5737 Mesmer Ave.
Los Angeles, CA 90230
(310) 391-2245
www.reason.org

Written Testimony of Guy Bentley
Director of Consumer Freedom, Reason Foundation
United States House Committee on Oversight and Government Reform
April 9, 2025

Chairman Comer, Ranking Member Connolly, and members of the Committee on Oversight and Government Reform, thank you for the opportunity to testify on restoring trust and efficiency at the Food and Drug Administration (FDA) and tackling the large and growing illicit market for e-cigarette products.

My name is Guy Bentley, and I'm the director of consumer freedom at the Reason Foundation, a non-profit public policy think tank. The Consumer Freedom Project analyzes and promotes policy solutions that improve public health while avoiding unintended consequences and protecting consumer choice.

State of the market

The Food and Drug Administration (FDA) was tasked with regulating tobacco products in 2009 under the Family Smoking Prevention and Tobacco Control Act (TCA). The FDA deemed e-cigarettes to fit the definition of "tobacco products" in 2016.

Under the current FDA regulatory landscape, it is easier to introduce a new cigarette to the market than an e-cigarette, nicotine pouch, or heated tobacco product, all of which the agency acknowledges are safer alternatives to smoking. Under the TCA, products that are substantially equivalent to those on the market in Feb. 2007, such as cigarettes, can gain authorization under the substantial equivalence pathway, which presents minimal regulatory costs. Products that were not on the market in 2007, such as e-cigarettes, must apply for authorization via a premarket tobacco product application (PMTA). For applicants to have their PMTA approved, they must pass the "Appropriate for the Protection of Public Health" (APPH) standard, demonstrating that authorization of their product is beneficial to public health as a whole, including tobacco users and those who do not use tobacco products.

The PMTA process was intended to encourage innovation and bring safer nicotine alternatives, such as e-cigarettes, to market. According to the prestigious Cochrane Review, considered the gold standard for analyzing evidence-based medicine, e-cigarettes are more effective than nicotine replacement therapies such as nicotine gums and patches for helping smokers quit.[1] Writing in the *New England Journal of Medicine* in 2024, Dr. Nancy Rigotti of Harvard Medical

[1] Lindson N, Butler AR, McRobbie H, Bullen C, Hajek P, Wu AD, Begh R, Theodoulou A, Notley C, Rigotti NA, Turner T, Livingstone-Banks J, Morris T, Hartmann-Boyce J. "Electronic cigarettes for smoking cessation." Cochrane Database of Systematic Reviews. Issue 1. Art. No.: CD010216. Jan. 29, 2025. https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD010216.pub9/full

5737 Mesmer Ave.
Los Angeles, CA 90230
(310) 391-2245
www.reason.org

School said, "It is now time for the medical community to acknowledge this progress and add e-cigarettes to the smoking-cessation toolkit."[2] However, instead of facilitating a pathway, the FDA's implementation of the PMTA process, especially its interpretation of the APPH, acts as a roadblock.

Since 2009, FDA's Center for Tobacco Products (CTP) has collected $8 billion in user fees but has authorized just eight vaping devices for sale and 34 vaping products in total. Vaping product authorizations account for 0.2% of all approved products compared to 22% for combustible cigarettes, the most dangerous tobacco product.[3] Thanks to the FDA's regulatory bottlenecks, illicit products have flooded the market to satisfy demand, with almost 90% of e-cigarettes sold being illegal, mainly consisting of disposable products from China.[4] There are around 18 million adult vapers, accounting for a third of all tobacco and nicotine users.[5] Facing few satisfying choices in the legal market, adult vapers are opting to purchase products that are unregulated and unaccountable to the FDA.

Fortunately, the rate of youth vaping has fallen by 78% since 2019 to 5.9% despite the surge in illicit imports of flavored e-cigarettes.[6] The dramatic decline of youth vaping coinciding with the increase in the illicit market suggests the availability and variety of e-cigarettes is not the determining factor in the rate of youth vaping. The most obvious reason for the decline in youth vaping was the increase in the purchase age to 21 under the first Trump administration in 2019.

