



## Zyn Fact Sheet

### **What is Zyn?**

Zyn is a brand of oral nicotine pouches that do not contain tobacco leaves. It belongs to a category of product called non-tobacco nicotine, defined as nicotine that did not come from a tobacco plant.<sup>1</sup> To use Zyn, a user tucks the pouch into the upper lip to deliver nicotine directly into the bloodstream through the mouth rather than inhaling through the lungs like combustible tobacco products. It is sold in 3mg and 6mg doses and in a variety of flavors including menthol, mint, citrus, cinnamon, and coffee. One tin of 15 pouches can cost less than \$5.00 in Maryland in 2024.

### **Is Zyn a tobacco product?**

Yes, Zyn is a tobacco product under both federal and state law, although the definitions of a tobacco product differ slightly.

*Federal* – as defined in section 201(rr) of the Food, Drug, and Cosmetic Act, in relevant part, a tobacco product means any product made or derived from tobacco, *or containing nicotine from any source*, that is intended for human consumption, including any component, part, or accessory of a tobacco product.<sup>2</sup>

*Maryland* – Zyn is classified as an “other tobacco product” which is defined in Maryland Code, Business Regulation Article, §16.5-101 as a product that is intended for human consumption or likely to be consumed, whether smoked, heated, chewed, absorbed, dissolved, inhaled, or ingested in any other manner, and that contains tobacco or nicotine.<sup>3</sup>

### **Zyn Popularity**

Zyn has led the steadily growing non-tobacco nicotine market in the US since late 2019. Philip Morris International, one of the largest tobacco companies and producers of Zyn, announced that its shipments of Zyn nicotine pouches rose nearly 80 percent in the first quarter of 2024.<sup>4</sup> In June, 2024 Philip Morris suspended nationwide online sales from zyn.com in order to respond to a subpoena from the District of Columbia (DC). DC’s Attorney General subpoenaed Zyn requesting information about its compliance with DC’s 2022 ban on the sale of all flavored tobacco. The company stated that zyn.com represents a “very small percentage of nationwide Zyn volumes.”<sup>5</sup> And, in fact, Philip Morris has announced that it will build a new Zyn manufacturing facility in Aurora, Colorado to help meet consumer demand.<sup>6</sup>

Evidence suggests that nicotine pouches are growing in popularity among youth, largely because they offer a discrete way to obtain nicotine without alerting adults to product use. In the 2023 National Youth Tobacco Survey, nicotine pouches were the fourth most used tobacco product among youth, after e-cigarettes, combustible cigarettes, and cigars.<sup>7</sup> Another recent study found a higher use rate for nicotine pouches among youth and young adults: 16 percent

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<sup>1</sup> <https://www.fda.gov/tobacco-products/products-ingredients-components/regulation-and-enforcement-non-tobacco-nicotine-ntn-products>

<sup>2</sup> U.S. Congress. (1934) United States Code: Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-392 Suppl. 5

<sup>3</sup> [Maryland Code, Business Regulation Article, § 16.5-101\(j\)](#)

<sup>4</sup> <https://www.bloomberg.com/news/articles/2024-04-23/philip-morris-boosted-by-rising-demand-for-smoke-free-products>

<sup>5</sup> <https://www.reuters.com/business/retail-consumer/philip-morris-suspends-nationwide-sales-zyncom-after-dc-subpoena-2024-06-17/>

<sup>6</sup> <https://www.reuters.com/markets/commodities/philip-morris-expand-zyn-production-us-with-new-plant-colorado-2024-07-16/>

<sup>7</sup> Jan Birdsey et al., Tobacco Product Use Among U.S. Middle and High School Students — National Youth Tobacco Survey, 2023, 72 Morbidity & Mortality Wkly. Rep. 1173 (2023).

of participants had ever used a nicotine pouch, and 12 percent reported current use.<sup>8</sup> This study also sounds an alarm that many youth and young adults using nicotine pouches are using them in combination with other tobacco products.

### **FDA Action**

To date, the FDA has issued 119 warning letters and filed 41 civil money penalty complaints against brick-and-mortar retailers that have sold Zyn nicotine pouches to people under 21 years old between October 2023 and February 2024.<sup>9</sup> The FDA has also issued warning letters to three online retailers for the sale of unauthorized, flavored Zyn nicotine pouches, including Espresso, Black Cherry, Lemon Spritz, and Cucumber Lime.

