May 11, 2026

VIA ELECTRONIC SUBMISSION AND HAND DELIVERY

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2026-D-1817 (91 Fed. Reg. 11980, Mar. 11, 2026) – "Flavored Electronic Nicotine Delivery Systems (ENDS) Premarket Applications—Considerations Related to Youth Risk"

Dear Sir or Madam,

RAI Services Company ("Reynolds") submits this response to the Center for Tobacco Products' ("CTP") draft guidance named "Flavored Electronic Nicotine Delivery Systems (ENDS) Premarket Applications—Considerations Related to Youth Risk," 91 Fed. Reg. 11980 (Mar. 11, 2026) ("Draft Guidance").[1]

The draft guidance doubles down on a flavor-prohibitionist playbook that harms Americans by handing over the marketplace to unregulated Chinese manufacturers whose illicit products evade FDA review and endanger youth. Today, these illicit Chinese products constitute about 86% of the market—and worse, they explicitly target youth by, among other things, incorporating popular cartoon characters and built-in video games. **This bears repeating: 86% of the American vape market is comprised of illicit Chinese vapes.** The guidance does nothing to correct this. Instead, it entrenches the exact failures it purports to address.

The guidance is a gut punch to American companies committed to playing by the rules. Responsible American manufacturers languish in a regulatory purgatory, whereas foreign companies that evade FDA and flood the market with illicit products have thrived. The path to protecting youth is **enforcement against illicit products**—not severely restricting American products. The draft guidance gets this exactly backwards.

In addition, FDA has a historic opportunity to help adults quit smoking. **FDA can help move adult smokers away from combustible cigarettes to less risky ENDS products—and it should make this transition easier, not harder.** But the guidance gets this backwards as well. Studies show that adult smokers who use flavored ENDS products like vapes and e-cigarettes are

[1] RAIS submits this comment on its own behalf and on behalf of its affiliated tobacco companies. RAIS coordinates regulatory compliance for the subsidiary companies of Reynolds American Inc. (RAI), including R.J. Reynolds Tobacco Company; American Snuff Company, LLC; Santa Fe Natural Tobacco Company, Inc.; R.J. Reynolds Vapor Company; and Modoral Brands Inc. References to "RAIS" or "Reynolds" in this letter may refer to RAIS itself and/or its affiliated RAI subsidiaries, as applicable.

significantly more likely to quit smoking than those who use tobacco-flavored ENDS or no ENDS at all. Flavors drive the switch, and steer adult smokers away from smoking combustible cigarettes. But FDA and its guidance get in the way of that switch. The guidance doubles down on a so-called "comparative efficiency standard," which is an unscientific bureaucratic fiat that requires companies creating flavored vapes to meet a heightened standard: They must prove that their non-tobacco flavored ENDS products statistically outperform tobacco-flavored products in head-to-head switching studies. This is the wrong comparison, and it leaves the vast majority of the public health benefit on the table. Millions of smokers who would switch for a fruit flavor will never switch for tobacco, and the comparative-efficacy standard writes them off as if they do not exist. FDA should make it simpler—not harder—to get these products to adult smokers who want to stop smoking cigarettes. Unfortunately, the draft guidance endorses an approach that makes it harder. In fact, it makes it virtually impossible, as demonstrated by the near-universal denials for non-tobacco flavored ENDS products. If Congress had wanted to ban such products, it would have said so. But Congress did not, and it is not for a regulatory agency to substitute its own judgment and policy preference for that of Congress.

Reynolds is committed to ensuring that no youth ever uses a tobacco or nicotine product, but the draft guidance does nothing to achieve that goal. Reynolds offers these comments to make the case for a regulatory framework that protects youth through aggressive enforcement, while giving adult smokers access to the flavored products that maximize their chances of quitting combustible cigarettes for good.

EXECUTIVE SUMMARY

Instead of opening the doors to the public health benefit of offering smokers better options from American companies, the draft guidance **allows illicit, Chinese-made ENDS to dominate the market**. It does so because of several critical flaws:

First, the guidance ignores studies showing that flavored vapes help adult smokers stop smoking combustible cigarettes. The guidance effectively bans flavored vape products from American companies, leaving most of the public health benefit that vapes offer on the table.

Second, FDA's approach to flavors is premised on the idea that flavors cause youth to vape. This is not true, and FDA's own data shows that.

Third, American companies have been cast into regulatory purgatory, with years-long wait times and more than 99% of applications denied. One example: It took FDA nearly **four years** to rule on Reynolds's application for a tobacco vape product. This is unacceptable.

Fourth, the market is now dominated by illicit Chinese products that are unregulated, that are unsafe, and that target youth. Numerous Chinese vapes even incorporate popular cartoon characters and video games to attract children.

A. Vapes are less harmful than cigarettes, and flavors are why smokers switch, yet FDA is inexplicably making it harder—not easier—for Americans to get these vapes.

Vapes are around 95% less harmful than cigarettes. That is not a small improvement—it is **the biggest public health opportunity in a generation**. And the evidence is clear: flavors make vapes work. One study shows that adults who use flavored vapes are much more likely to quit—46.3% using menthol quit, compared to 25.6% for tobacco. **Flavors are not the enemy. They are the engine that drives people away from cigarettes.**

FDA knows this, yet, inexplicably, FDA's draft guidance endorses a standard that makes it *harder* to get flavored vapes to American adults who need them to quit smoking. The Agency demands that manufacturers of flavored vapes meet a heightened standard: prove their flavored products beat tobacco-flavored vapes in a head-to-head switching study. That test has a 100% failure rate for non-tobacco, non-menthol flavors. Only two flavored vapes (both manufactured by Glas) have ever been authorized—and they didn't make it by satisfying this standard. Instead, FDA treated the Glas vapes differently because they have device access restriction (DAR). The Glas authorizations thus confirm that the comparative-efficacy standard is impossible to meet. Those two Glas vapes are not even on the market today, and it is uncertain whether they ever will be. Even if they do reach consumers, DAR imposes barriers to adult acceptance of the product and, in any event, two flavored vapes are wholly insufficient to meet the needs of 28 million adult smokers.

Not every adult smoker wants a tobacco-flavored vape to help them quit smoking. Some will switch only for mint or menthol. Others need fruit or sweet flavors to make the switch. By effectively banning most flavors, FDA is leaving behind large groups of adult smokers who would quit cigarettes, as shown here:

Think of it this way. The government says you can have a healthier potato chip—made with beef tallow instead of seed oils, just like what MAHA calls for—but only if the chip has no salt, no seasoning, and no flavor. Who is going to eat that? Most consumers would just keep eating the regular chips fried in seed oils. That is exactly what FDA is doing with vapes. Strip the flavors, and most smokers don't switch. The result is more smoking and more disease—the complete opposite of what FDA should be trying to do.

FDA has decided that no matter how many smokers would benefit from more flavored vapes, FDA would prefer to deny smokers options and allow them to suffer the consequences.

B. FDA's own data proves youth don't vape because of flavors—93% don't vape, and only 1.5% say flavors are why they started.

FDA's only explanation for its effective ban on flavored vapes is an unjustified concern that youth—especially youth who are not currently using any nicotine products—will start using flavored vapes.

But the actual data on youth use of flavored ENDS demonstrates that FDA's concern is misplaced. The 2025 National Youth Tobacco Survey shows that 93% of youth have not used *any* e-cigarette in the past 30 days, despite the widespread availability of flavored products accessible to youth on the illicit market. Only 1.5% of youth said flavors were a reason why they started. Instead, most started because their family members or friends vape. Those numbers demolish FDA's entire premise.

If flavors were driving youth to vape, would youth vaping drop year after year, even though flavored vapes are widely available on the illicit market? Of course not. And the supposed "gateway" to combustible cigarettes? Youth cigarette smoking is at an all-time low. FDA's entire premise—that flavors are pulling kids into vaping—is plainly false.

Adult smokers pay the price for FDA's decision to ignore the data. Blocking flavored vapes keeps millions of adults smoking cigarettes when they could be switching to something widely accepted as at least 95% less harmful. Taking flavors out of vapes is like ripping the adhesive off a nicotine patch and wondering why nobody wears it. Or putting optional side airbags only in unpopular vehicles and then expressing surprise that consumers choose cars without side airbags.

The hypocrisy is glaring. Walking through many grocery stores, gas stations, or liquor stores, there is a never-ending array of hard seltzers, canned cocktails, and spiked beverages in mango, berry, pineapple, coconut, and candy-inspired flavors. Underage drinking remains a serious public health problem, killing 4,000 young people a year. Yet nobody is making a liquor manufacturer prove its mango-flavored hard seltzer provides an "added benefit" over unflavored liquor. No sliding scale of proof based on whether a teenager might like the taste of mango. Meanwhile, FDA subjects flavored vapes—uniquely a flavored product that can help public health—to a practically unattainable authorization standard.

Flavored alcohol has zero public health benefit. Nobody is switching from a dangerous product to a less harmful one by drinking fruit-flavored hard seltzer—potentially filled with questionable ingredients and containing more alcohol than the average beer. Flavored vapes, by contrast, are the most effective tool available for helping adult smokers quit smoking. Yet vapes are the only product that faces an impossible regulatory gauntlet.

This Administration already knows how to do this right. When Secretary Kennedy went after red food dye, he did not ban everything that tastes like cherry. He targeted specific chemicals—like Red No. 3—that the science showed were harmful. FDA should take the same approach with ENDS: go after the actual problem, not the flavor.

C. FDA has denied more than 99% of vape applications, has never met its statutory 180-day deadline, and refuses to disclose its own standard for assessing vapes.

Under the prior Administration, the Agency denied more than 99% of the millions of ENDS applications—and 100% of non-tobacco, non-menthol flavored ENDS.

FDA also drags its feet before issuing its inevitable denials. Congress commanded the Agency to decide ENDS applications within 180 days. But, to our knowledge, FDA has never met that deadline—not once. Zero-percent compliance with a law passed by Congress. In any other job, zero-percent compliance, for years on end, would get you fired. Yet FDA faces no consequences. And on top of all that, FDA keeps its authorization standard—"appropriate for the protection of the public health" ("APPH")—deliberately vague and undefined, rendering it meaningless. It is a secret test with secret criteria.