E-cigarettes are not the only products stymied by the PMTA pathway. The nicotine pouch Zyn, authorized for sale in February 2025, took nearly five years to clear the FDA's regulatory process and remains the only nicotine pouch approved for sale. The last—and so far only—heated tobacco product the FDA authorized was in 2020, and its application was submitted in 2016. The lack of oversight and effective regulation of the market for safer alternatives to cigarettes threatens the integrity of the product landscape, puts American companies at an unfair disadvantage, and exposes consumers to substandard product quality.

FDA's regulatory bottleneck

[2] Nancy A. Rigotti, M.D. "Electronic Cigarettes for Smoking Cessation — Have We Reached a Tipping Point?" The *New England Journal of Medicine*. VOL. 390 NO. 7. Feb. 14, 2024. https://www.nejm.org/doi/full/10.1056/NEJMe2314977

[3] U.S. Food and Drug Administration. Searchable Tobacco Products. Content current as of: 03/24/2025. https://www.accessdata.fda.gov/scripts/searchtobacco/

[4] Truth Initiative. "U.S retail sales data shows 86% of e-cigarette sales are for illegal products." Nov. 06, 2024. https://truthinitiative.org/research-resources/tobacco-industry-marketing/us-retail-sales-data-show-86-e-cigarette-sales-are

[5] Jeffrey M. Jones. "Cigarette Smoking Rate in U.S. Ties 80-Year Low." Gallup. Aug. 13, 2024. https://news.gallup.com/poll/648521/cigarette-smoking-rate-ties-year-low.aspx

[6] U.S. Food and Drug Administration. "Youth E-Cigarette Use Drops to Lowest Level in a Decade." FDA Newsroom. Sept. 5, 2024. https://www.fda.gov/news-events/press-announcements/youth-e-cigarette-use-drops-lowest-level-decade#:~:text=The%20number%20of%20youth%20who,%E2%80%9D%20said%20Brian%20King%2C%20Ph.

5737 Mesmer Ave.
Los Angeles, CA 90230
(310) 391-2245
www.reason.org

The PMTA process presents an almost insurmountable barrier to most companies. In 2016, the FDA's Regulatory Impact Analysis assumed the average cost of a PMTA for an e-cigarette device would be below $500,000 and $131,000 for e-liquids. The FDA assumed there would be 4,050 e-liquid and 747 device applications.[7] In reality, the cost for an application with even a moderate chance of success is in the millions, and the FDA has received more than 27 million PMTAs, of which more than 99% have been rejected.[8] Only a few companies have the resources to afford to participate in the current application process, massively restricting consumer choice and incentivizing the illicit trade.

Each product and every variation must file a separate application and undergo an individual review, with FDA staff burdened by examining products that are substantially similar regarding their ingredients and potential for either benefit or harm. The FDA has also taken an unreasonable approach to the category of e-cigarette flavors other than tobacco, demanding that non-tobacco flavored products need to demonstrate a more significant public health benefit than tobacco flavors. The FDA justifies this approach by claiming that non-tobacco flavors are a disproportionate threat to youth, despite analysis from the Centers for Disease Control and Prevention (CDC) showing that just 13% of youth who vape cite the availability of flavors as their reason for vaping.[9] Even when CTP's Office of Science (OS) clears a flavored product, their decision can and has been overruled, as was the case when CTP director Brian King overruled the OS's judgment on a menthol e-cigarette made by Logic Technology.[10]

In 2022, an independent review of the FDA's performance as a tobacco regulator was published by the Reagan-Udall Foundation (RUF).[11] The RUF criticized the FDA's lack of transparency and timeliness in promoting and authorizing products that can reduce smoking-related harms, including e-cigarettes. The report also demanded clarity on how exactly the FDA interprets APPH and encouraged the FDA to shift from a reactive to a proactive state by publishing objective product standards for premarket authorization that would satisfy the statutory definition