### **Dangers of Zyn**

Zyn can cause an increase in blood pressure, heart rate, flow of blood to the heart, and a narrowing of the arteries. Nicotine may also contribute to the hardening of the arterial walls which can lead to heart attack. It can stay in your body for six to eight hours, and, as with most addictive substances, there are some side effects of withdrawal.<sup>10</sup> Nicotine pouches, including ZYN, are bad for gum tissue. They reduce blood flow and oxygen levels and impair healing in the gums, leading to cell death. Using nicotine pouches increases the user's odds of gum disease, gum recession, leukoplakia, decay, bad breath, dry mouth, and bruxism.<sup>11</sup> Nicotine use during adolescence can disrupt the formation of brain circuits that control attention, learning, and susceptibility to addiction.<sup>12</sup> Research has shown nicotine use in early age is correlated with daily use and lifetime nicotine dependence.<sup>13</sup> Nicotine use can also intensify symptoms of depression and anxiety.<sup>14</sup>

### **How is Zyn regulated?**

The FDA has legal authority to regulate tobacco products containing nicotine from any source, including non-tobacco nicotine. Zyn may only be legally marketed in the United States if it receives a marketing order from the FDA, which has not happened to date. However, Zyn did timely submit a premarket tobacco product application (PMTA) to the FDA, who is exercising enforcement discretion and allowing products to stay on the market while the FDA completes its PMTA review. The most recent guidance document from the FDA states that, "at this time, FDA has decided to prioritize use of its limited enforcement resources to address the sudden and dramatic increase in youth use of [ESD] products, as well as to focus on health and safety concerns connected to [ESD] products such as vaping-associated lung injuries. While acknowledging that all new tobacco products on the market without the required authorization are marketed unlawfully and are potentially subject to enforcement action, at any time, in FDA's discretion, FDA's primary focus will be to address the sudden and dramatic increase in youth use of [ESD] products," and other tobacco products will "therefore be a lower priority." This guidance is from 2020 and it seems that the tides are shifting; in March 2024 the FDA issued warning letters to at least four retailers selling Zyn, so there may be additional federal enforcement as Zyn continues to grow in popularity.

### **What are the federal laws related to Zyn?**

While Zyn remains on the shelves, it is regulated like any other tobacco product:

- May not be sold or marketed to anyone under 21<sup>15</sup>
- Retailer must check ID of anyone 27 or younger before selling<sup>16</sup>
- Cannot be sold in a vending machine unless in an adult-only facility<sup>17</sup>

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<sup>8</sup> Minal Patel et al., Patterns of Oral Nicotine Pouch Use Among U.S. Adolescents and Young Adults, 34 Preventative med. rep. 102239 (2023).

<sup>9</sup> Food and Drug Administration, "FDA Issues Warning Letters to and Files Civil Money Penalty Complaints Against Retailers for Underage Sales of ZYN Nicotine Pouches." Last accessed August 26, 2024.

<sup>10</sup> American Heart Association, "How Smoking and Nicotine Damage Your Body." Last accessed June 8, 2024.

<sup>11</sup> "Hygienist Explains: ZYN Nicotine Pouches Bad For Your Gums?" Last accessed August 26, 2024.

<sup>12</sup> E-Cigarette Use Among Youth and Young Adults: A Report of the Surgeon General. Last accessed June 8, 2024

<sup>13</sup> "Tobacco Use Among Children and Teens." Last accessed June 8, 2024.

<sup>14</sup> "Effect of nicotine and nicotinic receptors on anxiety and depression." Last accessed June 8, 2024.

<sup>15</sup> 21 USC 387f

<sup>16</sup> <https://www.fda.gov/tobacco-products/retail-sales-tobacco-products/selling-tobacco-products-retail-stores#references>

<sup>17</sup> 21 CFR 1140.14

- No free samples<sup>18</sup>
- Health warning statement on the package is required<sup>19</sup>
- No advertisements without a health warning statement<sup>20</sup>
- No marketing these products as modified risk tobacco products without FDA authorization<sup>21</sup>

### **What do I do if I see any of these federal laws being broken?**

Report federal violations to the FDA in one of four ways:

- Online at <https://www.accessdata.fda.gov/scripts/ptvr/index.cfm>
- Call the Tobacco Call Center using CTP's toll-free number at 1.877.CTP.1373
- Send an email to [CTPCompliance@FDA.hhs.gov](mailto:CTPCompliance@FDA.hhs.gov)
- Print and mail the paper form at <https://www.fda.gov/media/85811/download>

### **What are the Maryland laws related to Zyn?**

Zyn must follow the same laws as all other tobacco products in the state.

