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Can Nicotine Pouches Help People Quit Smoking?

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When e-cigarettes first hit the market, many public health experts hoped they would encourage people who smoke to move away from traditional cigarettes and toward a less harmful nicotine alternative. Although the switch proved successful for some, dangerous marketing tactics paved the way for a youth vaping crisis. A new initiative by the US Food and Drug Administration (FDA) may now be placing its harm reduction bet on a different product: nicotine pouches.

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In December, the agency announced the authorization of 6 nicotine pouch products from the on! PLUS brand. The decisions were the first to come out of a pilot program to streamline the FDA's review of marketing applications for nicotine pouches. The program, launched in September, came after the January 2025 authorization of 20 nicotine pouch products from Philip Morris–owned Zyn, the most popular brand in the oral tobacco and nicotine market. The FDA has said it is interested in making additional options available for adults who smoke cigarettes and want to switch to less-harmful nicotine pouches.

In addition to Zyn and on! PLUS, the pilot program will consider authorizing pouches from Velo and Turning Point Brands. In their premarket tobacco product applications (PMTAs), manufacturers must demonstrate that the "product is appropriate for the protection of public health." The FDA will then weigh the risks and benefits, factoring in whether current tobacco product users would quit if the new product came to market and, conversely, whether it would attract nonusers to tobacco.

The FDA also recently announced that its Tobacco Products Scientific Advisory Committee (TPSAC) will

already-authorized pouches. An MRTP designation would allow Zyn to explicitly market these products as being less harmful than cigarettes.

Research establishing the pouches' effectiveness as a harm reduction tool for cigarette smoking is sparse, but in interviews, public health experts expressed optimism. Nicotine pouches do not contain many of the carcinogenic chemicals found in cigarettes, they say, and their use does not require combustion and inhalation. Recent data also show that pouch use is common among those looking to quit smoking or vaping, suggesting that it's an attractive option for this population.

"As far as the risk profile of a single pouch, it looks more like nicotine gum," said Cristine Delnevo, PhD, MPH, director of the Rutgers Institute for Nicotine and Tobacco Studies and chair of TPSAC since 2021.

But with data about smoking cessation effectiveness and youth use still emerging, the FDA faces a challenge in weighing the risks and benefits of this burgeoning product category.

Safer Than Cigarettes

Oral nicotine pouches first appeared in US stores in 2016. Inside their rectangular, microfiber casings, the pouches contain a mixture of ingredients including synthetic or tobacco-derived nicotine powder, sweeteners, and pH stabilizers. Notably, they contain no tobacco and can vary in nicotine concentration and flavors. The currently authorized Zyn pouches come in 3-mg or 6-mg strengths with flavor options including coffee, menthol, peppermint, and cinnamon. The new on! PLUS products are authorized at 6-mg and 9-mg strengths in mint, wintergreen, and tobacco flavors. Unauthorized pouches with higher nicotine concentrations have also become available.

The pouches are kept between the lip and gum, and from there nicotine travels from the oral mucosa to the bloodstream and eventually to the brain. As with other nicotine products, the pouches carry a risk of dependence, and they've also been associated with gastrointestinal issues and oral health complications. A new expert consensus, published in the *European Heart Journal*, highlights the cardiovascular toxicity of all nicotine products, including pouches, and calls into question the "the misleading narrative of 'safer nicotine.'"

But the FDA and some public health experts consider nicotine pouches a "lower-risk alternative" to other products. The pouches don't involve combustion or inhalation like cigarettes and vapes. And unlike other oral products such as chewing tobacco or snus, nicotine pouches are tobacco free. These factors make pouches safer than other tobacco and nicotine products, according to Delnevo.

Nancy Rigotti, MD, director of the Tobacco Research and Treatment Center at Massachusetts General Hospital and a professor of medicine at Harvard Medical School, also likened the products to NRT, noting their lack of heating and their slow uptake into the bloodstream. "The absorption of nicotine is much slower, so it's more like having a nicotine lozenge," she said of the difference between pouches and combustible tobacco products. "It doesn't give you that quick hit."