[7] U.S. Food and Drug Administration. "Final Regulatory Impact Analysis." Office of Policy, Planning, Legislation and Analysis Office of the Commissioner. May. 2016. https://www.fda.gov/media/97875/download

[8] U.S. Food and Drug Administration. "FDA Makes Determinations On More Than 99% of the 26 million Tobacco Products for Which Applications Were Submitted." CTP Newsroom. Mar. 15, 2023. https://www.fda.gov/tobacco-products/ctp-newsroom/fda-makes-determinations-more-99-26-million-tobacco-products-which-applications-were-submitted

[9] Gentzke AS, Wang TW, Cornelius M, et al. "Tobacco Product Use and Associated Factors Among Middle and High School Students — National Youth Tobacco Survey, United States, 2021." MMWR Surveill Summ 2022;71. https://www.cdc.gov/mmwr/volumes/71/ss/ss7105a1.htm?s_cid=ss7105a1_w

[10] Jacob Sullum. "These Memos Show That FDA Regulation of E-Cigarettes Is Driven by Dubious Value Judgments Rather Than Science." Reason.com. Dec. 15, 2022. https://reason.com/2022/12/15/these-memos-show-that-fda-regulation-of-e-cigarettes-is-driven-by-dubious-value-judgments-rather-than-science/

[11] Reagn-Udall Foundation. "Operational Evaluation Of Certain Components of FDA's Tobacco Program. Dec. 2022. https://reaganudall.org/sites/default/files/2022-12/Operational%20Evaluation%20of%20Certain%20Components%20of%20FDA%27s%20Tobacco%20Program_Dec.%202022.pdf

5737 Mesmer Ave.
Los Angeles, CA 90230
(310) 391-2245
www.reason.org

of APPH. The FDA has made no effort to reform its current approach to the APPH standard or better inform companies of what kinds of data they will need to gain a successful PMTA at a cost that is not prohibitive. In response to the RUF report, the FDA issued a five-year strategic plan consisting of generalities with no hard metrics by which to measure success in authorizing more products or better informing the public of the relative risks of different tobacco products.[12]

Can enforcement solve the problem?

In June 2024, the U.S. Department of Justice (DOJ) and the FDA announced the creation of a federal multi-agency task force to combat the illegal distribution and sale of e-cigarettes.[13] While these efforts are welcomed, they highlight the failure of the FDA's approach to product authorizations. Current authorization bottlenecks are so significant that the DOJ and other agencies are forced to expend scarce resources to combat the flood of illicit products, a preventable and correctable problem.

The first line of defense against illicit products is America's ports. However, the rate of physical inspections by U.S. Customs and Border Protection (CBP) is around three percent.[14] Given the volume of illegal products entering the U.S. from China, even with a significant increase in inspections, which would entail substantial increases in personnel, technology, infrastructure, and delays, it's unlikely the illicit market could be significantly reduced. U.S. authorities are also unlikely to receive productive cooperation from the Chinese authorities on prevention or interdiction.

However, programs such as FDA inspections for policing underage tobacco sales do make a valuable contribution to containing youth tobacco use. Warning letters, civil money penalties, and no tobacco sales orders are useful tools in the FDA's arsenal to police bad actors. However, even with the creation of a multi-agency task force, increases in seizures, injunctions, and civil money penalties on irresponsible manufacturers and retailers, there has been no discernible change in the availability of illicit e-cigarettes. Enforcement efforts on the part of the FDA and other agencies are likely to achieve greater success when they can be concentrated and targeted on a shrinking illicit market if consumers have legal access to a wide range of regulated, satisfying alternatives that can effectively compete with the current illicit offerings.

