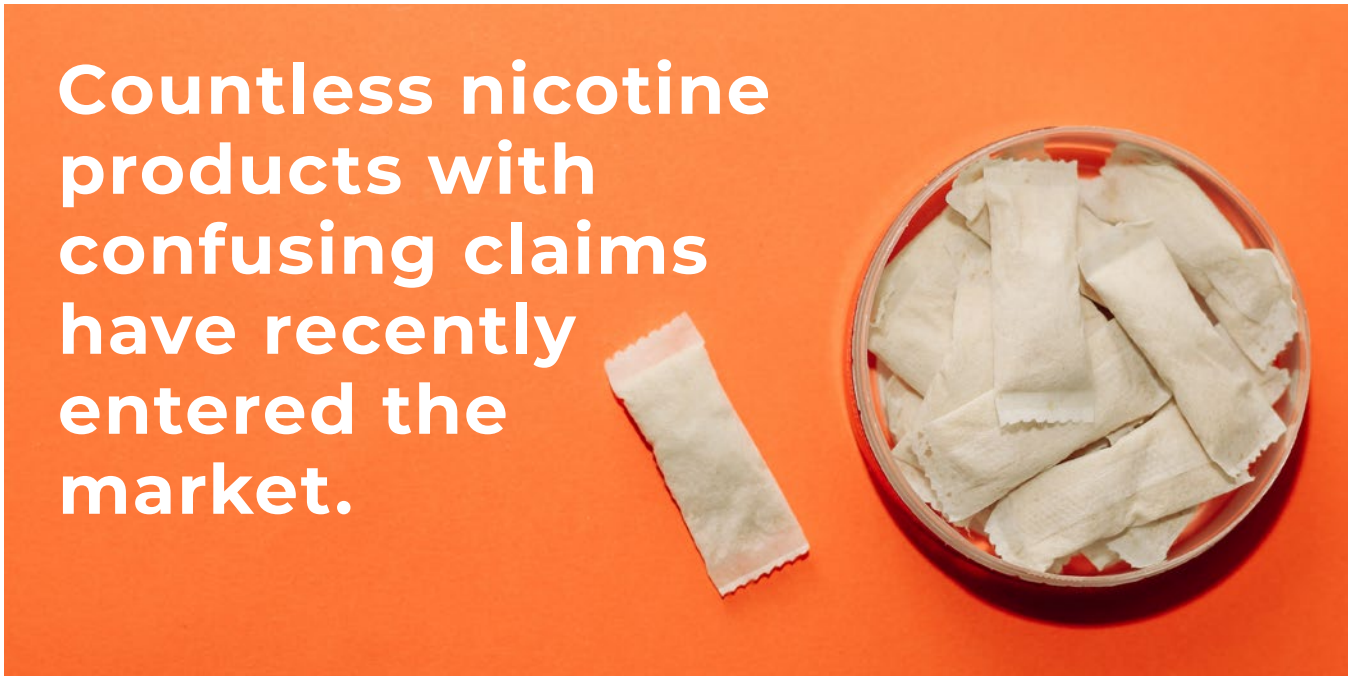
FREQUENTLY ASKED QUESTIONS ABOUT NICOTINE POUCHES

Nicotine pouches are smokeless commercial tobacco products, like snus and tobacco chew, that contain nicotine, whether naturally or synthetically derived.[1] Users place the pouch between the lip and gums where the nicotine can be absorbed through the gums and into the bloodstream.

The pouches are *not* nicotine replacement therapeutic products. This fact sheet contains answers to frequently asked questions about nicotine pouches.

Q: How popular are nicotine pouches?