Smoking Cessation Tool?

Trends on pouch use are still emerging, but the rates appear low. Data from the Population Assessment of Tobacco and Health, or PATH, survey, collected in 2022 and 2023, showed that about 3% of adults and less than 1% of adolescents had ever used pouches.

As for growing youth uptake, the 2024 National Youth Tobacco Survey found that less than 2% of middle and high schoolers said they had used pouches in the past month, a rate that held steady from 2023 to 2024. The FDA cited these data in its authorization of Zyn products last January.

However, rates for lifetime, past year, and past 30-day use all significantly increased from 2023 to 2024 among 10th and 12th grade students in the Monitoring the Future Study. Usage over the past month, for instance, doubled from 1.3% to 2.6%.

The PATH data, published this past May in *JAMA Network Open*, also found a higher likelihood of pouch use among those with current or former cigarette, e-cigarette, or smokeless tobacco use.

"The majority of people using nicotine pouches are not what I would call tobacco or nicotine naive," Delnevo said. "This product might've appealed as a potentially reduced-risk or less risky product."

Delnevo's research similarly has found that nicotine pouch use was highest among adults who currently used smokeless tobacco products or had recently quit smoking, vaping, or both. Studies have also found dual use of pouches alongside cigarettes or e-cigarettes to be common.

"Some of the work we've done suggests that people that have used e-cigarettes and cigarettes are looking to nicotine pouches as a way to transition away from that particular product," she said.

The approach could hold promise. Rigotti noted that people looking to wean off smoking or vaping often find alternative nicotine products more practical than NRT. She suggested that clinicians shouldn't shy away from these conversations and that the long-term goal should still be to quit all nicotine use.

"Public health somehow has to get around the idea that you just need to quit on your own or with a med,

paring the effectiveness of various nicotine pouch strengths and flavors for reducing cigarette smoking. The study will also measure how nicotine pouch use changes markers of toxicity and health effects in people who smoke.

The idea of using alternative products to quit smoking isn't new: e-cigarettes have been shown to be more effective than NRT for smoking cessation.

Current population-level survey data suggest that pouches could be similarly useful, but "it's not crystal clear," Foulds said, adding that data from clinical trials that compare pouches with NRT—such as those already conducted for e-cigarettes—are needed.

Avoiding Past Mistakes

Tensions between potential harm reduction benefits, the absence of clinical data, and concerns about youth uptake and dual use alongside other tobacco products have focused attention on the FDA's nicotine pouch pilot program. It wasn't too long ago that e-cigarettes quickly caught on among younger users under the guise of a less harmful alternative to smoking for adults.

The FDA has hinted that because of the pouches' relatively lower risk, the scientific review process may be shortened. The agency said it will "increase efficiency by focusing review on the most critical elements for this product category."

"What remains unknowable, given how few details have been shared, is exactly what part of the scientific review process is going to be altered," said Mitchell Zeller, JD, who served as the director of the FDA Center for Tobacco Products from 2013 before retiring in 2022.

Zeller's successor, Brian King, PhD, MPH, who left the FDA in April 2025, said that improving review efficiency is worthwhile and not uncommon but that there are still unanswered questions.

"Where this can be highly problematic is if the scientific integrity of the process is jeopardized," said King, who now serves as the executive vice president for US programs at the Campaign for Tobacco-Free Kids. "At present, we don't really know that much about the pilot program to be able to make that determination, and so it's important that FDA share that information."

Public health experts also haven't forgotten some of the mistakes made with e-cigarettes. Zeller said it will be critical to ensure that companies are not promoting youth or dual use. Much of this comes down to an evaluation of current sales data and marketing tactics, he added.

tion and so-called Zynfluencers, with whom Zyn has said they do not partner, may also attract younger audiences.

King said that such marketing may raise red flags at the FDA. When it authorized Zyn's products, the agency put restrictions on its radio and TV ads and on the age of actors in marketing materials. It also said that a spike in youth use could warrant suspending or withdrawing Zyn's PMTA.