D. FDA has handed the American vape market to China.

While American companies play by the rules and get nowhere, **Chinese manufacturers have conquered the American vape market.** Up to 86% of the ENDS products sold in the U.S. are illegal. Full stop. This is because FDA has handed the American vape market to China. These

Chinese companies do not submit a single page of paperwork to FDA. They mislabel shipments to dodge U.S. Customs. They use untested ingredients. And most Americans have no idea that the berry-flavored vape at their local store is completely unregulated. FDA's own policies are the reason.

Worst of all, these Chinese manufacturers often deliberately go after American kids—with vapes shaped like smartphones, vapes that play video games, and vapes featuring cartoon characters. FDA's draft guidance is, in effect, an industrial policy for China's illegal vape empire and a gut punch to every American company trying to follow the law. **It's putting China first at the expense of Americans.**

The question is not whether flavored vapes will be on the market—the illicit market has answered that question decisively. The only question is whether FDA will keep punishing responsible American companies while China wins—or whether FDA will finally do its job, set clear rules, process applications on time, and authorize flavored ENDS to make America healthier. Every day FDA delays is a day China gains ground.

E. FDA must change course—*now*—to crush the illicit Chinese vape market, inform Americans that vapes are less risky than smoking, and ensure that American manufacturers can actually get their vapes on shelves.

The fix is obvious. **Stop treating flavored ENDS as the enemy.** Start treating China's illicit vape market as the threat it is. Give adult smokers access to products that are less risky. **FDA needs to do four things right now.**

First, fix the broken authorization standard. The government should be a neutral decisionmaker—set clear rules that everyone can understand, not a secret test. The standard should be simple: Is this product reasonably likely to reduce the risk of disease and death compared to cigarettes? If yes, authorize it. FDA should also create an expedited pathway to market by setting clear and rigorous safety benchmarks so that vapes that meet those benchmarks (including flavored vapes) can immediately be marketed.

Second, stop ignoring Congress. Congress said to decide applications within 180 days. FDA has **never** met that deadline. FDA must start meeting the 180-day deadline.

Third, get serious about enforcement. FDA's recent enforcement guidance (issued May 8, 2026) is a commendable step in the right direction. But even that guidance acknowledged that FDA "lacks the resources to pursue enforcement against every product" without authorization and that the vapes youth actually use are illegal disposables, overwhelmingly from China. FDA should focus its limited resources on those illicit disposable vapes.

Fourth, tell Americans the truth. Less than 3% of adults know that vapes are much less harmful than cigarettes. Nearly 80% think nicotine causes cancer. FDA runs scare-tactic ads like the one shown below depicting vapes as worms eating people's faces. (Seriously.)

Instead of scaring people with propaganda, FDA should tell adult smokers the facts: vapes are 95% less risky than cigarettes. As written, this guidance keeps Americans in the dark, keeps American companies in limbo, and keeps China in business. **The status quo is broken and dangerous. FDA must correct course now.**

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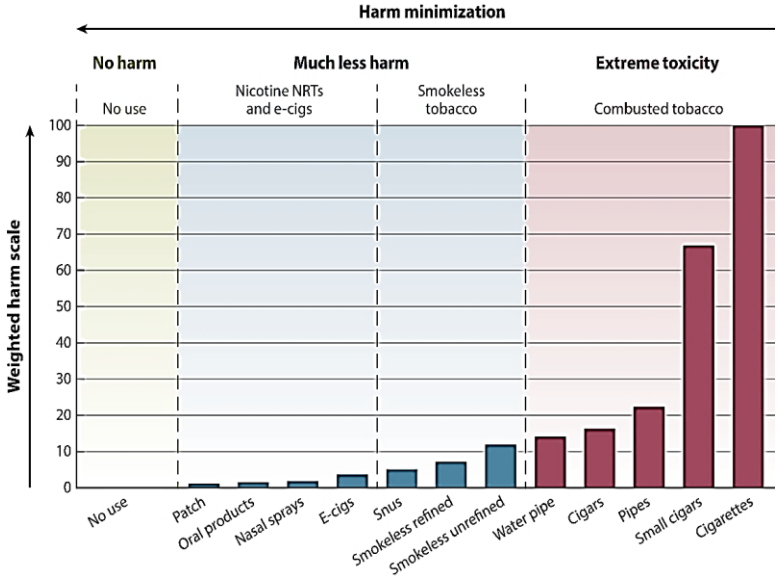
BACKGROUND

In 2009, Congress told FDA to reduce death and disease from tobacco while still allowing adults to buy tobacco products.[2] Congress wanted the government to help industry develop and sell less harmful products.[3] Former FDA Commissioner Scott Gottlieb got it right: "[e]nvisioning a world … where adults who still need or want nicotine could get it from alternative and less harmful sources, needs to be the cornerstone of our efforts."[4]

A. ENDS products present much less risk than combustible cigarettes.

Vapes do not burn tobacco. That matters because burning tobacco is what causes disease. FDA's own Center for Tobacco Products has said "tobacco products exist on a continuum of risk."[5] Vapes are "far down on that continuum."[6] A landmark 2015 report found vapes are "around 95% less harmful than smoking."[7] The picture below shows just how big that difference is:[8]



[2] *See* Tobacco Control Act, Pub. L. No. 111-31, § 3(7), 123 Stat. 1776, 1782 (2009).

[3] *Id.* § 3(4).

[4] Press Release, FDA, *FDA Announces Comprehensive Regulatory Plan to Shift Trajectory of Tobacco-Related Disease,* Death (July 28, 2017), https://tinyurl.com/2r74v4w4.

[5] Brian A. King & Benjamin A. Toll, *Commentary on Wackowski et al.: Opportunities and Considerations for Addressing Misperceptions About the Relative Risks of Tobacco Products Among Adult Smokers*, 118 Addiction 1892, 1892 (Aug. 15, 2023), https://doi.org/10.1111/add.16296.

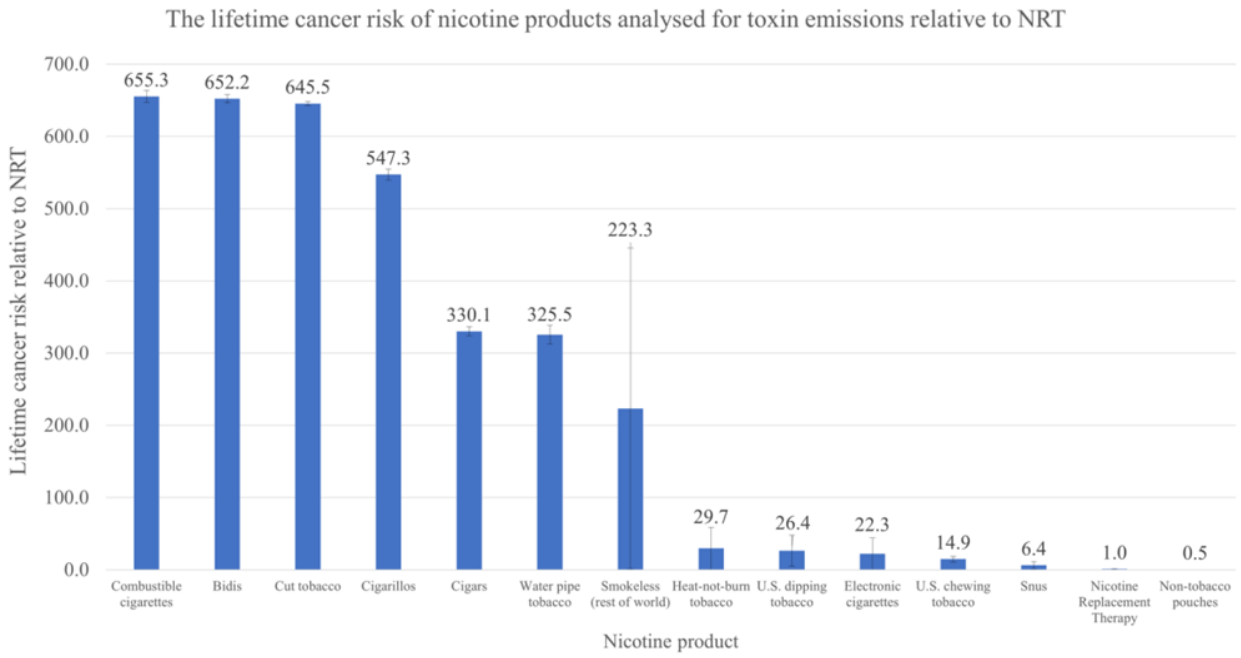
[6] David Abrams et al., *Harm Minimization and Tobacco Control*, 39 Ann. Rev. Pub. Health 193, 194 (2018), http://tinyurl.com/3nymhu3f.

[7] *E-cigarettes Around 95% Less Harmful Than Tobacco Estimates Landmark Review*, Public Health England (Aug. 19, 2015), https://tinyurl.com/4897man3.

[8] Abrams, *supra* n. 6, at 195 fig. 1.

The science keeps piling up. The National Academies of Sciences, Engineering, and Medicine found that "e-cigarettes are likely to be far less harmful than combustible tobacco cigarettes." [9] Population studies show that restricting vapes is "associated with increased mortality"—meaning more restrictions equals more death.[10] And FDA itself has admitted that nicotine does not "cause the serious health effects" like lung disease and cancer—those come from burning tobacco.[11]

ENDS cut the risk of cigarettes by 95% or more.[12] This chart comparing the lifetime cancer risk by category of product explains that the cancer risk for combustible cigarettes is nearly 30 times more than from electronic cigarettes:[13]



[9] Nat'l Acads. of Scis., Eng'g & Med., *Public Health Consequences of E-Cigarettes* (Nat'l Acads. Press 2018).

[10] Pesko et al., *E-Cigarettes in Historical Context—Innovation, Risk, and Regulation*, 6 JAMA Health Forum 1, 2 (2025), https://tinyurl.com/cdud4e5w.

[11] FDA, *Nicotine Is Why Tobacco Products Are Addictive*, https://tinyurl.com/dp7zu9jd (citation omitted).

[12] Royal Coll. of Physicians, *Nicotine Without Smoke: Tobacco Harm Reduction* (RCP 2016); *see also* Mark Bentley & Serge Maeder, *Quantification of HPHCs in ENDP Aerosols*, *in* TOXICOLOGICAL EVALUATION OF ELECTRONIC NICOTINE DELIVERY PRODUCTS, 41, 76 (Manuel C. Peitsch & Julia Hoeng eds. 2021) (citations omitted).

