Regulate Smarter
Coalition for Smarter Regulation of Nicotine

July 29, 2025

The Honorable Martin Makary, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Commissioner Makary:

I write to commend and support your commitment to address the illicit market of nicotine products – an urgent threat to U.S. sovereignty, public health, and law enforcement capacity. The U.S. is in the midst of a crisis created by the free flow of illegal nicotine products into the U.S. marketplace, the majority of which are supplied by Chinese companies that are knowingly breaking U.S. laws.

President Trump has rightfully warned that counterfeit pharmaceutical products, often linked to the People's Republic of China, threaten the security and safety of Americans.[1] The Food and Drug Administration (FDA) has the opportunity to address a similar crisis in the nicotine market by advancing a modern and common-sense approach to regulating nicotine products and effectively enforcing the Tobacco Control Act (TCA) to restore order to the marketplace. I applaud the steps you and your agency have recently taken to mitigate this threat.

During the Biden Administration, illicit Chinese vaping products, without any regulatory oversight or consumer protections, began flooding our market. Produced overseas without meeting FDA safety standards or common tobacco product manufacturing practices, these illicit vapor products are deliberately avoiding compliance with the law, and many are intentionally marketed to underage users with youth-appealing features, for example, Gummy Bear flavors and gaming device screens. Manufacturers of these illicit vaping products often use fraudulent shipping declarations and misclassified tariff codes to evade U.S. customs and trade laws. With no FDA oversight, review, or accountability, there is simply no way to protect adult consumers from the health risks posed by these unregulated nicotine products.

Over the past 16 years, FDA has collected more than $9 billion to regulate tobacco products, yet approximately 85% of vapor and electronic cigarette products sold in the U.S. are either illicit or

[1] https://www.whitehouse.gov/fact-sheets/2025/04/fact-sheet-president-donald-j-trump-declares-national-emergency-to-increase-our-competitive-edge-protect-our-sovereignty-and-strengthen-our-national-and-economic-security/

unauthorized due to FDA's failure to enforce against bad actors, its delays in review, and gaping lack of clarity in the regulatory status of these products.[2] [3] This is untenable.

Millions of adult consumers continue to move away from cigarettes to potentially less harmful, smoke-free options like vapor and nicotine pouches. According to FDA and the scientific community, smoke from conventional cigarettes causes all or almost all tobacco-related harm, while vaping products are considered a lower-risk and less harmful alternative.[4] Scientists agree smoke-free products like vapor are as much as 95% less harmful than combustible cigarettes for adults who switch.[5] Yet, FDA's Center for Tobacco Products (CTP) has refused to meaningfully acknowledge the risk continuum of smoke-free products and dragged its feet in properly regulating them. This has created confusion in the marketplace and led to the majority of products available to consumers being illicit or unauthorized.

Today there are over 20 million adult consumers of vapor and nicotine pouches, and that number is growing as more consumers understand the benefits of switching to less harmful alternatives. Yet, FDA has left these adult vapor and nicotine pouch consumers with far too few authorized smoke-free options to choose from and failed to give the market clear information regarding which specific products cannot be sold. Since 2020, FDA has received millions of applications for electronic nicotine products and other smoke-free products; however, it has authorized only a small fraction, creating the perfect conditions for the mass-scale illicit marketplace to emerge and continue to grow. FDA now has the opportunity to fully embrace harm reduction and help educate adult smokers that smoke-free products are less harmful than smoking.

The TCA gave FDA the authority to regulate tobacco products and requires that the agency issue marketing orders on applications for a new tobacco product within 180 days. FDA has routinely failed to meet this statutory deadline, often by many years. This amounts to FDA delaying access to less harmful alternative choices for millions of adult consumers seeking to move away from combustible tobacco products. FDA's inaction has inhibited technological advancements that would improve upon the risk continuum of these less harmful nicotine products and has propelled the growth of the illicit market.

We are not alone in calling for urgent action.[6] In April, 28 Republican Attorneys General urged action in "combating the flood of illegal Chinese products – including Chinese e-cigarettes marketed to minors."[7] The agency has been caught flat-footed time and again, with enforcement actions that are not at a scale needed to bring order to the marketplace. The Department of Justice and FDA's joint taskforce formed last year has been woefully inadequate to clear the shelves and protect consumers – and until now, appears to have done little, if anything to meaningfully enforce against bad actors. Your commitment to eliminate the practice of port

---

[2] As of July 17, 2025, FDA issued marketing granted orders for five new electronic nicotine delivery systems, the market share data and impact relative to these recently authorized products is still under evaluation.
[3] https://truthinitiative.org/research-resources/tobacco-industry-marketing/us-retail-sales-data-show-86-e-cigarette-sales-are
[4] https://www.fda.gov/tobacco-products/health-effects-tobacco-use/relative-risks-tobacco-products#:~:text=While%20e%2Dcigarettes%20can%20generally,Lower%2DRisk%20Alternative%20to%20Cigarettes?
[5] https://www.gov.uk/government/publications/e-cigarettes-and-heated-tobacco-products-evidence-review/evidence-review-of-e-cigarettes-and-heated-tobacco-products-2018-executive-summary
[6] https://www.energymarketersofamerica.org/weeklyreview/attachments/Letter_to_FDA_on_Enforcement_Final.pdf
[7] https://ago.wv.gov/Documents/2025.04.11-Letter-on-Chinese-E-Cigarettes.pdf

shopping is an important step to holding these actors accountable and enforcing U.S. law to stem the flow of illicit nicotine products across our borders.

I commend your resolve and initial actions to address this mass-scale illicit market crisis, but additional urgent action is needed. FDA should seize the opportunity to advance a comprehensive, effective regulatory framework that will:

1. Accelerate and streamline authorization of innovative, smoke-free nicotine products for adult consumers seeking less harmful, FDA-authorized options within the legal marketplace.

2. Rigorously enforce the law against companies manufacturing, distributing, and selling illicit vapor, pouch, and other products flooding the U.S. market from China and elsewhere – so that bad actors understand it's not optional to avoid FDA oversight.

3. Provide clear information to regulated industry so that businesses can help prevent illicit product from being sold to consumers.

4. Empower adult smokers with accurate information on the benefits of switching from cigarettes to FDA-authorized, smoke-free products to ensure adult consumers have the benefit of science-based information to make informed choices.

5. Use regulation and oversight of the industry to drive down underage use and ensure consumer protections for adult tobacco and nicotine consumers to realize the public health goals of the TCA.

I believe FDA can restore order to the marketplace and deliver on the harm reduction promise of the TCA by providing clarity to a stagnant and opaque application review process and fully enforcing against the entities responsible for growing the illicit market.

President Trump's vision of a safer, healthier and more prosperous America is achievable – it requires bold and immediate action. The Coalition for Smarter Regulation of Nicotine stands ready work with you to help address the crisis of illicit nicotine products and advance a modern regulatory framework grounded in science.

Thank you for your prompt attention to this issue.

Sincerely,

Richard Burr
Chair of the Coalition for Smarter Regulation of Nicotine

Cc: Secretary Robert F. Kennedy, U.S. Department of Health and Human Services;
Attorney General Pamela Bondi, U.S. Department of Justice

Regulate Smarter
Coalition for Smarter Regulation of Nicotine

The Coalition for Smarter Regulation of Nicotine is a coalition of regulated industry members committed to operating responsibly within the FDA-regulated marketplace, advancing a modern, common-sense approach to regulating tobacco and nicotine that is grounded in science.