United States Senate
WASHINGTON, DC 20510

December 5, 2025

Dr. Martin Makary, MD
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

Dear Commissioner Makary,

We are deeply concerned by the U.S. Food and Drug Administration's (FDA) recently announced pilot program related to the premarket review of nicotine pouch products, which could lead to weak standards and a harmful uptick in use among youth. As you know, Zyn and other nicotine pouch products are increasing in popularity. While youth use of nicotine pouches is still fairly low, it has steadily increased. Nicotine use among youth remains a serious public health concern, and appropriate oversight of nicotine pouches is needed. It is critical for FDA to avoid shortcuts that could undermine the scientific integrity of its review of these products.

Nicotine pouches come in a variety of appealing flavors such as peppermint, berry, citrus, and cinnamon, increasing their attractiveness to youth and non-smokers. Their odorless nature and discreet placement between the gum and lip make them difficult to detect in schools and homes. According to data from the 2024 National Youth Tobacco Survey, approximately 480,000 middle and high school students currently use nicotine pouches, more than double the number reported in 2021.[1] If left unchecked, these products will continue to contribute to increased nicotine addiction, posing serious public health risks among youth.

The nicotine pouch market has rapidly expanded in recent years. According to the CDC Foundation, total nicotine pouch dollar sales increased from $145.5 million in January 2023 to $510.5 million in August 2025, a 250% increase.[2] Leading brands such as Zyn, On!, and Velo are the most commonly used nicotine pouch products by youth and young adults.[3] These products are marketed as flavorful and healthier alternatives to traditional tobacco. Promoters on

[1] Centers for Disease Control and Prevention. (2024, September 5). *Notes from the field: E-cigarette and nicotine pouch use among middle and high school students — United States, 2024* (Vol. 73, No. 35). Morbidity and Mortality Weekly Report. https://www.cdc.gov/mmwr/volumes/73/wr/mm7335a3.htm

[2] Tobacco Epidemic Evaluation Network. (2025, October). *Monitoring Sales: Nicotine Pouch Trends (Data Brief – August 2025)*. https://tobaccomonitoring.org/wp-content/uploads/2025/10/Nicotine-Pouch-Sales-Data-Brief_8.10.2025.pdf

[3] CDC Foundation. (2025, September). Monitoring tobacco product use among youth and young adults in the U.S.: TEEN + Data Brief, Issue 2 [Data brief]. https://tobaccomonitoring.org/wp-content/uploads/2025/09/Tobacco-Epidemic-Evaluation-Network-Data-Brief-Issue-2.pdf

social media, often referred to as "Zynfluencers", portray nicotine pouch use in humorous situations, focus on young men, and downplay addiction.[4] While this advertisement appears to be mostly organic rather than company-sponsored, it has proven highly effective with the top 100 TikTok posts about Zyn alone having generated approximately 400 million views.[5] This trend is extremely concerning, given that flavored tobacco products have historically been marketed to appeal to youth and young adults.

Nicotine pouches are highly addictive and can deliver nicotine at levels similar to cigarettes.[6] Health experts warn that nicotine is especially dangerous for youth because nicotine exposure can harm the developing brain. Adolescents' brains are still maturing, making them more vulnerable to nicotine's addictive properties and potentially leading to lasting physical and cognitive changes. According to the Surgeon General, nicotine exposure during this critical period can impair attention, learning, and memory, while increasing the likelihood of addiction to nicotine and other substances later in life.[7,8] Additionally, the CDC's Vaping Resource Guide notes that nicotine exposure can negatively affect normal brain development by impacting concentration and reducing impulse control.[9] Given these significant risks, any increased use of nicotine pouches among young people is alarming, especially as these products remain loosely regulated under existing U.S. tobacco control polices, are easily concealed and are widely marketed, making prevention and enforcement efforts more difficult.[10]

Despite these concerns, FDA has launched a pilot program to streamline the premarket review of nicotine pouch products. The accelerated timeline and possible reduced documentation requirements raise serious questions about how thorough FDA's evaluations will be. To date, little information has been shared on how this expedited process is being implemented and whether it will uphold the rigorous review standards mandated by the Tobacco Control Act, which requires a careful assessment of risks and benefits to the public's health, including the impact on youth. Historically, insufficient oversight of new tobacco products, prior to their entry into the market, has contributed to widespread youth addiction and public health crises,