[13] Rachel Murkett, Megyn Rugh & Belinda Ding, *Nicotine Products Relative Risk Assessment: An Updated Systematic Review and Meta-Analysis*, 9 F1000 Research 1225, fig. 2 (2022).

Most dangerous chemicals in cigarettes come from burning tobacco.[14] Switching to vapes—which do not burn tobacco—slashes exposure to toxins and carcinogens.[15] The evidence indicates switching to vaping can lead to major reductions in heart disease[16] and the toxins that cause respiratory disease,[17] and real benefits for smokers with COPD or heart disease.[18]

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[14] U.S. Dep't of Health & Hum. Servs., The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General (2014) (concluding that combustion compounds in tobacco smoke are the primary contributors to the cardiovascular risk of tobacco use); FDA, *Chemicals in Every Puff of Cigarette Smoke* (May 16, 2019) ("Lighting up creates even more chemicals.").

[15] Maciej L Goniewicz et al., *Exposure to Nicotine and Selected Toxicants in Cigarette Smokers Who Switched to Electronic Cigarettes: A Longitudinal Within-Subjects Observational Study*, 19 Nicotine & Tobacco Res. 160, 165 (2016), https://tinyurl.com/bdd3znx6 ("[F]indings suggest that e-cigarettes may effectively reduce exposure to toxic and carcinogenic substances among smokers who switched to these products."); Roger Collier, *E-Cigs Have Lower Levels of Harmful Toxins*, 198 Canadian Med. Assoc. J. 331, 331 (2017), https://tinyurl.com/5a7b6h2n; M.N. Kanobe et al., *Part three: a randomized study to assess biomarker changes in cigarette smokers switched to Vuse Solo or Abstinence*, 12 Sci. Rep. 20658 (2022); M.N. Kanobe et al., *Changes in Biomarkers of Exposure and Potential Harm in Smokers Switched to Vuse Vibe or Vuse Ciro Electronic Nicotine Delivery Systems*, 11 Toxics 564 (2023); E.K. Round et al., *Biomarkers of Tobacco Exposure Decrease After Smokers Switch to an E-Cigarette or Nicotine Gum*, 21 Nicotine & Tobacco Res. 1239 (2019).

[16] Neal L. Benowitz & Evangelia Liakoni, Tobacco Use Disorder and Cardiovascular Health, 117 Addiction 1128, 1135 (2021), https://tinyurl.com/4f5mkku2 ("As discussed earlier in this paper, there are potential cardiovascular risks from nicotine and various thermal degradation products generated by ENDS, but it is highly likely that the risk is much less than that of combusted tobacco.").

[17] Yukio Akiyama & Neil Sherwood, *Systematic Review of Biomarker Findings from Clinical Studies of Electronic Cigarettes and Heated Tobacco Products*, 8 Toxicology Reps. 282, 289 (2021), https://tinyurl.com/9jju2kua.

[18] *See, e.g.*, Polosa et al., *COPD Smokers Who Switched to E-Cigarettes: Health Outcomes at 5-Year Follow Up*, 11 Therapeutic Advances in Chronic Disease 1, 1, 10 (2020), https://tinyurl.com/52z985nn ("The present study suggests that [electronic cigarette] use may ameliorate objective and subjective COPD outcomes, and that the benefits gained appear to persist long term. . . . A major finding of the study is that COPD exacerbations were reduced by approximately 50% in patients who stopped or considerably reduced their smoking consumption after switching to vaping."); Jacob George et al., *Cardiovascular Effects of Switching From Tobacco Cigarettes to Electronic Cigarettes*, 74 J. Am. Coll. of Cardiology 3112, 3119 (2019), https://tinyurl.com/52brsjz5 ("Smokers, particularly females, who switch from [cigarettes] to [electronic cigarettes] derive significant benefits in terms of vascular health, and this improvement is seen early on. From a vascular health perspective, recommendations of switching from [tobacco cigarettes] to [electronic cigarettes] could be considered a vascular harms reduction measure."); James D. Sargent et al., *Functionally Important Respiratory Symptoms and Continued Cigarette Use Versus E-Cigarette Switching: Population Assessment of Tobacco and Health Study Waves*

B. ENDS help smokers quit combustible cigarettes.

A decade of data proves that ENDS help smokers quit cigarettes. And not just some smokers—all kinds of smokers:

- adults who report having no interest in quitting,[19]
- smokers who failed prior quit attempts,[20]
- military personnel,[21]
- impoverished,[22] and
- smokers with substance abuse issues or psychiatric disorders.[23]

FDA has said that ENDS provide "public health benefits" through "increased switching and/or significant reduction in smoking."[24] FDA's own data confirms that adults who used ENDS were 50% more likely to quit smoking than those who did not.[25] Nicotine patches and gum,

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2-6, 79 eClinical Med. 1, 9 (2025), https://tinyurl.com/bdz6ahzh (explaining that people who "switch completely from cigarettes to e-cigarettes have similar risk for respiratory symptom onset and resolution to those who quit tobacco altogether").

[19] Karin A. Kasza et al., *Association of e-Cigarette Use With Discontinuation of Cigarette Smoking Among Adult Smokers Who Were Initially Never Planning to Quit*, 4 JAMA Network Open 1, 2 (2021) ("In this cohort study, daily e-cigarette use was associated with greater odds of cigarette discontinuation among smokers who initially had no plans to ever quit smoking.").

[20] Katie Myers Smith et al., *E-Cigarettes Versus Nicotine Replacement Treatment as Harm Reduction Interventions for Smokers Who Find Quitting Difficult: Randomized Controlled Trial*, 117 Addiction 224 (2022).

[21] Chase A. Aycock et al., *Motives for Using Electronic Nicotine Delivery Systems (ENDS) as a Cessation Tool Are Associated with Tobacco Abstinence at 1-Year Follow-Up: A Prospective Investigation Among Young Adults in the United States Air Force*, 35 Preventive Med. Reps. 1 (2023).

[22] Jaqueline C. Avila et al., *Using Pod Based e-Cigarettes and Nicotine Pouches to Reduce Harm for Adults With Low Socioeconomic Status Who Smoke: A Pilot Randomized Controlled Trial*, 26 Nicotine & Tobacco Res. 1150 (2024).

[23] Stéphanie Baggio et al., *Efficacy of E-Cigarettes for Smoking Cessation in Populations with Psychiatric and/or Substance Use Problems: A Secondary Analysis of a Randomized Controlled Trial*, 11 Tob. Prevention & Cessation 1 (2025).

[24] FDA, Technical Project Lead (TPL) Review of PMTAs: PM0000630–PM0000631 at 5 (June 10, 2022); *see also* FDA, Technical Project Lead (TPL) Review of PMTAs: PM0000635, PM0000636, PM0000646, PM0000712, PM0004287 & PM0004293 at 45 (May 11, 2022).

[25] Karin A. Kasza et al., *Divergence in Cigarette Discontinuation Rates by Use of Electronic Nicotine Delivery Systems (ENDS): Longitudinal Findings from the United States PATH Study Waves 1–6*, Nicotine & Tobacco Res. 1, 4 (2024), https://tinyurl.com/p89t43hv ("Between 2018/19 and 2021 (W5 and W6), those who used ENDS had an even higher rate of discontinuing cigarette smoking at follow-up than those who did not use ENDS."); *see also*

available for decades, have never achieved that.[26] As Acting CTP Director Bret Koplow recently said, "Unfortunately only about 9% of adult smokers who try approved NRT [nicotine replacement therapy like nicotine patches and gum] are successful in quitting.… For some, completely switching to a lower risk FDA-authorized product can increase the likelihood of living a longer, healthier life."[27] And as former Commissioner Gottlieb said: "If you could take every adult smoker … and fully switch them to e-cigarettes, that would have a substantial public health impact."[28]

Despite all this evidence, FDA has blown the biggest public-health opportunity in a generation. The Agency's failures are not abstract. They are measured in the lives of the Americans who die from smoking-related disease every year, many of whom could have been helped by the very products FDA has kept off shelves.

C. Flavors are a key driver of adult switching from combustible cigarettes to ENDS.

Flavors are what make adults actually switch from cigarettes to vapes. One study shows that adults who use flavored vapes are much more likely to quit smoking—46.3% using menthol quit, compared to 25.6% for tobacco.[29] Another national study showed that 27.2% of flavored e-cigarette users quit smoking, versus 20.6% for tobacco-flavored and just 16.1% for non-users.[30] Those differences are a big deal.

Other countries prove this works. The U.K. actively promotes vapes as part of its health strategy and lets adults buy any flavor. Among British adult vapers, fruit flavors are the most

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Olufemi Erinoso et al., *Estimating the Likelihood of Cigarette Maintenance and Dual Use Among People Using E-Cigarettes for Cigarette Cessation: Analysis of the Population Assessment of Tobacco and Health Study Waves 5 and 6*, 171 Addict Behav. 1, 5 (2025), https://tinyurl.com/bd3wkyt4 ("[D]aily e-cigarette use among adults who initially used e-cigarettes to quit cigarettes without success at baseline was associated with increased odds of past-month cigarette abstinence at follow-up two years later.").

[26] *See* Nicola Lindson et al., *Electronic Cigarettes for Smoking Cessation, Cochrane Database of Systematic Reviews*, Jan. 2025, at 2, https://tinyurl.com/336rek8c.

[27] Dr. Bret Koplow, Acting Dir., Ctr. for Tobacco Prods., *Remarks at the Food and Drug Law Institute Conference*, Washington, D.C. (May 6, 2026) (video recording at 7:13).

[28] CSPAN, *FDA Commissioner on E-cigarettes and Public Health Concerns*, at 10:25 (Sept. 25, 2018), https://tinyurl.com/mujce8hr.

[29] RAI Services, *PMTA for Vuse Alto*, Table H.5-2 (August 28, 2025) (on file with FDA).

