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Why the FDA is right about Zyn

Zyn has proven to be an especially controversial nicotine product. But there is some good news.

March 25, 2025, 5:57 PM EDT

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The U.S. Food and Drug Administration recently authorized the marketing of 20 nicotine pouch products under the Zyn brand, including flavors like Wintergreen and the "unflavored" Chill. That authorization sparked a new round of proposed legislation, trend pieces and frustration. Meanwhile, the stock price for Philip Morris International Inc., which manufactures the smokeless product, has caught fire.

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Tobacco-control professionals fought long and hard for comprehensive legislation that would give FDA regulatory oversight over tobacco products and nicotine products that do not make therapeutic claims. But Zyn has proven to be especially controversial given a series of buzzy stories about its use by young people and its seeming popularity on social media sites like TikTok. So-called "Zynfluencers" have led to fears that a new and youthful crowd could be looking to exploit the pouches for everything from long work days to clubbing. Most recently, Carrie Battan over at The New Yorker wrote about how Zyn pouches were becoming a "staple for American dudes" in a dispatch announcing "the new nicotine gold rush."

The good news is some of these fears may be overblown, especially fears about abuse by young people.

The reality is that after being available on the U.S. market for 10 years, only 2.4% of U.S. high school students had used a nicotine pouch in the previous 30 days in 2024 (as compared to 7.8 % for electronic cigarettes).

Zyn, like other new "nicotine pouch" products, contains no tobacco. It consists of a pouch, a bit like a mini teabag, containing powdered nicotine, along with a few other ingredients such as noncaloric sweeteners and flavors. Each tin contains 15 pouches which are typically placed under the upper lip for up to an hour to allow the nicotine to be absorbed through the lining of the mouth. The amount of nicotine delivered by the 3 mg and 6 mg strength pouches is slightly higher than that delivered by 2 mg and 4 mg nicotine gum, but the peak is lower and slower than the nicotine delivered by a cigarette.

In deciding whether to authorize these products, the FDA has to scrutinize a very detailed application and assess whether it is "appropriate for the protection of public health" to allow the products to be sold on the U.S. market. This involves weighing the likely risks and benefits to the population, including youth, those not currently using any tobacco products and existing users.

The 68-page summary of the FDA's January Zyn decision noted that the levels of 42 potentially harmful chemicals were so low in Zyn as to be undetectable. FDA officials concluded that the health risks from Zyn pouches are likely lower than potential risks from using snus (low toxicant smokeless tobacco) and the FDA has already concluded that some snus brands are significantly less harmful than cigarettes.

In their summary decision statement, FDA also referred to data produced by the applicants from studies on the effects of Zyn on existing tobacco users. Officials mentioned that in one study, more than 60% of existing tobacco users reported using Zyn to help reduce or quit smoking. Another study found that nearly a quarter of existing tobacco users completely switched to Zyn. While the manufacturers of Zyn are not claiming that Zyn is a medicinal smoking cessation aid, the fact that relatively few young people are taking up Zyn use, whereas a meaningful proportion of smokers are likely to switch to the product, suggests that the benefits are likely to outweigh the risks. This, combined with the very low toxicant delivery profile of Zyn (particularly compared to cigarettes), convinced the FDA that it is appropriate for public health for Zyn products to be marketed in the U.S.

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This is the FDA doing its job exactly as required by the 2009 Tobacco Control Act. The real controversy about this decision should be in relation to the length of time it took. Over 2,000 brands of cigarettes are currently available on the U.S. market. Each one emits thousands of toxic chemicals, including carcinogens that are inhaled directly into the lungs, with consequences we are all too familiar with. It is a good thing that smokers now have legal access to a product that can deliver the same drug many are already addicted to (nicotine) but with far lower health risks than cigarettes.

The day before announcing Zyn's marketing authorization, FDA Center for Tobacco Products announced another proposed rule that could have a massive impact on public health: a product standard that would limit the amount of nicotine permissible in cigarettes to nonaddictive levels. The timing may not have been coincidental.

This "low-nicotine cigarette" standard must pass through many steps before it can be implemented. One factor that may be key to its success is a wide selection of legal, less harmful (nonsmoked) nicotine products for nicotine-addicted smokers looking to switch. Zyn could be just such a product. So yes, it may seem like authorizing another nicotine product – especially one with its own youthful cultural cachet – is a risky decision. But when evaluating all the factors, it actually makes sense.

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