"What's incredibly important is that we collect the data and monitor it carefully over time," Rigotti said.

As for concerns that nicotine pouches could be a gateway to more harmful tobacco use, Foulds noted that there are not enough data to bolster the idea that the products are leading youth to cigarettes or e-cigarettes, especially as youth smoking and vaping rates have been declining. If survey and upcoming clinical trial data continue to support pouches as an effective alternative for people who smoke, their benefits may outweigh the risks.

"The whole idea is to provide a mechanism for companies to move away from highly toxic products like cigarettes and to use their ingenuity and technology to develop much less harmful products and move the whole tobacco field in that direction," he said.

Delnevo described the current nicotine product market as a "wild west." Still, experts said that granting more PMTAs will actually make it easier for the FDA to do its job. The agency could hold brands accountable if it observes a concerning uptick in youth use, and it could have a greater legal basis for targeting companies for poor marketing practices. Bringing more authorized options to the market will also help drive out unauthorized products, which often come in high nicotine concentrations and flavors particularly appealing to younger users.

In its December authorization of on! PLUS pouches, the FDA said its evaluation found the products to contain lower levels of most harmful and potentially harmful constituents than other oral and smokeless tobacco products. While acknowledging that no tobacco products are risk-free or safe, the agency concluded that the authorized pouches have "the potential to provide a benefit to adults who smoke cigarettes and/or use other smokeless tobacco products that is sufficient to outweigh the risks of the products, including to youth."

More decisions on the remaining batch of nicotine pouch applications could be forthcoming. And depending on TPSAC's review of Zyn's MRTP application, more pouch makers may be inspired to file similar "safer than cigarettes" claims.

Weighing the risks and benefits will be no easy task, Zeller said. "There's no formula."

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Conflict of Interest Disclosures: Mr Zeller reported serving as a regulatory policy advisor to an advisor to Qnovia Inc, a start-up developing smoking cessation products. Dr Delnevo reported receiving grant funding from the National Institutes of Health and FDA as well as serving as a special government employee in her role as chair of the FDA's TPSAC. Dr Foulds reported receiving research funding from the National Institute on Drug Abuse. Dr Rigotti reported being an appointed member of the FDA's TPSAC and receiving compensation from Wolters Kluwer for reviewing materials on smoking cessation and e-cigarettes for UpToDate, an online medical textbook, and receiving research funds from Achieve Life Sciences, a pharmaceutical company, to evaluate an investigational drug that is now under FDA review for licensure as a new smoking cessation medication. Dr King reported that the Campaign for Tobacco-Free Kids receives funding from foundations, nonprofit organizations, and individuals including Bloomberg Philanthropies, the Robert Wood Johnson Foundation, the American Heart Association, and Truth Initiative. No other disclosures were reported.

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January 2, 2026

Is it really safer given the ease of abuse?

Christian Awaraji, MD | Health Advisor

The below is a personal opinion based on my occupational medical practice.

In practice, patients who have a higher risk to develop a cardiovascular events are the ones who we usually target more aggressively trying to assist them with smoking cessation.

These patients, typically the heavy smoker category, are at a higher risk of abuse nicotine pouches quickly reaching potentially higher levels of plasma nicotine levels potentially capable of triggering a coronary vascular spasm precipitating a heart attack.

I believe that we have to counsel these patients about the maximum daily of milligrams of nicotine and about

January 4, 2026

Nicotine pouches, on-ramp to nicotine addiction

Robert Walter, MD | Private Pediatric Practice

Really nice focus on this cutting edge medical issue. Thank you. As a community pediatrician, I am obviously biased towards the pediatric populations and this feels like the beginning of the Jules vaping disaster all over again. With flavors like cool mint and cinnamon they're not targeting current smokers who are trying to quit - they are targeting nicotine naive users to create more nicotine addicts! This makes sense - even though these products don't have tobacco in them, their own owned by big tobacco, and they're in the nicotine addiction business. Of course it'll take time ...

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