[30] Yoonseo Mok et al., *Associations Between E-cigarette Use and E-cigarette Flavors With Cigarette Smoking Quit Attempts and Quit Success: Evidence From a U.S. Large, Nationally Representative 2018–2019 Survey*, 25 Nicotine & Tobacco Res. 541, 543 (2023); *see also* Mari Gades et al., *The Role of Nicotine and Flavor in the Abuse Potential and Appeal of Electronic Cigarettes for Adult Current and Former Cigarette and Electronic Cigarette Users: A Systematic Review*, 24 Nicotine & Tobacco Res. 1332, 1336 (2022) ("Compared with using tobacco or unflavored e-liquids alone, cigarette smokers who used one or multiple nontobacco flavored e-liquids were more likely to have reduced or quit smoking.").

popular at 47%, followed by menthol/mint at 17%—and tobacco flavor is dead last at 12%.[31] These are adults, not youth. They overwhelmingly choose the exact flavors FDA treats as suspicious.

FDA's own statements and regulatory history are consistent with this evidence. Acting CTP Director Koplow recently acknowledged: "For the most part adults like the same flavors that kids do."[32] The draft guidance likewise acknowledges that "ENDS products with flavors other than tobacco may, in certain circumstances, provide benefits to adults who smoke combusted cigarettes, including by facilitating switching away from combusted tobacco products, increasing quit attempts, supporting sustained smoking abstinence, and reducing cigarette consumption among adults who would otherwise continue smoking."[33] Moreover, no nicotine replacement therapy has ever been authorized in tobacco flavor—a fact that reflects FDA's longstanding recognition that non-tobacco flavors improve the acceptability and effectiveness of nicotine products designed to move consumers away from combustible cigarettes.

Twenty-eight million American adults still smoke. The flavors that work best for adult quitters—including fruit—are the same flavors adults prefer overall—which, as mentioned, Acting CTP Director Koplow recently recognized.[34] Restricting those flavors condemns people to keep smoking, keep getting sick, and keep dying. Indeed, Yale researchers confirmed this predictable result, finding that state laws restricting flavored vapes led to significant increases in cigarette sales.[35]

COMMENTS

I. FDA's Failures Have Blocked Lower-Risk Products, Fueled an Illicit Market, and Perpetuated Public Confusion.

The regulatory landscape for vapes is a catastrophe entirely of FDA's own making. Four failures define this mess: (1) FDA refuses to tell Americans that vapes are 95% less risky than cigarettes, (2) FDA treats flavors—the feature that makes vapes work—as the main threat, (3) FDA has turned the application process into a years-long black hole, and (4) all of this has created a massive illegal market dominated by China.

These four failures feed one another in a vicious cycle—and FDA is the driving engine. The Agency keeps adults in the dark about the 95% risk reduction of switching to vapes. It treats

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[31] Action on Smoking and Health (ASH), *Use of E-Cigarettes (Vapes) Among Adults in Great Britain* 17 (Aug. 2023).

[32] Dr. Bret Koplow, Acting Dir., Ctr. for Tobacco Prods., *Remarks at the Food and Drug Law Institute Conference*, Washington, D.C. (May 6, 2026) (video recording at 57:29).

[33] Draft Guidance at 5.

[34] Ping Du et al., *Changes in Flavor Preference in a Cohort of Long-Term Electronic Cigarette Users*, Penn State University College of Medicine, https://tinyurl.com/3495t2u2; Dr. Bret Koplow, Acting Dir., Ctr. for Tobacco Prods., *Remarks at the Food and Drug Law Institute Conference*, Washington, D.C. (May 6, 2026) (video recording at 57:29).

[35] *See* Abner S. Friedman et al., *Flavored E-Cigarette Sales Restrictions and Young Adult Tobacco Use*, 5 JAMA Health Forum e244594 (2024).

flavored vapes as guilty until proven innocent, despite the evidence. It sits on applications for years when Congress said to resolve them in 180 days. And while responsible American manufacturers rot in regulatory purgatory, Chinese manufacturers sell flavored vapes to American youth. When FDA does act against illicit products, it sends warning letters that get thrown in the trash.

American companies trying to help adult smokers quit are trapped in a bureaucratic black hole. Chinese manufacturers selling illegal vapes to American youth face no consequences. And even if an American company somehow survives FDA's labyrinthine premarket tobacco product application ("PMTA") process, the products most likely to help adult smokers—flavored ENDS—face a comparative-efficacy standard that only two brands (both menthol-flavored) have ever cleared. This situation is not an accident and should not come as a surprise. It is the direct and predictable result of FDA's own choices. The draft guidance cannot fix a crisis the Agency created by doing more of the same.

A. Consumers and doctors don't understand the health benefits of ENDS, but FDA has done nothing to correct this.

FDA recently started talking about "tobacco harm reduction" as official policy—and that is a good sign. Acting CTP Director Koplow acknowledged that the Agency stands at a historic moment,[36] and said harm reduction is the "natural outcome of applying the 'Appropriate for the Protection of Public Health' (APPH) standard outlined in the Tobacco Control Act."[37] Indeed, Dr. Koplow repeated this sentiment just days ago at the FDLI Annual Conference.[38] The draft guidance also acknowledges that vapes can help adult smokers quit or reduce their cigarette smoking.[39] Words are good. But words without action are worthless. FDA's own website says

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[36] Nicotine Insider, *FDA Signals Openness to THR in FDLI Keynote* (Oct. 29, 2025), https://tinyurl.com/3fbjxuu3.

[37] Chris Allen, *FDA's Acknowledgment of Harm Reduction Marks a Turning Point at FDLI 2025* (Nov. 4, 2025), https://tinyurl.com/svkk9mp5.

[38] "Tobacco harm reduction is the natural outcome of applying the Appropriate for the Protection of Health standard that Congress established in the Tobacco Control Act. It's predicated on recognition of the comparative risks among different categories of tobacco products with combustible tobacco products generally being the most harmful and posing the highest risk." Dr. Bret Koplow, Acting Dir., Ctr. for Tobacco Prods., *Remarks at the Food and Drug Law Institute Conference*, Washington, D.C. (May 6, 2026) (video recording at 5:15).

[39] *See, e.g.*, Draft Guidance at 7 ("It is possible for certain ENDS products to potentially reduce risks to current smokers if they facilitate complete switching and/or significant reduction in combusted cigarette use."); *id.* at 5 ("FDA recognizes that ENDS products with flavors other than tobacco may, in certain circumstances, provide benefits to adults who smoke combusted cigarettes, including by facilitating switching away from combusted tobacco products, increasing quit attempts, supporting sustained smoking abstinence, and reducing cigarette consumption among adults who would otherwise continue smoking."); *id.* at 13 ("FDA recognizes that flavored ENDS products may provide public health benefits for adult smokers by offering alternatives to combusted cigarettes and potentially increasing the likelihood of complete switching, thereby substantially reducing harm caused by combusted tobacco products.").

switching from cigarettes to vapes "may reduce exposure to many harmful chemicals."[40] FDA reviewers have called vapes a "public health benefit[]."[41] Even the draft guidance recognizes that the benefits of ENDS are not limited to complete cessation, acknowledging that authorization is appropriate where a product facilitates "significant reduction in combusted cigarette use."[42]

But none of this matters if adult smokers never hear about it. Vape manufacturers are legally barred from telling consumers that their products are less risky than cigarettes—unless FDA gives specific permission,[43] which has *never* been granted to any ENDS. And even in the few instances where FDA has granted that permission (to other categories of tobacco products), it has not significantly changed the consumer-confusion problem. That means adult smokers generally cannot learn the truth from the people who make the products.

That leaves FDA as the best entity to tell the truth. And FDA has been silent—or worse, actively misleading. The result: millions of adult smokers do not know they have a safer option. So they keep smoking.

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[40] FDA, *E-Cigarettes, Vapes, and other Electronic Nicotine Delivery Systems (ENDS)*, https://tinyurl.com/48uj4k4j; *see also* TobaccoReporter, *Acting CTP Director Offers 'Groundbreaking' Views at FDLI*, https://tinyurl.com/47zajk2u (report indicating that CTP Director Bret Koplow delivered a speech at the 2025 Food and Drug Law Institute (FDLI) Tobacco and Nicotine Conference that highlighted a commitment to tobacco harm reduction); Broughton, *FDA's Acknowledgment of Harm Reduction Marks a Turning Point at FDLI 2025* (Nov. 4, 2025), https://tinyurl.com/4umrd33w (same); FDA, *Technical Project Lead (TPL) Review of PMTAs* 6 (July 17, 2025), https://tinyurl.com/mu26s474 ("Current scientific literature demonstrates that ENDS are generally likely to have different toxicological risk and be associated with lower health risks than [combustible cigarettes]."); FDA, *The Relative Risks of Tobacco Products* (Mar. 12, 2026), https://tinyurl.com/5h36mxfx ("Non-combusted products—such as e-cigarettes and other smokeless tobacco products—generally have lower health risks than cigarettes and other combustible tobacco products."); Press Release, *FDA Authorizes Marketing of Tobacco- and Menthol-Flavored JUUL E-Cigarette Products*, FDA (July 1, 2025), https://tinyurl.com/4mpetswu (authorizing marketing of tobacco- and menthol-flavored ENDS products where "applicant submitted robust data—including a two-year longitudinal cohort study—demonstrating high rates of adults completely switching from cigarettes to either the tobacco- or menthol-flavored [ENDS] products").

[41] *See, e.g.*, FDA, Technical Project Lead (TPL) Review of PMTAs: PM0000630–PM0000631 at 5 (June 10, 2022).

[42] Draft Guidance at 7; *see also* Alex Norcia, *Memos Show FDA Overruled Science-Office Call to OK Menthol Vapes*, Filter (Dec. 14, 2022), https://filtermag.org/menthol-vapes-fda/; FDA, *Technical Project Lead Review of PMTAs* 5 (June 10, 2022), https://tinyurl.com/ybntpwt9; FDA, *Roundtable on PMTA Submissions for ENDS Products*, at 5:18:55-5:19:15 (Feb. 10, 2026), https://tinyurl.com/r3d943kn.

[43] 21 U.S.C. § 387k.

B. FDA's misguided flavor policy undermines the central promise of tobacco harm reduction.

FDA's flavor policy is at war with its own science. The data are clear: flavors are the reason vapes work for adult smokers.[44] But the draft guidance doubles down on the same prohibitionist approach to flavors that has already cost American lives: it reaffirms a comparative-efficacy standard that requires manufacturers to prove that their flavored product outperforms tobacco-flavored ENDS in head-to-head switching studies—a made-up standard with a 100% failure rate for non-tobacco, non-menthol flavors.

