present roadblocks, and some say the whole process could take years.

Nevertheless, Fucito says, it's an important step toward controlling a major health hazard.

Will reduced-nicotine cigarettes make it safe to smoke?

Even if nicotine is greatly reduced, a cigarette is still harmful. "Tobacco is dangerous," says Fucito. "It's tobacco that, in its leaf form, contains many toxic chemicals. And when you burn it, it generates even newer toxicants that cause harm."



Cigarettes contain 600 ingredients which, when burned, produce over 7,000 chemicals. At least 69 of those (such as ammonia, benzene, formaldehyde, and lead) can cause cancer. Tar, a substance that is created when tobacco is burned, contains most of the cancer-causing and other harmful chemicals. Tar coats the inside of the lungs, forming a sticky layer that can lead to cancer, emphysema, and other serious conditions.

Nicotine may also have important negative health effects—animal studies have shown it can cause issues with <u>brain function</u>, leading to problems with focus, learning, and memory, which can be long-lasting.

But the real issue with nicotine is that it is highly addictive. It's why people have such a hard time quitting smoking. Nii Addy, Ph.D., who specializes in the neurobiology of addiction, says nicotine, like any drug, hijacks the reward system in the brain. It does this by binding to a receptor in the brain and sending a signal to release dopamine, a neurotransmitter that helps create a 'feel-good' sensation. This trains the brain to repeat the action, so that when the nicotine leaves the body, the brain wants more.

Is it really possible to reduce nicotine in such a way that it becomes 'non-addictive?'

There are questions about how much nicotine needs to be reduced to make a cigarette non-addictive. Some research has suggested that people who smoked cigarettes with about 95% less nicotine noticed a decrease in dependency on them and smoked less of them. On the other hand, a less extreme reduction in nicotine led to them inhaling or smoking more.

It's important to note that there are a variety of ways to reduce nicotine in cigarettes: It can be stripped from a tobacco leaf, cigarette makers can



adjust the mix of tobacco leaves they use, or they can use genetic engineering to make low-nicotine tobacco.

Can cutting nicotine really get people to stop smoking?

Fucito works directly with people who want to quit smoking, sometimes because they have a health condition and doctors are recommending it, or they are preparing for surgery, and people who smoke are at higher risk for surgery-related infections and complications. "I advise patients that quitting smoking can be hard because nicotine is so addictive and cigarettes deliver nicotine to the brain in seconds," she says. Because the reward comes so quickly, it perpetuates the habit.

Medications can help interrupt the process, but one of the problems is that they do not mimic the sensory experience of smoking, which itself can be rewarding in addition to nicotine, she adds. "The benefit of having a reduced-nicotine cigarette is that you still have the habitual experience of smoking, but the cigarette is less addictive and enjoyable overall, which is important for helping people reduce their smoking and ultimately quit."

How can nicotine reduction impact public health?

"It would have a substantial impact," Fucito says, adding that she would expect many more people who have struggled with smoking to quit. In 2020, nearly 13 of every 100 adults in the U.S. smoked cigarettes, according CDC statistics. <u>A study published in the *New England Journal of Medicine* in 2018 found that lowering nicotine levels could save millions of lives and tens of millions of life-years over the next several decades.</u>



A massive reduction in smoking would have a positive health impact for smokers whose habit puts them at higher risk than nonsmokers for a long list of health concerns. They include (but are not limited to) cancer, stroke, respiratory disease, cataracts, macular degeneration, and type 2 diabetes. Smoking also raises the risk for erectile dysfunction and reduced fertility in men, and low bone density, altered menstrual cycles, and pregnancy complications in women, as well as dangers to unborn babies.

It would also help "priority populations that have not been able to quit smoking," Fucito says. "There are different populations that are disproportionately affected by smoking and tobacco-related harm." Those groups include people who are low income, have a low level of education, identify as members of minority groups, or have a mental health diagnosis. "For example, it is estimated that smokers with schizophrenia die 25 years prematurely due to cigarette smoking," Fucito says.

Would nicotine reduction have mental health consequences?

Quitting smoking can make people feel anxious, irritable, restless, and moody, among other things. "Quitting causes both physical and psychological withdrawal symptoms, which are worst during the first few days after quitting. Some symptoms, like changes in sleep and eating or appetite, can last a little longer. But, importantly, all of these resolve after a few weeks," Fucito says.

It can help to understand what smoking—and quitting—does to the body, she adds. "The effects of nicotine are short: When you smoke cigarettes, you get a quick burst of nicotine, which feels good and may boost your mood. But 1 to 2 hours later, these effects are gone and



withdrawal sets in unless you have another cigarette," she says. "This upand-down cycle throughout the day can make it hard to go without smoking. But, after a few weeks of being smoke-free, this mood variability normalizes. And medications can make this process more comfortable."

How can quitting smoking be a more tolerable experience?

People who want to quit smoking can start by having a conversation with their primary care doctor. The Tobacco Treatment Service at Smilow Cancer Hospital offers individual counseling tailored to a person's needs and prescriptions for FDA-approved nicotine-replacement therapies such as "the patch," gum, lozenges, and inhalers, as well as other approved medications for tobacco use, including varenicline (Chantix) and bupropion (Zyban).

They also advise patients of potential tobacco harm reduction strategies such as switching to alternative tobacco products (e-cigarettes, oral nicotine products) in place of <u>cigarettes</u>. The Smilow program and many other programs that help people quit smoking also offer clinical trials focused on testing new medications and behavioral strategies.

Quitting smoking can be unpleasant, but it's not life-threatening, says Fucito. "It may help to remember that cigarette withdrawal symptoms are the worst in the first few days. But by about four weeks, for most people, things normalize," she says.

Provided by Yale University

Citation: Are reduced-nicotine cigarettes coming? (2022, August 4) retrieved 21 May 2024 from



https://medicalxpress.com/news/2022-08-reduced-nicotine-cigarettes.html

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