

As low-nicotine cigarettes hit the market, anti-smoking groups press for wider standard

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The idea seems simple enough. Preserve all the rituals of smoking: Light

up a cigarette, inhale the smoke, including the nasty stuff that can kill you, and exhale. But remove most of the nicotine, the chemical that makes tobacco so darn hard to quit, to help smokers smoke less.

The Food and Drug Administration has been contemplating that strategy for at least six years as one way to make it easier for smokers to cut back, if not quit entirely. Less than two years ago, it authorized 22nd Century Group, a publicly traded plant [biotech company](#) based in Buffalo, New York, to advertise its proprietary low-nicotine cigarettes as modified-risk tobacco products.

Now, the first authorized cigarettes with 95% less nicotine than traditional smokes are coming to California, Florida, and Texas in early July, after a year of test-marketing in Illinois and Colorado. It's part of an aggressive rollout by 22nd Century that, by year's end, could bring its products to 18 states—markets that together account for more than half of U.S. cigarette sales.

But anti-smoking groups oppose greenlighting 22nd Century's products. Instead, they urge [federal regulators](#) to expand on their original plan of setting a low-nicotine standard for all combustible cigarettes to make them minimally or nonaddictive. They expect the FDA to take the next step in that industrywide regulatory process as early as this fall.

"Unless and until there is a category wide requirement that nicotine goes down to low, nonaddictive levels, this is not going to make a difference," said Erika Sward, a spokesperson for the American Lung Association.

Major tobacco companies Altria, R.J. Reynolds, and ITG Brands did not respond to requests for comment.

Cigarette smoking is estimated to cause more than 480,000 deaths a year in the U.S., including from [secondhand smoke](#), and contributes to

tobacco use being the leading preventable cause of death nationally. In 2018, then-FDA Commissioner Scott Gottlieb wrote that setting a maximum nicotine level "could result in more than 8 million fewer tobacco-caused deaths through the end of the century—an undeniable public health benefit."

The FDA reasoned that people would collectively smoke fewer cigarettes and have less exposure to the deadly toxins that are still present in low-nicotine cigarettes.

22nd Century says it used a patent-protected process to control nicotine biosynthesis in the tobacco plant, enabling it to create a pack of cigarettes with about as much nicotine as one Marlboro. It says generally that it uses "modern plant breeding technologies, including genetic engineering, gene-editing, and molecular breeding."

Keeping 5% of the nicotine is enough to prevent smokers from seeking more to satisfy their craving, said John Miller, president of 22nd Century's smoking division.

"There's just enough in there that your brain thinks it's getting it, but it's not," Miller said. "That was really one of the reasons we got to these levels of nicotine, is because you don't have that additional smoking."

Miller said the low-nicotine cigarettes can help some smokers cut back or quit, perhaps in conjunction with a nicotine patch or gum, when they've tried and failed with other stop-smoking programs.

Campaign for Tobacco-Free Kids President Matthew L. Myers supports the development of an industrywide low-nicotine standard, saying the concept would work only if consumers no longer had the alternative of a higher-nicotine cigarette.

"The concern with a product that's still addictive, but delivers low levels of nicotine, in fact is that consumers will smoke more, because the evidence shows that somebody who's addicted will smoke enough to satisfy their craving," Myers said.

Both the FDA and anti-smoking groups cited studies that found lower levels of nicotine don't prompt smokers to smoke more to reach the same nicotine levels. But those studies assumed smokers wouldn't have a high-nicotine alternative, anti-smoking groups and researchers said.

Allowing low-nicotine cigarettes while conventional cigarettes remain available may be a public health detriment if they discourage smokers from quitting entirely or encourage others to start smoking because they think there's a safe way to experiment with cigarettes, the Campaign for Tobacco-Free Kids and several health associations wrote in a letter urging the FDA to reverse its 22nd Century decision.

22nd Century's cigarettes are still dangerous, and consumers must substantially cut back or quit smoking to get health advantages. But anti-smoking groups fear many smokers won't understand that.

"If people are looking at this as a magic bullet and are still continuing their tobacco use, they are not doing anything to change their risk," said Sward, of the lung association.

Anti-smoking groups particularly object to allowing 22nd Century to market menthol cigarettes even as the FDA is considering outlawing such cigarettes nationwide.

FDA spokesperson Abby Capobianco confirmed that 22nd Century has the only FDA-authorized low-nicotine cigarette but did not respond to requests for comment on the FDA's plans for regulating nicotine in cigarettes.

California already outlaws menthol flavoring, and Miller said the company won't challenge that state's ban and won't sell its menthol cigarettes in California.

But Miller hopes the company will eventually win an exemption from any federal ban, in part, he said, because more than half of menthol smokers are likely to switch to conventional cigarettes.

"That's not what the FDA wants to happen," Miller said. "They need an offramp for these menthol smokers and ours is obviously the natural."

The company is expanding into California, Florida, and Texas because of the nation-leading size of their smoking populations. It previously announced plans to also begin selling its very low-[nicotine](#), or VLN, cigarettes this year in Arizona, New Mexico, and Utah, and it may move into 10 more states.

The company is prioritizing seven states that offer [tax incentives](#) for products the FDA has said reduce tobacco risk, believing its cigarettes will have a price advantage over others in Colorado, Connecticut, Kentucky, Michigan, North Carolina, New Mexico, and Utah. Miller said the company may lobby California lawmakers to add similar incentives as part of the state's extensive efforts to discourage smoking, which still addicts 10% of its residents.

Miller declined to disclose the company's market share from the two test states but said sales were above expectations.

"If we can get this to the level of, like, a nonalcoholic beer—you know, 3% to 5% of the category—it's a game changer," Miller said. "We know that there's a latent demand in the market for this product."

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