Think about how illogical this is. FDA says it supports tobacco harm reduction. Then it puts the highest barriers around the products most likely to achieve it. The only flavored vapes available to adult smokers are the unregulated, illicit ones from China. FDA's recent authorization of two flavored Glas vapes doesn't change this: Those Glas vapes use DAR, which is a barrier to adult acceptance, and in any event they are not currently on the market and it's uncertain whether (and if so, when) they ever will be. The Agency's flavor policy is therefore fueling the illegal market, deepening public ignorance, and making the application process a dead letter for the products that matter most.

C. Failures and delays in the PMTA process have created a muddy, slow review process that keeps reduced-risk products off the market.

FDA has refused to authorize nearly enough lower-risk products to matter. Twenty-eight million American adults still smoke. Under the prior Administration, FDA rejected more than 99% of the millions of vape applications—and 100% of the non-menthol, non-tobacco flavored vapes.[45]

Congress told FDA to take no more than 180 days to decide applications.[46] But, to our knowledge, FDA has *never* met that deadline. Applications from major American manufacturers sit for *years*.[47] Reynolds's application for a tobacco-flavored Alto vape took nearly four years—

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[44] Yoonseo Mok et al., *Associations Between E-cigarette Use and E-cigarette Flavors With Cigarette Smoking Quit Attempts and Quit Success: Evidence From a U.S. Large, Nationally Representative 2018–2019 Survey*, 25 Nicotine & Tobacco Res. 541, 543 (2023).

[45] *See* Press Release, FDA, *FDA Makes Determinations On More Than 99% of the 26 Million Tobacco Products For Which Applications Were Submitted* (Mar. 15, 2023), https://tinyurl.com/wrsrrkyy.

[46] *See* 21 U.S.C. § 387j(c)(1)(A).

[47] *See, e.g.*, Letter from U.S. Rep. Raja Krishnamoorthi (Chair of House Subcommittee on Economic and Consumer Policy) to Janet Woodcock (Acting FDA Commissioner) 1–2 (Sept. 10, 2021) (describing FDA's failure to rule on PMTAs within statutory or judicial deadlines), https://tinyurl.com/94u26839; *Am. Acad. of Pediatrics v. FDA*, Status Report, No. 8:18-CV-00883 (D. Md. Jan. 22, 2024) (noting, more than three years after the submission deadline, that more than one dozen applications from major manufacturers remained under review).

almost *eight times* the statutory limit—for FDA to decide.[48] These delays are illegal. They block less-risky products from reaching adult smokers. And they hand the market to illegal Chinese competitors.

The review process is not just slow—it is designed to be impenetrable. FDA has a secret standard that no applicant can figure out, no court can meaningfully review, and no amount of effort can satisfy. The draft guidance says: "FDA considers the full range of potential public health risks and benefits."[49] That tells American companies exactly nothing. It is a blank check for arbitrary decisions.

Companies have begged FDA to provide "a clear regulatory definition of the APPH standard, with product category-specific guidance about what is required to meet the target."[50] FDA said no. FDA openly "does not provide a precise definition of the standard."[51] It refuses to set any fixed (or, as it puts it "static") requirements. [52] FDA will not tell you what the test is. It will not tell you what passing looks like. It will not commit to any clear rules.

FDA's excuse is even worse than the refusal. The Agency says it cannot define the standard because the market changes over time.[53] Translation: the goalposts are on wheels. What passes today might fail tomorrow, and FDA will never tell you why. The rules change at FDA's sole discretion, without notice, without explanation, and without any accountability.

When a small manufacturer asked for clear standards, an FDA spokesman responded that FDA "give[s] guidance to [its] own staff"—in secret—but will not share it with the public.[54] The spokesman admitted: "We'd love to be able to say, 'If it's this good, you're fine.' But that puts boundary conditions on this industry that we're not sure is appropriate yet."[55] In other words: FDA knows exactly what the standard is—it just will not share it, because secrecy preserves its power to deny anything, anytime, for any reason.

American companies invest millions of dollars and years of work in applications, only to get their products denied under secret criteria. Meanwhile, adult consumers who could switch to

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[48] Press Release, FDA, *FDA Authorizes Marketing of Vuse Alto Tobacco-Flavored E-Cigarette Pods and Accompanying Power Unit* (July 18, 2024), https://tinyurl.com/2tk636yv.

[49] Draft Guidance at 12.

[50] *See Premarket Tobacco Product Applications and Recordkeeping Requirements*, 86 Fed. Reg. 55,224, 55,384–85 (Oct. 5, 2021).

[51] *Id.* at 55,384.

[52] *Id.* at 55,385.

[53] *Id.*

[54] FDA, *Roundtable on PMTA Submissions for ENDS Products*, at 43:38–46:04 (Feb. 10, 2026), https://tinyurl.com/r3d943kn.

[55] *Id.* at 46:42–46:58.

something less risky keep smoking cigarettes. This state of affairs is untenable, indefensible, and a betrayal of every goal the Tobacco Control Act ("TCA") was enacted to advance.

D. The illicit market crisis is a direct consequence of the authorization shortfall.

FDA's refusal to authorize vapes from law-abiding manufacturers has created one of the most predictable disasters in regulatory history: a massive illegal vape market dominated by Chinese flavored disposable vapes. Under the prior Administration, the number of illegal vapes in the U.S. nearly tripled.[56] FDA itself admits that "[a]s much as 54% of vaping products sold nationally are illegal."[57] Other estimates say 86%.[58] The overwhelming majority of the American vape market has been abandoned to unregulated manufacturers who answer to nobody.

These manufacturers—mostly in China—do not submit vape applications to FDA. They mislabel shipments to dodge Customs. They use ingredients no regulator has reviewed.[59] They

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[56] Matthew Perrone, *Thousands of Unauthorized Vapes Are Pouring Into the US Despite the FDA Crackdown on Fruity Flavors*, Associated Press (June 26, 2023), https://tinyurl.com/bdfe7yc4 (reporting that the "number of different electronic cigarette devices sold in the U.S. has nearly tripled to over 9,000 since 2020, driven almost entirely by a wave of unauthorized disposable vapes from China").

[57] FDA, *A Statement From FDA Commissioner Marty Makary, M.D., M.P.H.: Encouraging Retailers to Stop Selling Illegal Vapes* (Sep. 30, 2025), https://tinyurl.com/9fsam393; *see also* Eunice Park-Lee et al., *E-Cigarette and Nicotine Pouch Use Among Middle and High School Students — United States, 2024*, 73 Morbidity & Mortality Wkly. Rep. 774, 774 (2024), https://tinyurl.com/mrpzdtsf ("The device types used most often by students reporting current e-cigarette use were disposables (55.6%).").

[58] *See, e.g.*, Truth Initiative, *U.S. retail sales data show 86% of e-cigarette sales are for illegal product* (Nov. 8, 2024), https://tinyurl.com/3jx4d73m.

[59] *See* Chris Kirkham & David Kirton, *China E-cigarette Titan Behind "Elf Bar" Floods the US With Illegal Vapes*, Reuters (Dec. 6, 2023), https://tinyurl.com/4zrxfy7k (explaining that "flouting of FDA rules [is] a common playbook across China's e-cigarette industry"); *$76 Million in Illegal E-Cigarettes Seized in Joint Federal Operation*, FDA (Oct. 22, 2024), https://tinyurl.com/bdhkd8d8 (explaining that, "[i]n an attempt to evade duties and detection," the seized "e-cigarettes were intentionally mis-declared as items with no connection to vaping products"); Matthew Perrone, *US Seizes More Illegal E-cigarettes, But Thousands of New Ones are Launching*, Associated Press (Dec. 30, 2023), https://tinyurl.com/yxx85pde (explaining that shipments of e-cigarettes from China "were mislabeled as shoes, toys and other items"); David Barboza, *China's E-cigarette Boom Lacks Oversight for Safety*, N.Y. Times (Dec. 13, 2014), https://tinyurl.com/yp4r4h85 ("Experts say flawed or sloppy manufacturing [by Chinese manufacturers] could account for some of the heavy metals, carcinogens and other dangerous compounds … that have been detected in some e-cigarettes."); *see id.* (reporting that some Chinese e-cigarette manufacturers "either had no safety testing equipment or specialized in counterfeiting established brands, often with cheaper parts"); *see also* Letter from U.S. Senator Marco Rubio to Robert Califf (FDA Commissioner) at 1 (Feb. 7, 2024) (explaining that foreign manufacturers of illicit e-cigarettes are not subject to FDA inspections and some disposable Chinese e-cigarettes contain "deadly substances like fentanyl"); Anthony Carothers, *E-cigarettes From Overseas*

design products to appeal to American kids—vapes shaped like smartphones, vapes that play video games, and vapes featuring cartoon characters.[60] This is the market that FDA built. Chinese manufacturers run wild while American companies trying to play by the rules get punched in the gut.

Enforcement has been tepid at best—at least until this Administration. Under the prior Administration, it was mostly scattered warning letters sent to only the worst offenders. Between 2022 and 2025, DOJ took just 88 enforcement actions—and more than half just added names to a list of unauthorized online sellers.[61]

The current Administration has done better. Operation Vape Trail seized millions of illicit vaping products.[62] The Administration has also driven Congress to mandate that FDA dedicate at least $200 million annually to illicit enforcement. But FDA has still not designated a single dollar for that purpose.[63] That needs to change immediately. Indeed, 71 members of Congress recently sent a letter to Treasury Secretary Bessent and U.S. Trade Representative Greer demanding more enforcement against Chinese vapes, underscoring the urgency of this issue.[64]

Here is the bottom line: FDA's authorization failures, its refusal to tell adults about how much less risky vapes are, its war on flavors, and the exploding illegal Chinese vape market are not separate problems. They are one connected disaster, created by FDA. The draft guidance makes it worse. Every day this continues, more Americans smoke who could have switched, and more illicit products pour into American communities.

II. The Draft Guidance Does Not Solve These Core Issues.

The draft guidance just pours gas on the fire. It lays out a framework that illicit Chinese manufacturers—who dominate 86% of the market—will never follow. The draft guidance is a prohibitionist manifesto dressed up as a public health document, riddled with logical

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Exploiting FDA Loophole, The Telegraph (Mar. 27, 2023), https://tinyurl.com/3whec7uz (observing that illegal e-cigarettes from China "are often produced without any oversight or government standards" and "can be made with poisonous chemicals and substandard manufacturing processes").

