LEGISLATIVE
TESTIMONY

January 8, 2026

MICHAEL D. LAFAIVE

Mackinac Center Comment to FDA Regarding Modified Risk Tobacco Products

U.S. Food & Drug Administration

MACKINAC CENTER
FOR PUBLIC POLICY

MACKINAC CENTER
FOR PUBLIC POLICY

Docket No. FDA-2025-N-0835

Written Comment Regarding Modified Risk Tobacco Product (MRTP) Applications

Thank you for the opportunity to submit a comment on Docket No. FDA-2025-N-0835 regarding pending Modified Risk Tobacco Product (MRTP) applications. This comment is offered for the purpose of informing the Agency's evaluation under section 911(g)(1) of the federal Food and Drug, and Cosmetic Act. It focuses particularly on FDA's obligation to assess whether an MRTP, as actually used by consumers, is likely to benefit the health of the population as a whole.

In assessing population-level effects, consumer behavior and market responses are central considerations. One such response — well documented across tobacco and nicotine markets — is substitution toward illicit or unauthorized products when regulated alternatives become comparatively more costly, less accessible, or subject to prolonged regulatory uncertainty. These substitution effects directly influence patterns of use, product quality, and exposure, and therefore bear on the population-health determination required by section 911.

I submit this comment from the perspective of an economist whose research focuses on cigarette smuggling, excise taxation, and regulatory-induced illicit markets. For more than two decades, my colleague, Ball State University Professor Todd Nesbit, and I have examined how differences in regulation, taxation, and enforcement affect consumer behavior and the scale of contraband trade. This body of work is relevant to FDA's MRTP review to the extent that regulatory conditions shape how products are obtained and used in the marketplace.

The unintended consequences of long delays in the approval of marketing orders for products like Zyn or Velo stymie efforts to legally market products with lower health risk profiles than tobacco products already on the market. Preventing firms from doing so disrupts vital information to consumers that may lead to healthier product choices and outcomes. It could also create a maintenance of illicit profit for those who deal in contraband products. Contraband also comes with questions of origin and quality and safety.

Regulatory asymmetry can arise when illicit producers and distributors, who have no desire to play by the rules, sense an opening. Last September the Food and Drug Administration itself helped seize (along with Customs and Border Protection) nearly $90 million (4.7 million units) in unauthorized e-cigarettes. This is the type of thing we see when legal pathways are constrained. Although this was a bust involving vaping products, nicotine pouches get trafficked too.

Consider first a few pouch-related examples just from the border area of Three Nations Crossing between Massena, New York, and Cornwall, Ontario, last year:

- According to a media statement by the Royal Canadian Mounted Police, officials there seized a total of 180,000 pouches along with other contraband products between January 1 and April 1 of 2025.

This is just one-third of the year at just one international border crossing.

- The RCMP statement above does not mention the January arrest of a New York woman who possessed 2,600 tins of unauthorized pouches among other contraband. She pled guilty to unlawful possession of tobacco products in August 2025, according to the Canada Border Services Agency.

It is not hard to see why trafficking pouches into and around Canada may be a draw. Canada has only authorized the sale of one brand of pouch that can be used as a nicotine replacement and access to it is hyper-regulated, limiting its access and appeal.

A July 31 Reuters article says that industry participant Altria "sent data to the U.S. Food and Drug Administration on growth in illegal nicotine pouches," and that it reflected previous experience in the growth of the now large illicit market for vaping products. Illicit growth in vaping, of course, postdates the massive illicit market for combustible cigarettes.

The marketplace for illicit trade in tobacco and other nicotine-related products is very large. The best example of how a marketplace can transform itself into a large illicit one is the cigarette market. Three studies published in the last 15 years estimated a national smuggling (or tax evasion and avoidance rate) of combustible smokes at 21%. Professor Nesbit and I estimate that more than 50% of the combustible cigarette products consumed in California and New York in 2023 were illegally smuggled there. In California alone, 514 million packs of cigarettes were consumed in 2023 as a function of tax evasion and avoidance.

Clearly, cigarettes are not pouches and certainly not a healthier alternative to other nicotine products. Lessons from the illicit cigarette market, however, are worth considering. Governments around the world have regulated and taxed the product significantly.

The unintended consequence of heavily regulating and taxing popular products is to create a modern-day Prohibition era with many of the consequences that attended this country's failed ban on alcohol. Sometimes the prohibition is a ban (menthol, for instance), and sometimes it is prohibition by price. This includes smuggling and counterfeit, adulterated products that are probably much less healthy than legal and regulated products.

These experiences suggest an important implication for FDA's evaluation of MRTP applications under section 911(g)(1). The statute directs the Agency to consider how a product will be used by consumers "as actually used," including effects on initiation, cessation, and switching behavior at the population level. That assessment necessarily depends on whether consumers can access regulated products through lawful channels, with accurate information about relative risk, rather than through illicit markets where quality, labeling, and manufacturing standards are unknown.

Prolonged regulatory uncertainty does not eliminate demand for nicotine products. Instead, it alters how that demand is satisfied. As the examples cited above illustrate, when legal options are constrained, illicit markets respond — sometimes with remarkable reach, including cross-border trafficking and penetration into controlled environments such as correctional facilities. These outcomes undermine public health objectives by shifting consumption toward products that are unregulated, potentially adulterated, and untethered from FDA oversight.

None of this is to suggest that FDA should relax its scientific standards for MRTP authorization. Rather, it underscores that the Agency's population-health analysis should account for substitution toward illicit products as a foreseeable market response to delayed or foreclosed authorization of lower-risk alternatives. Failure to consider these dynamics risks overstating the benefits of restriction while understating the real-world costs borne by consumers and public health alike.

For these reasons, I respectfully urge the Agency to incorporate illicit-market substitution effects into its evaluation of MRTP applications and to weigh whether timely authorization of qualifying products — accompanied by appropriate post-market oversight — may better advance the statutory goal of improving population health than continued regulatory limbo.

Thank you for the opportunity to comment.

Michael D. LaFaive

Senior Director of the Morey Fiscal Policy Initiative

Mackinac Center for Public Policy

mackinac.org

MACKINAC CENTER
FOR PUBLIC POLICY

The Mackinac Center for Public Policy is dedicated to improving the understanding of economic principles and public policy among private citizens and public officials. A nonprofit and nonpartisan research and education institute, the Mackinac Center has grown to be one of the largest state-based think tanks in the country since its founding in 1987.

Additional information about the Mackinac Center and its mission to improve the quality of life in Michigan through sound public policy can be found at **www.mackinac.org**.

140 West Main Street P.O. Box 568 Midland, Michigan 48640

989.631.0900 Mackinac.org mcpp@mackinac.org