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**COMMENTARY**

*The Battle over Nicotine Pouches: Schumer, Zyn and the FDA's  
Regulatory Expansion*

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In a significant move towards tightening regulation on nicotine products, Senate Majority Leader Chuck Schumer has proposed an investigation into Zyn, the increasingly popular nicotine pouches. This proposal comes at a time when the U.S. Food and Drug Administration (FDA) has been granted new powers to regulate nicotine from any source, including synthetic variants. This article examines the facts surrounding Schumer's initiative, the FDA's expanded regulatory framework, prior regulatory efforts against nicotine products, and the potential economic impact on the industry.

In January of this year, Chuck Schumer called upon federal agencies to crack down on Zyn nicotine pouches.<sup>1</sup> Schumer cited concerns of Zyn's marketing strategies and the nicotine product's effects on teen health. Zyn is the leading brand of nicotine pouches in the U.S., having sold more than 808 million units in just the first few months of 2022.<sup>2</sup> The widespread adoption of Zyn has been fueled by social media personalities, dubbed "Zynfluencers,"<sup>3</sup> who often share humorous content and coin catchy phrases associated with the product. However, Philip Morris International, the parent company of Zyn,

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<sup>1</sup> Kinsey Crowley, *Sen. Chuck Schumer Asks Feds to Crack Down on Teen Use of Zyn Nicotine Pouches*, USA TODAY (Jan. 24, 2024, 4:18 PM), <https://www.usatoday.com/story/news/politics/2024/01/24/chuck-schumer-zyn-nicotine-pouches/72340548007/>.

<sup>2</sup> Anuja Majmundar et al., *Nicotine Pouch Sales Trends in the US by Volume and Nicotine Concentration Levels from 2019 to 2022*, JAMA NETWORK OPEN (Nov. 1, 2022), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9667333/>.

<sup>3</sup> Sasha Rogelberg, *A New Wave of Gen Z 'Zynfluencers' are Fueling a Tobacco Industry Resurgence with Nicotine Pouch Sales*, FORTUNE (Jan. 26, 2024, 2:31 PM), <https://fortune.com/2024/01/26/gen-z-zynfluencers-tobacco-zyn-nicotine-pouch/>.

firmly denies engaging in influencer marketing and maintains it does not target the under-21 demographic in its advertising efforts.<sup>4</sup>

Amid concerns over marketing and health impacts highlighted by Senator Schumer, recent legislative developments have significantly broadened the FDA's regulatory authority over nicotine products. The Consolidated Appropriations Act, signed into law by President Biden on March 15, 2022, amended the Federal Food, Drug, and Cosmetic Act to include nicotine from any source under the FDA's purview.<sup>5</sup> This amendment is a direct response to the growing concerns over nicotine products like Zyn.

Following this amendment, the FDA set forth new guidelines effective on April 14, 2022, requiring entities involved in the distribution, sale, and manufacturing of non-tobacco nicotine (NTN) products to comply with several key provisions.<sup>6</sup> These include, inter alia, not selling to individuals under 21, refraining from marketing products as modified risk without FDA authorization, and the prohibition of free sample distributions.<sup>7</sup> This updated regulatory stance serves as the backdrop for Schumer's call for more stringent oversight of nicotine pouches, reflecting a concerted effort to mitigate potential public health risks.

The concerns expressed by Senator Schumer are not the first instance of governmental scrutiny of nicotine products. The journey towards Senator Schumer's recent proposal, as well as the FDA's enhanced authority, is rooted in prior regulatory initiatives aimed at reducing the appeal of nicotine products among the youth. Several jurisdictions have introduced prohibitions on flavored nicotine products<sup>8</sup>, recognizing their allure to younger demographics. Additionally, significant legal actions have been taken against entities such as Juul Labs.<sup>9</sup> These legal battles have primarily centered around accusations of marketing tactics designed to appeal to minors, underscoring the regulatory focus on curbing nicotine addiction among young people.<sup>10</sup> This reflects a concerted regulatory effort to mitigate the public health risks associated with youth nicotine consumption.

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<sup>4</sup> Dave Lozo, *Chuck Schumer Calls for Crackdown on Zyn, Sparking Uproar from Conservatives*, MORNING BREW (Jan. 28, 2024), <https://www.morningbrew.com/daily/stories/2024/01/28/chuck-schumer-calls-for-crackdown-on-zyn>.

<sup>5</sup> U.S. Food & Drug Admin., *New Law Clarifies FDA Authority to Regulate Synthetic Nicotine*, CTP NEWS (Mar. 18, 2022, 3:54 PM), <https://content.govdelivery.com/accounts/USFDA/bulletins/30f82ff>.

<sup>6</sup> U.S. Food & Drug Admin., *Requirements for Products Made with Non-Tobacco Nicotine Take Effect April 14*, CTP NEWS (Apr. 13, 2022), <https://www.fda.gov/tobacco-products/ctp-newsroom/requirements-products-made-non-tobacco-nicotine-take-effect-april-14>.

<sup>7</sup> *Id.*

<sup>8</sup> Yong Yang et al., *The Impact of Flavored E-Cigarette Bans on E-Cigarette Use in Three US States*, NAT'L INST. OF HEALTH (May 1, 2023), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10246123/>.

<sup>9</sup> *See In re JUUL Labs, Inc. Marketing, Sales Practices, and Products Liability Litigation*, No. 19-md-02913-WHO (N.D. Cal.).

<sup>10</sup> *Id.*

In light of the proposed regulatory adjustments and the bolstering of the FDA's authority, the NTN industry will likely face heightened compliance expenses, a need for altered marketing approaches, and a possible transformation of market dynamics. As the industry navigates these changes, the overarching goal should be to mitigate public health risks associated with nicotine products while also ensuring that regulations are balanced and not overly burdensome on the industry.