[60] *See, e.g.*, *FDA Warns Firms Illegally Selling E-Cigarettes Resembling Products With Smart Technology, Including Phones and Gaming Devices*, FDA (Oct. 30, 2024), https://tinyurl.com/m5ws3h5a; Louise Matsakis, *The US is Being Flooded by Chinese Vapes*, Wired (June 25, 2024), https://tinyurl.com/kdkdnc9t (describing e-cigarettes with LCD screens that "can be used to play knockoff version of games like *Tetris* and *Pac-Man*").

[61] Sarah Todd, *GAO Report Shows Gap Between Scale of Illegal Vapes and Enforcement*, STAT (Apr. 10, 2026), https://tinyurl.com/3kus49zm.

[62] *See, e.g.*, DEA, *Operation Vape Trail Cracks Down on Illegal Substances in Vape Shops* (Sep. 22, 2025), https://tinyurl.com/57mds2sf.

[63] *See* Continuing Appropriations, Agriculture, and Related Agencies Act 2026, Pub. L. No. 119-37, § 772(a), 139 Stat. 495, 555-56 (2025).

[64] *See* Letter to Sec. Bessent and Amb. Greer (Mar. 4, 2026), https://tinyurl.com/bddhy92s.

contradictions, built on a foundation of cherry-picked data, and utterly divorced from the public-health mission Congress gave FDA when it passed the Tobacco Control Act.

A. The draft guidance doubles down on a misguided and unlawful comparative-efficacy standard.

The draft guidance says certain flavors (fruits, candy, etc.) pose high youth risk and must meet a "correspondingly high evidentiary burden."[65] Manufacturers must prove their flavored products provide "an added benefit relative to tobacco-flavored ENDS."[66] The required level of proof varies by flavor—less for menthol and mint,[67] but more for flavors FDA considers "high risk of youth appeal."[68] But FDA never says how much proof is enough. It is a rigged game with no rules.

1. The comparative-efficacy standard blocks adult smokers who want to switch to a less risky nicotine product.

FDA's test asks the wrong question. Instead of asking whether flavored vapes pose less risk than cigarettes—which is what actually matters—FDA asks whether the flavored vape outperforms a tobacco-flavored vape in a head-to-head study. FDA's test overlooks that some smokers will switch only if mint or menthol options are available. Others will switch only for fruit or other sweet flavors. Every flavor FDA restricts cuts off another group of potential quitters and condemns them to keep smoking, as shown here:

[65] *Id.* at 4, 8.

[66] *Id.* at 12.

[67] *Id.* at 14.

[68] *Id.*

Here is an analogy that explains this: Imagine the government let chip companies sell a healthier chip made with beef tallow instead of seed oils—exactly what MAHA calls for—but required that the chip have zero salt, zero seasoning, and zero flavor to avoid encouraging consumption of junk food, especially by youth. Nobody would eat it. Everyone would keep buying the regular chips fried in seed oils with the yummy seasoning. The healthier option becomes useless because the government stripped out the feature that makes people actually choose it.

That is what FDA is doing with vapes. By blocking flavored vapes, FDA is destroying the feature that makes millions of adults actually switch from cigarettes. Those smokers will keep smoking. They will keep getting sick. No rational policy does this to healthier food alternatives, and no rational policy should do it to the most important harm-reduction tool in the history of tobacco regulation.

This Administration already proved it knows how to do smart regulation. When Secretary Kennedy went after red food dye, he did not ban everything that tastes like cherry. He targeted the specific chemicals—Red No. 3—that science showed were harmful. That is how you regulate: go after the actual problem. The public health threat is not that vapes come in fruit and sweet flavors. The threat is a massive, unregulated market—dominated by Chinese manufacturers that submit no vape applications, undergo no safety review, and deliberately target American kids—that exploded because FDA's failures left consumer demand unmet by legal products. Restricting flavors in the legal market does not protect kids. It drives adults and kids alike toward the unregulated products that pose the real danger. Secretary Kennedy's approach to red food dye is a template: go after bad actors and dangerous ingredients, not the flavors that make vapes work.

The comparative-efficacy standard has no basis in science. Flavor preferences are personal and change over time.[69] Even the draft guidance admits that flavors help adults: "FDA recognizes that ENDS products with flavors other than tobacco may, in certain circumstances, provide benefits to adults who smoke combusted cigarettes, including by facilitating switching away from combusted tobacco products, increasing quit attempts, supporting sustained smoking abstinence, and reducing cigarette consumption among adults who would otherwise continue smoking."[70] The numbers speak for themselves: 27.2% of flavored e-cigarette users quit smoking, versus 20.6% of those who use tobacco-flavored vapes and only 16.1% for non-vape users.[71] Another study shows that 46.3% using menthol quit, compared to 25.6% for tobacco.[72] Flavors are not incidental—they are the mechanism that makes vapes work.

That's why no nicotine replacement therapy has ever been authorized in a tobacco flavor. Yet FDA penalizes vape manufacturers for using the strategy FDA endorsed for nicotine patches and gums. Taking flavors out of vapes is like ripping the adhesive off a nicotine patch and wondering why nobody wears it.[73] Or putting optional side airbags only in unpopular vehicles and then expressing surprise that consumers choose cars without side airbags.

The double standard becomes obvious when you consider the youth-appealing flavors in alcohol. Flavored hard seltzers, vodkas, and rums are sold in every fruit, candy, and dessert flavor imaginable. No alcohol company has to prove its whipped-cream vodka provides an "added benefit" over unflavored liquor. There is no sliding scale of proof based on "youth-appeal." Underage drinking kills thousands of youth per year, per the CDC.[74] Yet FDA demands this impossible showing only from vape manufacturers—a flavored product that actually helps adults quit smoking. Flavored alcohol has zero public health benefit. Nobody switches from something dangerous to something safer by drinking a hard seltzer. But consumers of flavored vapes do exactly that. The regulatory asymmetry is indefensible.

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[69] *See* Draft Guidance at 13 ("The heterogeneity of adult preferences underscores the potential value of multiple flavor options to increase the likelihood that individual adult smokers will find products that meet their needs and preferences.").

[70] *Id.* at 5.

[71] Yoonseo Mok et al., *Associations Between E-cigarette Use and E-cigarette Flavors With Cigarette Smoking Quit Attempts and Quit Success: Evidence From a U.S. Large, Nationally Representative 2018–2019 Survey*, 25 Nicotine & Tobacco Res. 541, 543 (2023).

[72] RAI Services, *PMTA for Vuse Alto*, Table H.5-2 (August 28, 2025) (on file with FDA).

[73] Mok et al., *Associations Between E-cigarette Use and E-cigarette Flavors With Cigarette Smoking Quit Attempts and Quit Success: Evidence From a U.S. Large, Nationally Representative 2018–2019 Survey*, 25 Nicotine & Tobacco Res. 541 (2023), https://pubmed.ncbi.nlm.nih.gov/36250607/.

[74] The CDC reports "[a]bout 4,000 young people (under 21) die from excessive alcohol use each year." CDC, *About Underage Drinking* (Jan. 14, 2025), https://tinyurl.com/3vw7kpfk.

Other countries have already proven that a better approach works. The U.K. promotes vapes as a harm reduction tool and lets adults buy a wide range of flavors. British adults overwhelmingly prefer fruit vapes (47%), then menthol and mint (17%). Tobacco is last at only 12%.[75] This shows that letting adults buy flavored vapes does not cause a youth vaping crisis. It produces a marketplace in which adult smokers actually switch.

2. The comparative-efficacy standard is unlawful.

This comparative-efficacy standard is not just bad policy—it is illegal. It is a tobacco product standard that FDA adopted without the required notice-and-comment rulemaking. The Fifth Circuit has held that imposing a comparative-efficacy requirement triggers notice-and-comment requirements under both the TCA and the Administrative Procedure Act ("APA").[76] The TCA explicitly requires notice-and-comment rulemaking for "any tobacco product standard."[77] The ordinary meaning of "standard" is "a level of quality, achievement, performance that is

[75] Action on Smoking and Health (ASH), *Use of E-Cigarettes (Vapes) Among Adults in Great Britain* 17 (Aug. 2023).

[76] *R.J. Reynolds Vapor Co. v. FDA*, 65 F.4th 182, 194 (5th Cir. 2023); *see also Wages & White Lion Invs., L.L.C. v. FDA*, 90 F.4th 357, 384 n.5 (5th Cir. 2024) (en banc), *vacated and remanded on other grounds*, 604 U.S. 542 (2025).

[77] 21 U.S.C. § 387g(c)-(d).

considered acceptable or desirable."[78] Additionally, the TCA specifically refers to flavor-based requirements as a "tobacco product standard" and states that any requirement related to a "property" of a tobacco product is a product standard.[79] Thus, the comparative-efficacy requirement for flavored ENDS is a tobacco product standard. Likewise, the APA requires notice-and-comment rulemaking when an agency adopts a substantive rule.[80]

Notably, FDA does not appear to apply the comparative-efficacy requirement to flavored products in other categories—such as oral nicotine pouches, heat-not-burn products, and low-nicotine cigarettes—which refutes the claim that the standard is mandated by the statute.[81]

The draft guidance incorrectly asserts that the Supreme Court affirmed the overall lawfulness of the comparative-efficacy standard in *FDA v. Wages & White Lion Invs.*, 604 U.S. 542 (2025).[82] In fact, the Court went out of its way to say that it was not resolving that issue.[83] The decision did not validate the comparative-efficacy standard as a matter of statutory interpretation or scientific merit, and CTP should not cite it as authority for the broader proposition that its approach to flavored ENDS is lawful or prudent.

FDA's recent enforcement guidance compounds the unlawfulness and arbitrariness of the comparative-efficacy standard. The enforcement guidance imposes an additional condition on non-tobacco flavored vapes that does not apply to tobacco-flavored products: FDA will deprioritize enforcement only where the Agency has determined that the product's application "includes data

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[78] Standard, Merriam-Webster, https://tinyurl.com/3rpyeb39 (definition 3b).