A: Nicotine pouches have gained popularity across the U.S. in recent years, particularly in response to growing public scrutiny and increased regulation of combustible and non-combustible tobacco products like cigarettes and e-cigarettes. One of the most popular nicotine pouch brands is Philip Morris International's Zyn. Other brands include Altria's On! and British American Tobacco's Velo. According to the Centers for Disease Control and Prevention and tobacco researchers, nicotine pouch sales in the United States have exploded since 2016, going from 6 million sold to 334 million by 2023, with Zyn leading the charge.[2]



Q: Do nicotine pouches contain commercial tobacco?

A: Products like Zyn claim to be commercial tobacco-free. Although they may not contain tobacco leaves, most nicotine pouches use nicotine derived from tobacco leaves. Some products other than Zyn claim to use *synthetic* nicotine that is not derived from tobacco leaves; however, the accuracy of such claims is, at best, suspect. The reality is that countless nicotine products with confusing claims have recently entered the market with confusing claims — products that are neither authorized nor approved by the U.S. Food and Drug Administration.[3] The FDA considers nicotine pouches to be commercial tobacco products that are under its authority to regulate and restrict, but far more nicotine products are in the market today than there are FDA regulators and agents.

Q: How can nicotine pouches be sold without marketing authorization from the FDA?

A: In part because of the deluge of product applications that the FDA received for marketing authorization, the agency clarified after the Deeming Rule that it would allow companies to continue to sell their products as long as the companies submitted premarket tobacco product applications (PMTAs) by August of 2020. Zyn appears to fall into this category, as do other nicotine pouches like On! and Velo, since the companies owning these products all submitted

PMTAs for them in 2020.[4] However, the FDA has not made a final decision on any of these applications, nor has it issued a marketing granted order or a marketing denial order for any brand of nicotine pouches. These companies therefore have temporary permission from the FDA to continue to sell their products, even though they lack a marketing granted order.

Q: What has the FDA done about nicotine pouches?

A: Clearly, what the FDA has *not* done is issue a marketing granted order for products like Zyn, On!, and Velo. This suggests that the agency has not yet decided whether it would be appropriate for the protection of public health to grant these products authorization.

The FDA is also surveilling the nicotine pouch market to see if such products are being sold to underage consumers. For example, the agency sent youth decoys to attempt to purchase nicotine pouches at retailers across the country between 2023 and 2024. The agency then issued 119 warning letters and 41 civil monetary penalty complaints against numerous brick and mortar retailers for selling to underage consumers.[5]

Q: Are nicotine pouches really that bad?

A: Some public health researchers, such as those supported by the tobacco industry, are happy to argue that smokeless tobacco products are a net win for public health, and that products like e-cigarettes and nicotine pouches can be vehicles to improving health. Other public health researchers contend that whether a product is combusted, or even contains tobacco leaf, has little bearing on how the harm of using such a product should be assessed and regulated.

Nicotine is a highly addictive substance; the U.S. Surgeon General found nicotine comparable to heroin in terms of addictiveness.[6] The effects of nicotine dependence can be even more pronounced when teenagers and young adults use nicotine. And flavor molecules, especially those found in menthol, might make nicotine addiction and its consequences much worse, owing to how the molecules interact in the brain.

Q: Are nicotine pouches rising in popularity among youth?

A: One of the selling points for nicotine pouches is their ability to be used discreetly. Nicotine pouches do not produce smoke or vapor and are small enough to be inconspicuous when used. The most popular nicotine pouches today come in small containers that look like they contain mints or gum. The companies market these products for use almost everywhere, including at times and places where other tobacco products are banned.

