What the research says...

CAsToR Briefing

November 2025

The Center for the Assessment of Tobacco Regulations (CAsToR) aims to provide evidence-based and expert-informed modeling of the behavioral and public health impacts of FDA tobacco rules or other regulatory actions, focusing on Impact Analysis, Behavior and Health Effects as Scientific Domains.

Oral nicotine pouches (ONPs): What we know so far.

This brief summarizes findings from "The Potential Impact of Oral Nicotine Pouches on Public Health: A Scoping Review" by Travis et al. (2024) and the Cochrane review "Oral nicotine pouches for cessation or reduction of use of other tobacco or nicotine products" by Hartmann-Boyce et al. (2025).

Background

Oral nicotine pouches (ONPs) are small microfiber sachets that contain synthetically-derived nicotine powder, flavorings, and other ingredients.

ONPs first emerged in the late 2000s. Since their introduction to the global market in 2016, ONP use has rapidly expanded. Brands include ZYN, LYFT, and VELO. These products and formulations may have significant implications for public health.

The U.S. regulatory landscape for ONPs has recently changed. Beginning in September 2025, the FDA implemented a pilot program to expedite the review of premarket tobacco product applications (PMTAs) for ONPs.[1] Currently, 20 ZYN ONP products were authorized for marketing by the FDA.

Researchers and decision makers are interested in evaluating ONP's health and behavioral effects. In this brief, we summarize findings from two recent publications by CAsToR researchers.

Key takeaways

- In the U.S., the use of ONPs is increasing.
- The evidence base on ONPs is rapidly growing.
- The health impacts of ONP use remain understudied.
- There is a need for more evidence on the effects of ONP use on other tobacco product use.

What is the current state of evidence on the impacts of ONPs on public health?

This brief is based on two reviews, Travis et al. (2024) and Hartmann-Boyce et al. (2025).

Travis et al. published a scoping review in *Nicotine & Tobacco Research* on the literature of ONP use. The review summarizes 62 empirical studies published through January 2024, of which 17 were industry-funded. An updated scoping review is forthcoming and includes 73 new studies through September 2025.

Hartmann-Boyce et al. (2025) is a Cochrane systematic review that summarizes completed randomized controlled trials (RCTs) on ONP impacts on tobacco and nicotine use. There were 4 included studies (n=284), conducted between 2006 and 2023, one of which was funded by the tobacco industry. Searches identified 10 additional relevant studies that are currently underway.

Current evidence on ONPs

1. Use patterns and behaviors

Nationally representative U.S. surveys in Travis et al show an increase in lifetime (1.9% to 2.3%) and current (0.8% to 1.5%) use among adolescents between 2021 and 2023.

Among U.S. adults, studies of lifetime and current use estimates were limited to those with a history of tobacco use.

TCORS | Center for the Assessment of Tobacco Regulations [CAsToR]

tcors.umich.edu | CastorPAD@umich.edu

CAsToR is funded by the National Cancer Institute of the National Institutes of Health (NIH) and FDA Center for Tobacco Products (CTP) under Award Number U54CA229974. The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH or the Food and Drug Administration.

By 2023, ONP use among current and former tobacco users was 3%; lifetime use among current and former tobacco users was estimated at 16.4%.

Current cigarette and e-cigarette users are more likely than non-users to be current ONP users.

2. Product characteristics

ONPs contain high levels of free-base nicotine, with nicotine plasma concentrations increasing proportionally with nicotine dose. Nicotine uptake from higher strength ONPs (6 mg or higher) generally exceeds that of cigarettes in adult smokers.

Both industry and non-industry studies indicate that while the levels of total and free-base nicotine in ONP are comparable to conventional smokeless tobacco, there is a high degree of variability in nicotine content between ONP brands.

3. Toxicity

In Travis et al., both industry and non-industry-funded studies consistently found that ONP samples contained formaldehyde. Chromium, ammonia, and nickel were also detected in many samples. Except for formaldehyde, the chemical composition of ONPs suggests fewer harmful or potentially-harmful compounds at lower levels compared to cigarettes and smokeless tobacco.

Non-industry funded studies found tobacco-specific nitrosamines (TSNAs) in 26 of 44 ONP samples from 20 manufacturers, though the highest detected levels were much lower than those typically found in cigarettes and snus.

4. Health effects

Evidence on the health effects of ONP remains limited. In Hartmann-Boyce et al., evidence of ONP impacts on the biomarker NNAL and carboxyhemoglobin when compared to a minimal control condition is of very low certainty and were thus inconclusive.

Hartmann-Boyce et al. found three studies with data on serious adverse events (SAEs). These studies reported that no participants experienced SAEs, but this evidence is of very low certainty. Evidence on non-serious adverse events was of very low certainty, and was thus inconclusive.

Hartmann-Boyce et al. reviewed one study that compares ONP with nicotine replacement therapy (NRT). ONP use was associated with fewer reports of gastrointestinal side effects than NRT.

5. Marketing and sales

Based on Travis et al., ONP sales and marketing expenditures are on the rise. Social media has become a key channel for product promotion. Marketing strategies increasingly emphasize potentially youth-appealing claims about the discreet and convenient use of ONP.

6. Impacts of ONP on smoking

Hartmann-Boyce et al. found limited evidence on the use of ONP for cessation or reduction of cigarette use in people who smoke, compared to no intervention or using a nicotine e-cigarette.

Low certainty evidence suggests that people provided with ONP may be slightly less likely to quit smoking than those provided with nicotine e-cigarettes, but this data is from one small study and therefore imprecise.

7. Impacts of ONP on other tobacco and nicotine product use

Hartmann-Boyce et al. found no evidence from RCTs on the use of ONPs for cessation or reduction of non-combustible tobacco/commercial nicotine products. They also did not find any evidence on the impact of ONPs on the prevalence of other tobacco/commercial nicotine product use.

Conflicts of interest: None. None of the authors accept funds from the tobacco or vaping industries.

[1] FDA. 2025. “FDA Launches Program to More Efficiently Review Nicotine Pouch Applications.” FDA, FDA, September 18. https://www.fda.gov/tobacco-products/ctp-newsroom/fda-launches-program-more-efficiently-review-nicotine-pouch-applications.