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COMMENTARY

No Smoke, No Problem: The FDA and the Rise of Nicotine Pouches

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The tobacco industry has made significant strides in the past decade in transitioning away from cigarettes, making explicit their intentions to move smokers away from cigarettes and towards alternatives, including heated tobacco units and nicotine pouches.¹ As cigarette sales continue to decline and nicotine pouches rise in popularity,² Big Tobacco and the Food and Drug Administration (FDA) are increasingly locked in regulatory battles over the future of nicotine. This article briefly discusses the trajectory of the industry before exploring the newest developments in the fight over nicotine regulation.

Prior to 1996, the FDA played no role in tobacco regulation as tobacco was regulated by the states directly or by Congress.³ In 1996, the FDA asserted authority to regulate tobacco under 21 U.S.C. § 301 *et seq.*, which provides that the FDA may regulate “drugs and devices.”⁴ Rules were subsequently issued with the intention of reducing cigarette use by children.⁵ In 2000, the U.S. Supreme Court held that Congress had not granted the FDA such authority.⁶ Finally, in 2009, the Family Smoking Prevention and Tobacco Control Act was signed into law, giving the FDA explicit authority to regulate tobacco as a drug.⁷ In 2016, the FDA issued its “Deeming Rule,”

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¹ Philip Morris Int'l, *Why is Philip Morris International still selling cigarettes?* (2026), <https://www.pmi.com/our-progress/why-is-philip-morris-international-still-selling-cigarettes?>; British American Tobacco, *Who We Are: We are BAT*, <https://www.bat.com/who-we-are> (last visited Sep. 10, 2026); Altria, *Moving Beyond Smoking*, <https://www.altria.com/moving-beyond-smoking?src=home-page-video> (last visited Sep. 10, 2026).

² Hugo Lhomedet & Emma Rummney, *Can Nicotine Pouches Drive Big Tobacco's Future Beyond Cigarettes?*, REUTERS (Aug. 17, 2026, at 10:02 PM MST), <https://www.reuters.com/business/healthcare-pharmaceuticals/can-nicotine-pouches-drive-big-tobaccos-future-beyond-cigarettes-2026-08-18/?>.

³ *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 144 (2000).

⁴ *Id.* at 125.

⁵ *Id.* at 126.

⁶ *Id.*

⁷ Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009).

allowing it to define categories of tobacco products,⁸ and eight years later, Congress clarified that the FDA had authority to regulate products containing nicotine from any source, including synthetic nicotine.⁹

Usage of nicotine pouches exploded in the U.S. when the Swedish brand, Zyn, entered American markets in 2016. By 2020, Zyn pouches were available in about 100,000 U.S. stores,¹⁰ and two years later, the creators of the Zyn brand, Swedish Match, were acquired by tobacco giant Philip Morris International.¹¹ Since then, many Big Tobacco companies have pivoted heavily to the growing nicotine market as cigarette sales continued to fall.

This year, Big Tobacco has shown its hand even more clearly, doubling down on efforts to ease regulatory restrictions surrounding nicotine pouches while launching advertising campaigns that tout their purported health and cognitive benefits.¹² Tobacco executives have increasingly pushed back against FDA policies that they see as overly restrictive, preventing growth in the market. Out of millions of applications for new nicotine products submitted to the FDA for approval since 2020, only roughly 75 have actually been approved as of March of this year.¹³ One major concern of such a slow process is the influx of illegal vapes from China that fill the gaps.¹⁴

In response, tobacco giant Altria filed suit against the FDA in September of this year, seeking to overhaul the product review process.¹⁵ The suit comes in the wake of an extensive lobbying campaign targeted at President Donald Trump, where he received over \$20 million in campaign donations from several Big Tobacco companies.¹⁶ Altria is asking the federal court to set aside the current system and require the FDA to develop a new one. They argue that the current system violates the legal requirement that applications be decided upon within 180 days of receiving them, as Altria alleges the FDA has never met that deadline.¹⁷

In the wake of the lawsuit, and amid the Trump Administration's broader easing of regulatory enforcement, the path toward developing and bringing new nicotine products to market may become increasingly accessible in the years ahead. Some will view these changes favorably,

⁸ Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, 81 Fed. Reg. 28973-01 (May 10, 2016) (codified at 21 C.F.R. pts. 1100, 1140, 1143).

⁹ Consolidated Appropriations Act, 2022, Pub. L. No. 117-103 (codified at 21 U.S.C. § 387a).

¹⁰ Swedish Match, *A World Without Cigarettes Can Be a Reality* (2020), https://www.swedishmatch.com/globalassets/reports/annual-reports/2020_swedishmatchannualreport_interactive_en.pdf?

¹¹ Philip Morris Int'l, *Annual Report 2022* (2023), https://www.pmi.com/resources/docs/default-source/investor_relation/pmi_2022_annualreport.pdf?

¹² Tobacco Insider, *September 2026: ZYN Rolls Out "When It Clicks" Campaign* (Sep. 4, 2026), <https://tobaccoinsider.com/zyn-in-usa/>.

¹³ Emma Rumney & Jonathan Stempel, *Altria Sues FDA Over Tobacco Product Review System*, REUTERS (Sep. 2, 2026), <https://www.reuters.com/world/altria-sues-us-fda-court-records-show-2026-09-02/>

¹⁴ *Id.*

¹⁵ *Id.*

¹⁶ Yasmeen Abutaleb, Emma Rumney & Chris Prentice, *Big Tobacco Comes Out On Top After US FDA Shake-Up*, REUTERS (May 26, 2026, at 3:03 AM MST), <https://www.reuters.com/legal/litigation/big-tobacco-comes-out-top-after-us-fda-shake-up-2026-05-26/>.

¹⁷ *Id.*

particularly if nicotine pouches can provide a less harmful alternative to combustible cigarettes and, potentially, vaping products. Others will remain cautious, pointing to the rapid growth of these products among the youth and the risk that their increased availability could encourage a new generation of nicotine users. Regardless of where the pendulum ultimately settles, one thing seems increasingly clear: nicotine is unlikely to disappear anytime soon. Indeed, even the potential cognitive effects of nicotine—including its purported effects on attention and alertness—are often overlooked amid the substance’s broader stigma and well-documented risks. The more difficult question, then, is not whether nicotine will remain a part of the market, but how regulators should balance protecting public health with allowing the development and availability of potentially safer alternatives for existing nicotine users.