The explosion in youth e-cigarette use beginning around 2010 and 2011 led to an entire generation of young people beginning to use "alternative" tobacco products and normalizing tobacco product use.[7] In response to this upsurge, local and state lawmakers have enacted measures to curb the youth appeal of tobacco products — including non-tobacco nicotine products — and have especially targeted flavors.[8] As these laws take effect, adults and youth alike have turned to other, even more discreet means of satiating their need for nicotine. According to the National Youth Tobacco Survey results in 2023, among youth under 18 years old, nicotine pouch use is around 1.5 percent, which is comparable to cigarettes and cigar use, and much lower than e-cigarette use.[9] But according to the 2021 National Youth Tobacco Survey results, youth use of nicotine pouches stood at 0.8 percent, while the use of those other three products were about the same.[10]

Another selling point for nicotine pouches is that many of these brands are flavored, which is essential to their appeal to young people. While states like California and Massachusetts have moved to prohibit the sales of most flavored tobacco products, and numerous cities and counties have done the same, a great many other places have not. And even in California, high school use of nicotine pouches stood at 1.1 percent in 2023 — and the overwhelming majority of tobacco products used by youth in that state were flavored.[11]

Q: What can the public health community do about these products?

A: Although products such as Zyn, On!, and Velo can be sold temporarily because of the grace period they enjoy while their PMTAs are reviewed, other brands are likely to emerge that have not attempted to go through the required premarket review process. The FDA does not have a publicly available list of all PMTAs under review, but it does provide a list of products with marketing granted and marketing denial orders. For those who believe a nicotine pouch product is being sold without the FDA's authorization, the agency provides an online form for notifying the agency of tobacco product violations.

Nicotine pouches are commercial tobacco products, and the best way to regulate their sale and use is with comprehensive state and local laws. State and local laws that define commercial tobacco products as those that use tobacco or nicotine (and are not FDA-approved nicotine replacement therapy drugs) unequivocally capture nicotine pouches, regardless of the purported source of their nicotine.

Banning the sale of all commercial tobacco products is the single best way to curb commercial tobacco product use across all generations. Short of that, enacting strong flavor laws restricting all flavored commercial tobacco products has been and remains one of the best ways to address youth use. Local jurisdictions that have the legal authority to enact their own measures may consider doing so, independent of or in conjunction with their states.

By using the Public Health Law Center's comprehensive model definitions for "tobacco product" and "flavored tobacco product," jurisdictions will capture all nicotine pouch products, including flavored nicotine pouches:

"Tobacco Product" means:

(1) any product containing, made of, or derived from tobacco or nicotine that is intended for human consumption or is likely to be consumed, whether inhaled, absorbed, or ingested by any other means, including but not limited to, a cigarette, a cigar, pipe tobacco, chewing tobacco, snuff, or snus;

(2) any electronic smoking device and any substances that may be aerosolized or vaporized by such device, whether or not the substance contains nicotine; or

(3) any component, part, or accessory of (1) or (2), whether or not any of these contains tobacco or nicotine, including but not limited to filters, rolling papers, blunt or hemp wraps, hookahs, mouthpieces, and pipes.

"Tobacco product" does not mean drugs, devices, or combination products authorized for sale by the U.S. Food and Drug Administration, as those terms are defined in the Federal Food, Drug, and Cosmetic Act.

"Flavored tobacco product" means any tobacco product that imparts:

(1) a taste or smell, other than the taste or smell of tobacco, distinguishable by an ordinary consumer either prior to or during the consumption of such tobacco product, including but not limited to the taste or smell of fruit, chocolate, vanilla, honey, candy, cocoa, dessert, alcoholic beverage, mint, wintergreen, menthol, herb, or spice; or

(2) a cooling or numbing sensation distinguishable by an ordinary consumer either prior to or during the consumption of such tobacco product.

"Presumptive flavored tobacco product." Any communication by, or on behalf of, the manufacturer or retailer of a tobacco product that indicates that the product imparts: a taste or smell other than the taste or smell of tobacco, or a cooling or numbing sensation, constitutes presumptive evidence of a violation of this section. Presumptive evidence may include but is not limited to the use of terms such as "cool," "chill," "ice," "fresh," "arctic," or "frost" to describe the product.