How to break the bottleneck

[12] Azim Chowdhury, Kaitlyn Johnson. "CTP Releases New 5-year Strategic Plan." The Continuum of Risk. Apr. 3, 2022. https://www.thecontinuumofrisk.com/2024/04/ctp-releases-new-5-year-strategic-plan/

[13] FDA Newsroom. "Justice Department and FDA Announce Federal Multi-Agency Task Force to Curb the Distribution and Sale of Illegal E-Cigarettes." U.S. Food and Drug Administration. Jun. 10, 2024. https://www.fda.gov/news-events/press-announcements/justice-department-and-fda-announce-federal-multi-agency-task-force-curb-distribution-and-sale

[14] Darren Prokop. "Commentary: Cargo Screening vs. Inspection." Freight Waves. Nov. 17, 2019. https://www.freightwaves.com/news/commentary-cargo-screening-vs-inspection#:~:text=U.S.%20Customs%20and%20Border%20Protection%20(CBP)%20physically%20inspects%20about%203,%2C%20theft%2C%20smuggling%20and%20terrorism.

5737 Mesmer Ave.
Los Angeles, CA 90230
(310) 391-2245
www.reason.org

Streamlining the PMTA process is the safest and most effective way to achieve a coherent marketplace that protects youth while offering adult smokers safer nicotine alternatives and disrupting the illicit market. Application costs should be radically reduced, and reviews must be completed within the statutorily mandated 180 days. These goals can be achieved within the bounds of the TCA as presently structured.

The major obstacle for applicants is demonstrating that their products abide by APPH. The FDA is tasked with determining whether a product authorization will increase or decrease the likelihood that existing users of tobacco will stop using such products and the increased or decreased likelihood that those who do not use tobacco will start using such products.[15] The process by which the FDA determines the appropriate trade-offs to satisfy the APPH standard is unknown to applicants, the public, and Congress. For example, no objective formula calculates how many quality-adjusted life-years would be gained or lost by a product authorization. Applicants are forced to try to provide predictions of future marketplace dynamics and consumer preferences that are inherently unknowable at the premarket stage.

Whether the FDA considers what impact a PMTA denial will have on the illicit market is also unknown, but given the mass denials of products, it appears unlikely. A new and transparent approach to the PMTA process must be adopted to protect public health and combat the illicit market. A new approach should focus on reducing the harms of smoking-related disease, transparent product standards, consumer safety, and marketing practices that do not appeal to youth.

Tobacco control expert Clive Bates has written that applicants can adequately meet these tests at the premarket stage by demonstrating that their products are safer than cigarettes, pose no greater risk than the products currently being purchased on the illicit market, and that their marketing is not appealing to youth. In a market where smoking is still the most popular form of nicotine consumption, the illegal trade e-cigarettes is significant, and where many products are still under review, there are ample opportunities for the FDA to make a judgement as to what is in the best interest of public health and to authorize a host of products that can effectively displace the illicit market.[16] The FDA is not legally tied to its current interpretation and practice of APPH when evaluating PMTAs. Streamlining the PMTA process would negate the need for any additional financial resources and dramatically reduce the burden on the FDA staff.

Post-market surveillance can also be leveraged to understand the product landscape better. If problems with a particular product emerge, such as significant increases in youth use or unacceptable marketing practices, the FDA can use its authority to withdraw a specific product

[15] U.S. Food and Drug Administration. Section 910 of the Federal Food, Drug, and Cosmetic Act - Application for Review of Certain Tobacco Products. https://www.fda.gov/tobacco-products/rules-regulations-and-guidance-related-tobacco-products/section-910-federal-food-drug-and-cosmetic-act-application-review-certain-tobacco-products

[16] Clive Bates. "Fixing the Broken and Lawless American Tobacco and Nicotine Market." The Counterfactual. Jan. 19, 2025. https://clivebates.com/fixing-the-broken-and-lawless-american-tobacco-and-nicotine-market/