[79] *See* 21 U.S.C. § 387g(a)(1)(A); *see also id.* § 387g(a)(2). FDA's menthol rule and 2020 e-cigarette guidance said banning flavors would be a tobacco product standard: Tobacco Product Standard for Menthol in Cigarettes, 87 Fed. Reg. 26,454, 26,455-56 (May 4, 2022) (calling ban on menthol as a characterizing flavor in cigarettes a "tobacco product standard"); 2020 Guidance 34 (same for flavor ban for e-cigarettes). And in 2016, FDA submitted a draft rule to the White House, which would have established a tobacco product standard prohibiting non-tobacco-flavored e-cigarettes. Deeming Draft RIA as Submitted to OMB 76-77 (May 27, 2016), https://tinyurl.com/37bvsw88. Although the White House ultimately removed that provision, this still shows that FDA has acknowledged that a proposed flavor ban would be a tobacco product standard. *See* Deeming Rule Final Rule Redline Changes 22-23 (May 27, 2016), https://tinyurl.com/yv9djenb.

[80] *City of Arlington v. FCC*, 668 F.3d 229, 240 (5th Cir. 2012), *aff'd*, 569 U.S. 290 (2013).

[81] *See* FDA, *Technical Project Lead (TPL) of Nicotine Pouch PMTAs* (Dec. 23, 2024), https://tinyurl.com/2j7a7z6p.

[82] Draft Guidance at 4, 12.

[83] 604 U.S. at 565. Indeed, the Court's holding was narrower and more procedural in nature—that FDA's denial orders were "sufficiently consistent with its predecisional guidance" such that FDA did not engage in an arbitrary change in position as to the standard it was applying to the products at issue in that case. *Id.* at 571.

necessary to evaluate" whether the product should be authorized.[84] No such condition is imposed on tobacco-flavored vapes, which benefit from deprioritized enforcement based solely on having a pending application in scientific review.[85] This two-tiered enforcement framework is yet further evidence that FDA has singled out non-tobacco flavored vapes for uniquely disfavored treatment at every stage of the regulatory process.

The time to correct course is now. Stop singling out flavored vapes for differential treatment, both at the product authorization and enforcement stages. If the comparative-efficacy standard stays, FDA must at least tell companies where specific flavors fall on the sliding scale. Right now, nobody knows. For example, FDA says menthol ENDS might qualify with a "relatively small" benefit compared to tobacco-flavored ENDS.[86] But what does that actually mean? FDA has only authorized three brands of menthol ENDS (NJOY, JUUL, and Glas) and denied all others. That is not guidance. That is a guessing game.

B. The draft guidance erroneously relies on flavors as a proxy for youth risk.

FDA treats flavors as the primary predictor of youth vaping. The data says otherwise. The 2025 National Youth Tobacco Survey shows that 93% of youth have not used *any* e-cigarettes in the last 30 days—even though illicit flavored vapes are widely available from questionable vape shops filling streetcorners and storefronts across the country.[87] If flavors drove youth use, that number would be impossible to explain. That single data point should force FDA to tear up the foundation of this entire draft guidance.

But if more is needed, look no further: The vast majority of youth who vape do not cite flavors as the reason they started.[88] Only 1.5% of youth said flavors were a reason they tried vaping.[89] Instead, most did so because their friends or family members use e-cigarettes.[90] This proves that flavors are *not* driving youth vaping. FDA must either rewrite this guidance to match its own data or explain why it is choosing to ignore it.

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[84] FDA, *Enforcement Priorities for Certain New Tobacco Products Marketed Without Premarket Authorization: Guidance for Industry* at 3 (May 8, 2026) ("Enforcement Guidance").

[85] *Id.*

[86] Draft Guidance at 14.

[87] *See* Nat'l Youth Tobacco Survey, 2025 Codebook, at 549, https://tinyurl.com/3jbuyrtz (only 5.2% of all students reported they used ENDS or e-cigarettes in the last 30 days).

[88] *See id.* at 61-64.

[89] *See id.* at 59, 60.

[90] *Id.* at 57.

The confirmation doesn't stop there. Youth vaping surged from 2017 to 2019, but then dropped dramatically—year after year—while flavored vapes remained available through the illicit market.[91] Again, if flavors were driving youth use, why would youth vaping decline for several years in a row while flavored vapes remain available?

The guidance ignores this trend and emphasizes instead that 87.6% of youth vapers report using flavored products.[92] All that tells us is that the small percentage of youth who vape (5.9%) mostly use the Chinese illicit vapes that intentionally target youth—and which are nearly all flavored. Reporting that 87.6% of youth vapers use flavored products is about as revealing as reporting that 90% of kids who drink energy drinks consume flavored ones. Of course they do—virtually everything on the market is flavored. This shouldn't come as a surprise. Nearly all vapes on the (predominantly illicit) market are flavored.[93] Many illicit products are sold at vape shops that don't check IDs.[94] So kids who vape report using flavored products because flavored products are virtually the only thing available. That is not science. That is circular reasoning.

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[91] *See id.* at 9; *see also* FDA, *Results from the Annual National Youth Tobacco Survey (2024)*, https://tinyurl.com/2s47x6nf; *Results from the Annual National Youth Tobacco Survey (2023)*, https://tinyurl.com/2v2kx3ym; FDA, *National Youth Tobacco Survey Codebook* (2022), https://tinyurl.com/2zbrhvup; FDA, *National Youth Tobacco Survey Codebook (2021)*, https://tinyurl.com/2zbrhvup.

[92] Draft Guidance at 10.

[93] *Id.* at 9.

[94] *See* April Roeseler et al., *Assessment of Underage Sales Violations in Tobacco Stores and Vape Shops*, 8 JAMA Ped. 795 (2019), https://tinyurl.com/nhzrm2jt ("Although FDA regulation requires retailers to check ID for all persons under 27 years, 49.8% of tobacco and vape shops failed to check ID for underaged decoys when decoys attempted to purchase vape products. The violation rate in tobacco and vape shops was significantly higher than for other types of

C. The draft guidance erroneously conflates initiation and established use by youth.

The draft guidance also conflates two concepts: (1) youth trying a vape product once and (2) youth who become regular vapers. The main study cited for the point that flavors drive both first-time use and regular use has serious problems.[95] The study is based on just 49 observations of tobacco/mint/menthol/flavorless use—a tiny comparison group—versus 739 observations of nontraditional flavors use. It only studied Los Angeles high schoolers and thus cannot be generalized to all youth nationwide. Meanwhile, National Youth Tobacco Survey data shows youth use continues to fall year over year, undermining any claim that one-time triers become regular users.[96]

The problems go beyond that one study. FDA cites Rostron (2020) for the claim that flavored ENDS pose a "known and substantial risk" to youth—but that study is built on decade-old data, includes no regression or longitudinal analysis, and makes no claim of causality. Five years of newer data show flavors are not a leading cause of youth initiation.[97]

FDA also applies a double standard to its own evidence. When adult data on flavors have limitations, FDA flags those caveats prominently.[98] When youth data have limitations—and these data have major ones—FDA says nothing. That is not fair analysis.

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retailers ($P < .05$) (Figure, A). Furthermore, 44.7% of tobacco and vape shops sold vape products to underage decoys also at a higher rate compared with other tobacco retailers ($P < .05$) (Figure, B)."); Carla J Berg et al., *The Reshaping of the E-Cigarette Retail Environment: Its Evolution and Public Health Concerns*, PubMed Central, https://tinyurl.com/yvcwynmp ("[A]mong youth, the most commonly reported source for e-cigarettes and hookah was smoke shops (49.8 and 51.3%, respectively).").

[95] *See* Draft Guidance at 10 n.25 (citing Adam M. Leventhal, et al. "Flavored E-Cigarette Use and Progression of Vaping in Adolescents." Pediatrics 144, no. 5 (2019), https://doi.org/10.1542/peds.2019-0789).

[96] Martin Cullip, *The Youth-Smoking Collapse Nobody Wants to Talk About*, Filter (Mar. 16, 2026), https://tinyurl.com/2scp5xaj (In 2025, National Youth Tobacco Survey data revealed that "[y]outh vaping declined for the third consecutive year, plummeting to 5.2 percent, the lowest level in a decade.").

[97] *See* Nat'l Youth Tobacco Survey, *supra* n.87, at 57-61.

[98] *See, e.g.*, Draft Guidance at 5 n.6 ("FDA notes that much of the available evidence is subject to methodological limitations, and FDA evaluates the totality of scientific evidence in assessing whether a product meets the APPH standard.").

D. The draft guidance fails to account for major differences in how adult and youth populations are impacted.

Here is the math FDA ignores: about 95% of youth do not use ENDS.[99] And youth ENDS use has been declining for years.[100] Meanwhile, roughly 28 million Americans still smoke cigarettes. The same flavors FDA treats as a threat to kids are the flavors adult smokers most need to quit. Any honest risk-benefit analysis must face this reality: the benefit of flavored vapes for tens of millions of adult smokers vastly outweighs the risk from a small, declining fraction of youth users. FDA's refusal to do this basic math is not an oversight—it is a deliberate choice to prioritize a false narrative over public health.

E. The draft guidance fails to clarify how the benefit of flavors to adults affects APPH analysis.

The draft guidance will not even fully admit a basic fact: the flavors FDA says are most popular with youth—like fruit—are also the most popular with adults trying to quit smoking.[101] This invalidates FDA's premise. If adults and kids prefer the same flavors, then a flavor's popularity among kids is not evidence of unique "youth appeal." Restricting those flavors punishes tens of millions of adult smokers who depend on them to quit cigarettes.

Even when the draft guidance grudgingly admits flavored vapes might help adults, it refuses to say how much help is enough. What switching rates? What magnitude of benefit? What scientific proof would tip the balance? Silence on all counts. Manufacturers invest millions of dollars and years of work without ever knowing what FDA actually expects. This is not a regulatory standard. It is a guessing game with our nation's health at stake.

F. The draft guidance purports to address device access restriction, but it imposes an especially high burden on certain flavored ENDS without actionable guidance.

Given that zero non-menthol flavored vapes—and only two menthol brands—have ever passed the "comparative efficacy" standard, it appears that the only real pathway to FDA authorization for (non-menthol) flavored vapes is through using device access restriction (DAR) technology. But effectively requiring all flavored vapes to use DAR locks out the very adults it is supposed to help. The Glas products FDA just authorized require government ID verification, smartphone Bluetooth pairing, and random facial-recognition check-ins.[102] That is an enormous burden for anyone who is not tech-savvy or cannot afford to pay a higher price. It may be a challenge for or even "put off" older smokers, as Acting CTP Director Koplow recently

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[99] *See* Nat'l Youth Tobacco Survey, *supra* n. 87, at 549.