Enforcement will be a challenge. Focusing on non-compliant individuals is unlikely to be as effective as enforcing policies for retailers and suppliers, which buttresses the case for state and local action to regulate tobacco retailers as strongly as possible. A "presumptive flavored tobacco product" provision helps local enforcement as well, since it puts the burden on the tobacco industry to prove its products are not flavored in the way that an ordinary consumer would consider it, while giving local enforcement agents a potent source of information (consumer experiences and product reviews) upon which to base their actions.

For more information about nicotine pouches, see *Zyn & the Rise in Popularity of Nicotine Pouches* (2024), a publication from the Public Health Law Center for our California partners.

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Endnotes

1 Traditional and commercial tobacco are different in the ways they are planted, grown, harvested, and used. Traditional tobacco is and has been used in sacred ways by Indigenous communities and Tribes for centuries. Commercial tobacco is manufactured for recreational use and profit, resulting in disease and death. When the word "tobacco" is used throughout this document, a commercial context is implied and intended. For more information, visit the National Native Network website: https://keepitsacred.itcmi.org.

2 Kristy L. Marynak et al., *Nicotine Pouch Unit Sales in the US, 2016–2020*, 326 JAMA 566 (2021); Anuja Majmundar et al., *Nicotine Pouch Sales Trends in the U.S. by Volume and Nicotine Concentration Levels from 2019 to 2022*, 5 JAMA e2242235 (2022).

3 Willow Anderson, *The Regulatory Puzzle of Metatine and the Challenge of No-Nicotine Claims*, Public Health Law Center (2024), https://www.publichealthlawcenter.org/commentary/240202/2/2/24-regulatory-puzzle-metatine-and-challenge-no-nicotine-claims.

4 *Swedish Match Results Presentation: Q1 2020*, Swedish Match, https://www.swedishmatch.com/globalassets/documents/presentations/2020_q1_interimpresentation_swedishmatch_en.pdf; *The Science of Oral Tobacco-Derived Nicotine*, Altria Science, https://sciences.altria.com/en/product-platforms/oral-tobacco-derived-nicotine; *VELO Pouch Premarket Tobacco Applications Submitted to FDA for Review by Reynolds*, PR Newswire, https://www.prnewswire.com/news-releases/velo-pouch-premarket-tobacco-applications-submitted-to-fda-for-review-by-reynolds-301122281.html.

5 *FDA Issues Warning Letters to and Files Civil Money Penalty Complaints Against Retailers for Underage Sales of ZYN Nicotine Pouches*, FDA (Apr. 4, 2024), https://www.fda.gov/tobacco-products/ctp-newsroom/fda-issues-warning-letters-and-files-civil-money-penalty-complaints-against-retailers-underage-sales.

6 *Surgeon General's Report: Smoking and Nicotine Addiction*, C-SPAN (1988), https://www.c-span.org/video/?2611-1/surgeon-generals-report-smoking-nicotine-addiction.

7 Karen A. Cullen et al., *E-Cigarette Use Among Youth in the United States, 2019*, 322 JAMA 2095 (2019).

8 *See, e.g.*, Public Health Law Center, *U.S. Sales Restrictions on Flavored Tobacco Products* (2024), https://www.publichealthlawcenter.org/sites/default/files/resources/US-sales-restrictions-flavored-tobacco-products.pdf.

9 Jan Birdsey et al., *Tobacco Product Use Among U.S. Middle and High School Students — National Youth Tobacco Survey*, 2023, 72 MORBIDITY & MORTALITY WKLY. 1173 (2023).

10 Andrea S. Gentzke et al., *Tobacco Product Use and Associated Factors Among Middle and High School Students — National Youth Tobacco Survey, United States, 2021*, 71 MORBIDITY & MORTALITY WKLY. 1 (2022).

11 California Department of Public Health, *California Tobacco Facts and Figures 2024*, 14 fig. 8 (2024), https://www.cdph.ca.gov/Programs/CCDPHP/DCDIC/CTCB/CDPH%20Document%20Library/ResearchandEvaluation/FactsandFigures/CaliforniaTobaccoFactsAndFigures2024.pdf.