5737 Mesmer Ave.
Los Angeles, CA 90230
(310) 391-2245
www.reason.org

from the market. There is little reason to believe that authorizing significantly more products will have a significant impact on youth tobacco use. Youth smoking is at its lowest level on record despite thousands of new cigarettes being approved for sale. As previously mentioned, youth vaping has fallen by 78% since 2019, despite illicit flavored e-cigarettes being more available and in greater variety than ever.[17]

Though operating under a different regulatory structure than the FDA, one that focuses on product standards rather than individual product evaluations, the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA), which works on less than 30% of CTP's budget, has registered more than 1,400 times as many vaping products as the U.S. and has a similar, low level of youth vaping at seven percent.

Reshoring American jobs

Easing the process by which e-cigarettes and other safer nicotine alternatives can be authorized would benefit not just American consumers and public health but also American workers.

Allowing American e-cigarette and other tobacco harm reduction companies to get their products to market would increase opportunities to reshore jobs in manufacturing, bottling, and packaging conducted with more robust consumer safety standards than those that apply in China. A 2019 analysis showed vape shops were the fastest-growing retail segment of the previous decade, with two-thirds of vape shop employees working in businesses with 10 employees or less.[18] Another 2019 economic analysis revealed that a ban on non-tobacco flavored vapor products, which is in effect FDA's current policy, would cost 150,000 jobs.[19]

With a large consumer market worth billions of dollars, there is clear potential to increase the health of American businesses and the health of the public.

Educating consumers on relative risks

According to the Centers for Disease Control and Prevention (CDC), 28 million American adults still smoke combustible cigarettes, the most harmful form of nicotine consumption.[20] Despite decades of scientific evidence demonstrating the reduced risks of noncombustible nicotine

[17] U.S. Food and Drug Administration. "Youth E-Cigarette Use Drops to Lowest Level in a Decade." FDA Newsroom. Sept. 5, 2024. https://www.fda.gov/news-events/press-announcements/youth-e-cigarette-use-drops-lowest-level-decade#:~:text=The%20number%20of%20youth%20who,%E2%80%9D%20said%20Brian%20King%2C%20Ph.

[18] Andrew Van Dam. Trump's vaping crackdown could help Juul by ending the decade's biggest small-business success story. *The Washington Post*. Sep. 23, 2019. https://www.washingtonpost.com/business/2019/09/23/trumps-vaping-crackdown-could-help-juul-by-ending-decades-biggest-small-business-success-story/

[19] John Dunham Associates. "The Economic Impact of a Ban on Flavored Vapes." Nov. 21, 2019. https://vaportechnology.org/wp-content/uploads/2019/11/Dunham-Economic-Impact-of-Flavor-Ban-11-21-19.pdf

[20] Centers for Disease Control and Prevention. "Burden of Cigarette Use in the U.S." Oct. 8, 2024. www.cdc.gov/tobacco/campaign/tips/resources/data/cigarette-smoking-in-united-states.html

5737 Mesmer Ave.
Los Angeles, CA 90230
(310) 391-2245
www.reason.org

products compared to smoking, public misperceptions persist—a failure of communication that undermines tobacco harm reduction efforts. A 2022 National Institutes of Health (NIH) survey found that 50% of adults incorrectly believe e-cigarettes are as harmful as—or more harmful than—combustible cigarettes, while just 8.5% responded that e-cigarettes were less or much less harmful.[21]

This misinformation extends to healthcare professionals. A 2022 survey revealed that over 60% of U.S. physicians falsely believe all tobacco products pose equal risks,[22] while an earlier 2020 survey found that more than 80% erroneously linked nicotine directly to cancer.[23] Most alarmingly, only 18% of smokers—the very group that stands to benefit most by switching to safer products—correctly identified e-cigarettes as containing fewer harmful chemicals than cigarettes, according to a 2023 survey.[24]