- Zyn cannot be sold or marketed to anyone under 21<sup>22</sup>
- Retailer must check ID of anyone 30 or younger before selling<sup>23</sup>
- Cannot be sold in a vending machine unless in an adult-only facility<sup>24</sup>
- Must be located behind the counter and only accessible by the licensed retailer<sup>25</sup>
- Retailer must post a sign in a location that is clearly visible to the consumer that states, "No person under the age of 21 may be sold tobacco products"<sup>26</sup>

### **What do I do if I see any of these Maryland laws being broken?**

Report Maryland violations to the Acting Deputy Director of the Alcohol, Tobacco, and Cannabis Commission (ATCC), Jeffrey Herndon at [jeffreyh.herndon@maryland.gov](mailto:jeffreyh.herndon@maryland.gov). For more information, please refer to the ATCC Tobacco Compliance Bulletin 24-002

[https://content.govdelivery.com/attachments/MDCOMP/2024/05/02/file\\_attachments/2866297/TCB-24-002-Updated.pdf](https://content.govdelivery.com/attachments/MDCOMP/2024/05/02/file_attachments/2866297/TCB-24-002-Updated.pdf)

### **Will Congress ban Zyn?**

In January 2024, Senate Majority Leader Charles Schumer held a press conference urging the Federal Trade Commission (FTC) and FDA to investigate Zyn for concerns relating to marketing and health effects. Neither the FDA nor the FTC have taken any action on this request.

### **Have there been any lawsuits filed against Zyn?**

In March 2024 a lawsuit was filed in the Southern District of California against Philip Morris, the parent company to Zyn, and Swedish Match, which manufactured this product prior to 2022, when Philip Morris International bought it for \$16 billion. The plaintiff, Bailey Wolters, alleges addiction and dental issues resulting from Zyn use. The lawsuit says that the pouches deliver more nicotine than cigarettes, and that the company benefits from "Zynfluencers" who promote the brand on social media. According to the plaintiff, the companies failed to warn consumers about the risk of addiction and other harmful effects like cognitive issues, cardiovascular injuries, gastrointestinal problems, and gum disease. The

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<sup>18</sup> [21 CFR § 1140.16\(d\)\(2\)](#)

<sup>19</sup> [21 CFR 1143.3](#)

<sup>20</sup> *Id.*

<sup>21</sup> [Food, Drug, and Cosmetic Act 911g](#)

<sup>22</sup> Maryland Code, Business Regulation Article, § 16.5–214.2(b)(1); Criminal Law Article § 10-107(b)(2); Health-General Article § 24-307(b).

<sup>23</sup> Maryland Code, Business Regulation Article, § 16.5–214.2(b)(3); Health-General Article § 24-307(b)(3).

<sup>24</sup> Maryland Code, Business Regulation Article § 16-3A-02

<sup>25</sup> Maryland Code, Business Regulation Article, § 16.5–214.2(a)(2); Health-General Article § 24-307(b)(1)(ii).

<sup>26</sup> Maryland Code, Business Regulation Article, § 16.5–214.1

suit is seeking, and likely will be granted, class-action status. It will be many years before this suit is settled. On June 17, 2024, Philips Morris International announced that it will stop the online sales of Zyn nicotine pouches on ZYN.com.

Washington, DC also recently came to a settlement with Zyn. In 2024, the DC Office of the Attorney General (OAG) opened an investigation into whether sales of flavored Zyn products violated the District's ban on flavored tobacco and nicotine products. The investigation uncovered evidence indicating that from October 1, 2022 (when the flavor ban was enacted) until June 30, 2024, tens of thousands of flavored tobacco products were sold to DC consumers through its website shop.zyn.com, in violation of the ban and of the District's Consumer Protection Procedures Act (CPPA). Under the terms of a settlement agreement that resolves the investigation, Zyn must:

- Pay \$1.2 million to DC.
- Monitor Zyn distributors and take steps to ensure compliance with DC's flavor ban.
- Send annual compliance reminders to DC distributors and retailers.
- Prohibit the future sale of flavored tobacco products in DC through shop.zyn.com or any other e-commerce shop associated with zyn.com.

**This document was developed by the Legal Resource Center for Public Health Policy in consultation with the Maryland Department of Health. It is not intended to serve as legal advice; you should always confer with your county attorney or Assistant Attorney General on any particular legal questions. If you have any questions about the materials in this guide—or any questions about tobacco regulation—feel free to contact the LRC at (410) 706-0842 or [publichealth@law.umaryland.edu](mailto:publichealth@law.umaryland.edu).**

