Nicotine pouches: Why FDA clearance doesn't mean widespread access

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> The US Food and Drug Administration (FDA) recently authorized the sale of four flavored on! nicotine pouch products, a move that solidifies the market presence of these newer tobacco alternatives. This regulatory decision follows a premarket tobacco product application (PMTA) review, signaling the FDA's assessment that these specific products are appropriate for public health. But the retail market for such products is already complex, with distribution patterns that vary significantly by geography and demographics, according to a 2022 study published in Preventive Medicine Reports.1

KEY TAKEAWAYS

- The Pivot: The FDA authorized four on! nicotine pouch products, allowing their continued sale in the US market.
- The Data: Nicotine pouches were available in around 50% of audited stores, with availability ranging from 32% to 76% across different US sites.1
- The Action: Clinicians should be aware of the increasing regulatory approval and varied retail availability of nicotine pouches, particularly in areas with higher percentages of non-Hispanic White residents.

The FDA's authorization of four specific on! nicotine pouch products (2 mg and 4 mg strengths in Wintergreen and Mint flavors) means these products can continue to be legally marketed in the United States. This decision stems from a rigorous review process, where manufacturers must demonstrate that their products are appropriate for the protection of public health, considering both the risks and benefits to the population as a whole, including users and non-users. The authorization is not an endorsement of safety, but rather a determination that the marketing of these products is permissible under the Tobacco Control Act. These products are smokeless, spitless, and designed to deliver nicotine without tobacco leaf.1

But the regulatory guidelines are only one piece of the puzzle. Understanding how these products reach consumers is important for public health. Rose and colleagues conducted a four-site study in 2021, auditing 242 tobacco retailers across New Jersey, Kentucky, North Carolina, and New York.1 The investigators aimed to identify store and neighborhood characteristics associated with the availability of newer tobacco products, specifically nicotine pouches and disposable e-cigarettes. They geocoded stores and linked them to census tract demographics, including the proportion of non-Hispanic White residents, households under poverty, and proximity to schools. This granular approach allowed for a detailed examination of retail marketing patterns.1

The Retail Environment for Newer Tobacco Products

The study found that nicotine pouches were widely available, present in approximately 50% of the audited stores overall.1 But this availability varied substantially across the four study sites, ranging from 32% to 76%.1 This wide range suggests that local market dynamics, state-specific regulations, or differing distribution strategies by manufacturers play a significant role in product accessibility. For example, some states may have more restrictive local ordinances on tobacco product sales, or different retail chains may have varying policies on stocking newer tobacco products.1

In adjusted analyses, the investigators observed that nicotine pouches were less likely to be available in certain store types compared to chain convenience stores (IRR range 0.2-0.6).1 This indicates that chain convenience stores serve as a primary retail channel for these products. But the most striking finding related to demographics: nicotine pouches were more likely to be available in stores located in census tracts with a greater percentage of non-Hispanic White residents (IRR range 1.8-2.3).1 This demographic correlation suggests a targeted marketing or distribution strategy, or perhaps a higher demand for these products within these specific communities. Clinicians should be aware of these disparities, as they may influence patient exposure and use patterns.

The study also examined disposable e-cigarettes, finding them available in around half of the stores overall, similar to nicotine pouches.1 But their retail distribution patterns differed. Disposable e-cigarettes were more likely to be available in tobacco/vape shops (IRR 1.9; 95% CI, 1.4-2.5) than in convenience stores.1 They were also less likely to be found in non-specialty store types like groceries (IRR 0.2; 95% CI, 0.1-0.4).1 This contrast highlights distinct marketing and distribution channels for different categories of newer tobacco products, suggesting that manufacturers tailor their strategies based on product type and target consumer. The Oxford Handbook of General Practice offers a concise overview of public health issues, including tobacco control, that may be relevant for primary care clinicians navigating these evolving product landscapes.

Understanding the Implications of Retail Patterns

The differential availability of nicotine pouches across store types and demographic areas has significant public health implications. If nicotine pouches are more readily available in certain neighborhoods, it could exacerbate health disparities related to tobacco product use. The study's focus on neighborhood-level availability, rather than individual-level use, provides a macro perspective on how these products are integrated into communities. This understanding is vital for informing future regulatory policies, especially as more newer tobacco products undergo the FDA's pre-market authorization process.1

The investigators used a standardized store audit methodology, which ensured consistency in data collection across the four diverse US sites. This approach allowed for robust comparisons of availability patterns. But the study was cross-sectional, capturing a snapshot in time in 2021. It cannot account for changes in retail availability that may have occurred since then, especially with ongoing regulatory actions and evolving market strategies. The study also relied on census tract data for demographic information, which provides a broad picture but may not capture the full complexity of individual consumer behavior or local micro-environments.1

Still, the findings provide a baseline for understanding the initial penetration of nicotine pouches into the retail market. As these products become subject to increased regulation, ongoing monitoring of retail environments will be essential. Policymakers and public health officials can use this data to develop targeted interventions or to refine existing policies regarding the sale and marketing of nicotine pouches, ensuring that regulatory efforts align with real-world distribution

patterns. The FDA's authorization of specific on! products highlights the need for continued vigilance in monitoring their accessibility and impact on public health.1

CLINICAL IMPLICATIONS

The FDA's authorization of on! nicotine pouches means these products are here to stay, and clinicians will encounter patients using them. The retail data from Rose and colleagues makes it clear that availability is not uniform; these products are more accessible in some communities, particularly those with a higher proportion of non-Hispanic White residents. This demographic skew suggests a need for targeted patient education and screening in these populations.

But the authorization is not a green light for safety. It simply means the FDA has determined the products meet the public health standard for marketing. Clinicians must still counsel patients on the risks of nicotine addiction, regardless of the delivery mechanism. The distinction between regulatory authorization and health endorsement will be lost on many patients.

The differing retail patterns for nicotine pouches versus disposable e-cigarettes also highlight a fragmented market. This complexity means a one-size-fits-all approach to tobacco cessation or harm reduction counseling will likely be ineffective. Understanding which products are prevalent in a patient's local environment can inform more tailored advice.

The onus remains on clinicians to stay informed about these evolving products and their real-world distribution. The FDA's role is to regulate, but the clinical impact unfolds in the examination room, where patient choices are influenced by both availability and perception.

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REFERENCES

1. 1. Rose SW, Annabathula A, Westneat S. Neighborhood distribution of availability of newer tobacco products: A US four-site study, 2021. Prev Med Rep. 2022;30:102022. doi:10.1016/j.pmedr.2022.102022

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