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[4] Zenone, M., Harries, B., & Hartwell, G. (2025, January 29). *The promotion of oral nicotine pouches for non-smoking cessation purposes on TikTok*. *Nicotine & Tobacco Research*, ntaf024. https://doi.org/10.1093/ntr/ntaf024

[5] American Lung Association. Emerging Commercial Tobacco and Nicotine Products. *American Lung Association*. Last updated July 16, 2025. https://www.lung.org/quit-smoking/smoking-facts/health-effects/emerging-products

[6] American Lung Association. Emerging Commercial Tobacco and Nicotine Products. *American Lung Association*. Last updated July 16, 2025. https://www.lung.org/quit-smoking/smoking-facts/health-effects/emerging-products

[7] U.S. Department of Health and Human Services. *E-Cigarette Use Among Youth and Young Adults. A Report of the Surgeon General*. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2016, https://stacks.cdc.gov/view/cdc/44007.

[8] HHS, *How Tobacco Smoke Causes Disease: The Biology and Behavioral Basis for Smoking-Attributable Disease: A Report of the Surgeon General,* Centers for Disease Control and Prevention, Office on Smoking and Health, 2010 http://www.ncbi.nlm.nih.gov/books/NBK53017/

[9] U.S. Department of Health and Human Services. (2025, September 8). *Vaping and youth: Stay in the know* [Data sheet]. https://www.hhs.gov/sites/default/files/osg-youth-vaping-data-sheet.pdf

[10] Truth Initiative. What is Zyn and what are oral nicotine pouches? *Truth Initiative. Last updated Ocotber,16,2025. https://truthinitiative.org/research-resources/emerging-tobacco-products/what-zyn-and-what-are-oral-nicotine-pouches*

highlighting the critical need for thorough review.[11]

As public health experts have emphasized, any efforts to speed up FDA review must not come at the expense of protecting youth from highly addictive nicotine products.[12] That is why we request answers to the following questions by December 19th, 2025:

1. How will FDA ensure that this expedited process does not increase youth use of tobacco products or compromise public health?
2. Under the pilot program, will FDA's scientific review of premarket applications for nicotine pouches change? In its press statement, FDA said it will focus its review on "the most critical elements for this product category." Which elements will FDA focus on and which elements will it de-emphasize?
3. Are news reports accurate that under the pilot program manufacturers may not be required to submit product-specific studies in several areas and could instead rely on general research about the category of nicotine products? Hasn't FDA's experience reviewing e-cigarettes demonstrated the importance of product-specific data in determining whether a product is "appropriate for the protection of the public health"?
4. Given FDA's previous finding that flavored tobacco products present a higher risk of youth use, will FDA require manufacturers to provide evidence that a flavored nicotine pouch will help more people switch away from cigarettes than a tobacco-flavored nicotine pouch under the expedited review pilot program?
5. How will FDA consider the impact of nicotine pouch marketing in the expedited review process?
6. How will FDA monitor and respond if youth use rises as a consequence of these changes?
7. To ensure transparency, will FDA commit to holding a public meeting on the pilot program and issuing written materials on how FDA is implementing it?

Thank you for your commitment to protecting the health and well-being of our nation's children. We look forward to working with you on these issues.

Sincerely,

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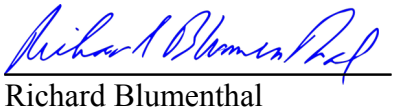
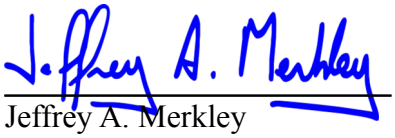
[11] American Lung Association**.** Nicotine Pouches Need Thorough and Scientific Review, Not a Fast-Track. Published September 18, 2025. Available at: https://www.lung.org/media/press-releases/nicotine-pouches-2025

[12] American Lung Association. Nicotine Pouches Need Thorough and Scientific Review, Not a Fast-Track. *American Lung Association*. Published September 18, 2025. https://www.lung.org/media/press-releases/nicotine-pouches-2025



Richard Blumenthal
United States Senator



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Amy Klobuchar
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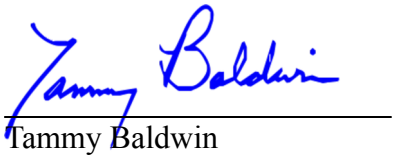

Tammy Baldwin
United States Senator

Tammy Duckworth
United States Senator

Jack Reed
United States Senator