To address these persistent misperceptions, the FDA must act decisively to educate both consumers and healthcare professionals on the well-established risk continuum of nicotine products. A coordinated, agency-wide campaign—featuring unambiguous FDA guidance on nicotine and the relative risks of products, scientifically grounded comparisons communicated in accessible language, and collaboration with medical associations—could dispel myths and empower adult smokers to make informed harm reduction choices. Crucially, the agency must also adopt a balanced communication strategy that fulfills its duty to provide truthful information to adults seeking smoking alternatives alongside its youth prevention efforts. Without such efforts, the agency's silence will continue to perpetuate needless confusion and undermine public health by leaving millions of smokers unaware of less harmful alternatives.

Conclusion

According to the prestigious Cochrane Review, considered the gold standard for analyzing evidence-based medicine, e-cigarettes are more effective than nicotine replacement therapies such as nicotine gums and patches for helping smokers quit.[25] Writing in the *New England*

[21] National Cancer Institute Health Information National Trends Survey (2022), https://hints.cancer.gov/view-questions/question-detail.aspx?PK_Cycle=14&qid=1929 (accessed 2 Apr 2025).
[22] Cristine D Delnevo, Michelle Jeong, Arjun Teotia, et al. "Communication Between US Physicians and Patients Regarding Electronic Cigarette Use." JAMA Network Open. Apr. 1, 2022. https://pubmed.ncbi.nlm.nih.gov/35426926
[23] Michael B. Steinberg, Michelle T. Bover Manderski, Olivia A. Wackowski, et al. "Nicotine Risk Misperception Among US Physicians." *Journal of General Internal Medicine*. Sept 1. 2020. https://link.springer.com/article/10.1007/s11606-020-06172-8
[24] Olivia A Wackowski, Michelle T Bover Manderski, Stefanie K Gratale, et al. "Perceptions about levels of harmful chemicals in e-cigarettes relative to cigarettes, and associations with relative e-cigarette harm perceptions, e-cigarette use and interest." *Addiction*. Oct. 2023. https://pubmed.ncbi.nlm.nih.gov/37218410
[25] Lindson N, Butler AR, McRobbie H, Bullen C, Hajek P, Wu AD, Begh R, Theodoulou A, Notley C, Rigotti NA, Turner T, Livingstone-Banks J, Morris T, Hartmann-Boyce J. "Electronic cigarettes for smoking cessation." Cochrane Database of Systematic Reviews. Issue 1. Art. No.: CD010216. Jan. 29, 2025. https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD010216.pub9/full

5737 Mesmer Ave.
Los Angeles, CA 90230
(310) 391-2245
www.reason.org

Journal of Medicine in 2024, Dr. Nancy Rigotti of Harvard Medical School said, "It is now time for the medical community to acknowledge this progress and add e-cigarettes to the smoking-cessation toolkit."[26]

The TCA was designed, in part, to create a regulatory regime that facilitates innovation for smoke-free alternatives to cigarettes. In practice, the FDA's interpretation of its responsibilities under the TCA, particularly concerning the APPH, resulted in a marketplace where most e-cigarette products consumed by adults are illegal, and jobs and manufacturing have been shipped to China. It is within the FDA's authority to change its approach to help those who wish to quit smoking via a safer nicotine alternative do so with products that are regulated and conform to the highest safety standards. By focusing on product standards, risks relative to cigarettes and illicit e-cigarettes, and responsible marketing practices at the premarket stage, the FDA can authorize a host of products that will displace the illicit market without enticing youth to initiate nicotine use. At the post-market stage, the FDA can quickly identify problematic actors through well-resourced surveillance and intervene when necessary. These changes do not require congressional action and would safeguard public health.

[26] Nancy A. Rigotti, M.D. "Electronic Cigarettes for Smoking Cessation — Have We Reached a Tipping Point?" The *New England Journal of Medicine*. VOL. 390 NO. 7. Feb. 14, 2024. https://www.nejm.org/doi/full/10.1056/NEJMe2314977