[100] Press Release, FDA, *FDA Educational Efforts Prevented Nearly 450,000 Youth from Starting E-Cigarette Use in One Year* (March 14, 2025), https://tinyurl.com/mr49zmbd.

[101] *See* Ping Du et al., *Changes in Flavor Preference in a Cohort of Long-Term Electronic Cigarette Users*, Penn State University College of Medicine, https://tinyurl.com/3495t2u2.

[102] FDA, *FDA Expands Market Access, Authorizes New ENDS Products* (May 5, 2026), https://tinyurl.com/5ekjc9a5.

recognized.[103] Research confirms biometric requirements would "complicate internet and retail sales for adults," "raise the price," and limit "accessibility to low-income adult smokers seeking potentially reduced harm products."[104] And such "random biometric check-in" means an app is surveilling the user at unpredictable times—with zero transparency about data storage, retention, or third-party access. Adults trying to quit smoking should not have to surrender their basic privacy to do so.

Even if a manufacturer is willing to try the DAR pathway, the draft guidance gives no roadmap for when DAR is enough. The Glas saga proves the point. In February 2026, FDA's Director of the Office of Science recommended approving four Glas flavored e-liquids with locking technology.[105] The next day, an FDA Deputy Commissioner overruled that recommendation.[106] Then FDA reversed itself yet again and authorized the products, calling DAR a "potential game changer."[107] One day DAR is not enough; the next it is a game changer. Nobody can build a business on that.

The draft guidance says flavors with "high youth appeal" that rely on DAR face an "especially high burden"—and never explains what would satisfy it.[108] At minimum, the final guidance should specify what age-gating or geo-fencing technologies meet that burden. Tell manufacturers: if a one-time device unlock reduces youth access by X%, that is enough. If re-verification after a timeout reduces access by Y%, explain how that factors in. Any specifics would be better than the draft's blanket skepticism, which once again leaves manufacturers guessing.

III. FDA Must Act Now to Solve These Pressing Problems.

Four things must be done immediately to solve the above-mentioned problems: FDA must (1) fix the broken authorization standard, (2) start obeying Congress's 180-day deadline, (3) get serious about enforcement against illegal Chinese vapes, and (4) tell adult smokers the truth about the risks of vapes relative to cigarettes.

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[103] Dr. Bret Koplow, Acting Dir., Ctr. for Tobacco Prods., *Remarks at the Food and Drug Law Institute Conference*, Washington, D.C. (May 6, 2026) (video recording at 59:20).

[104] David L. Ashley et al., *E-Cigarettes: How Can They Help Smokers Quit Without Addicting a New Generation?*, 140 Preventive Med. 106145 at 2, 4 (2020), https://tinyurl.com/y2wzd86x.

[105] Mem. from Matthew Farrelly, Ph.D., Director of Office of Science re: Decision on Glas PMTAs (Feb. 17, 2026).

[106] Mem. from Sara Brenner M.D., M.P.H., Principal Deputy Commissioner to Bret Koplow, Acting Director, CTP re: Glas PMTAs (Feb. 18, 2026).

[107] FDA, *FDA Expands Market Access, Authorizes New ENDS Products* (May 5, 2026), https://tinyurl.com/5ekjc9a5.

[108] Draft Guidance at 17.

A. FDA should clarify the APPH standard and implement commonsense safety benchmarks for ENDS.

FDA must stop hiding behind vague language and must give manufacturers clear rules. The draft guidance takes a half-step by naming three categories of flavor risk, but that is not enough. FDA has the power to turn this guidance into a document that actually makes Americans healthier. The question is whether the Agency has the courage to use it.

1. FDA should clarify that the APPH standard is based on whether marketing of the product is likely to present lower risk of morbidity and mortality compared to combustible products.

The draft guidance gives manufacturers nothing to work with. No objective standards. No benchmarks. It demands proof that flavored vapes outperform tobacco-flavored ones but never quantifies how much better is "enough."[109] FDA says menthol and mint "may present a lower risk of youth initiation"[110]—but how much lower? Nobody knows, because the guidance does not say. Which flavors are "high risk"? Which are "lower risk"? It is anyone's guess.

The government's job is to be a neutral decisionmaker—set clear rules so people know what is expected. That is basic fairness. The current authorization standard fails completely: it is unclear, undefined, and applied unpredictably. Manufacturers invest millions of dollars and years of science—and get denied under secret criteria that apparently change at will. This is not regulation. It is arbitrary power. The government should be a neutral referee, not an erratic gatekeeper with secret rules.

Commissioner Makary himself said it: "markets like predictability, innovators like predictability, manufacturers like predictability, investors like predictability. We owe it to all of those stakeholders to provide predictability."[111] True. But the draft guidance does the exact opposite. It perpetuates the same inscrutable standard that has left everyone guessing for years—undermining the very reform the Commissioner has promised.

The standard should be simple: is the marketing of a product reasonably likely to reduce the risk of disease and death compared to cigarettes? Period. A manufacturer that demonstrates reduced emissions of carcinogens and toxins is demonstrating reduced exposure to those substances—and reduced exposure is the best and most commonsense method of showing reduced risk of morbidity and mortality. To obtain authorization, manufacturers should not need to produce long-term epidemiological studies proving that their products have already reduced disease and death in practice. Nobody demands that a seatbelt manufacturer wait twenty years before selling a

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[109] *See, e.g.*, Draft Guidance at 12, 14 ("Some flavors may be shown to have lower youth appeal, perhaps such as coffees, teas, or spices, such that they may pose a lower risk of appeal to youth and may be APPH if the added benefit they provide compared to tobacco-flavored products is relatively small.").

[110] *Id.* at 14.

[111] FDA, *Roundtable on Premarket Tobacco Application Submissions for Electronic Nicotine Delivery Systems Products* (Feb. 10, 2026), https://tinyurl.com/r3d943kn.

less risky car. The standard is risk. Showing that a product materially reduces a user's exposure to the chemicals that cause disease and death is showing reduced risk.

That standard is consistent with the law, gives manufacturers and doctors the clarity they need, and returns the government to its proper role as a neutral decisionmaker.[112] To earn authorization, a manufacturer must show sufficient adult benefit—and one reliable, scientifically grounded way to establish that benefit is to demonstrate that the product carries a lower risk of morbidity and mortality than cigarettes. If youth initiation is substantial enough to offset the enormous benefits to individual smokers and public health, the product fails. If a flavored vape has broad adult appeal, the sheer number of adult smokers who could benefit must count—even if the per-person switching advantage is modest. And youth concerns mainly should be handled through enforcement and post-market surveillance—methods that have driven the decline in youth use of tobacco products—not by denying products at the front door.

FDA should also make clear that a product's potential reach matters. A flavored vape might produce only a small increase in switching compared to a tobacco-flavored product—but if millions of adults would use it instead of smoking cigarettes, the total public health benefit is enormous. Population-level impact must be part of the analysis.

The draft guidance's own admissions show how weak its foundation is. FDA concedes that "the effect of adults' stated preference is uncertain."[113] FDA admits that "available data do not capture every discrete flavor."[114] FDA acknowledges that products not in youth surveys may still be "appealing to youth" and that low usage "may be a function of" survey design.[115] These are huge concessions. FDA should rely on better data—including studies on whether specific flavors are associated with longer periods of quitting or reduced cigarette use among adults, data covering a wider range of flavors, and youth surveys designed to actually capture real usage patterns.

2. FDA should establish clear and rigorous safety benchmarks and allow ENDS meeting those benchmarks to immediately be marketed.

FDA should also create a new, streamlined pathway to get vapes (including flavored vapes) on the market: Create a list of clear and rigorous safety and quality benchmarks and provide that, if a product meets those benchmarks, the manufacturer can notify FDA, wait a set period, and then launch. This would dramatically accelerate market access for responsible manufacturers while still giving FDA oversight authority.

This model is precisely the type of efficient regulatory pathway that the TCA envisioned. The Act expressly authorizes FDA to adopt product standards and outlines the contents of those standards, providing a mechanism for establishing science-based benchmarks to streamline the

[112] 21 U.S.C. § 387f(d)(1).

[113] Draft Guidance at 13.

[114] *Id.* at 12.

[115] *Id.* at 12-13.

authorization of reduced-risk products.[116] Congress's inclusion of a 180-day deadline for acting on premarket applications further confirms that the Act contemplates prompt and efficient review—not the years-long process that has become the norm.

The benchmarks could set limits on nicotine content, the aerosol collected mass per puff, and emission of harmful and potentially harmful constituents. FDA could also specify a common-sense range of flavors, like fruit, mint, and menthol; require high-purity nicotine; require that device batteries meet certain standards; and set forth related safety and shelf-life parameters. If a product meets these product standards, the manufacturer should be able to start marketing and selling it.

This approach rewards companies that follow the rules, promotes innovation, and gets safer products to adult smokers—while FDA keeps full authority to go after products that do not meet the benchmarks.

B. FDA must immediately begin complying with the statutory command to resolve all PMTAs within 180 days.

Reynolds appreciates FDA's decision to launch a pilot program that aims to increase efficiency and streamline the premarket review process for new nicotine pouches.[117] That program was a step in the right direction—but a small one that has not delivered results.[118] Critically, it did not cover vapes—the biggest category of noncombustible products and the one with great potential to help smokers quit.

FDA must promptly and efficiently resolve all applications for new tobacco products, including—and especially—those for ENDS products. Congress did not set a 180-day review deadline as a suggestion. It *required* compliance with that deadline for every product category, without exception. FDA has inexcusably flouted Congress's direct command. FDA must start meeting the 180-day deadline for all products, and it must bring particular urgency to ENDS, which represent the largest share of the market for noncombustible nicotine products and the greatest opportunity for population-level public health benefit.

The contrast with this Administration's own stated priorities could not be starker. At a recent FDLI conference, Commissioner Makary stressed the importance of efficiency in the FDA approval process—specifically in the context of the Commissioner's National Priority Voucher program—noting that "cutting idle time" is critical and that "we owe it to Americans to get a

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[116] *See* 21 U.S.C. § 387g.

[117] *See* FDA, FDA Launches Program to More Efficiently Review Nicotine Pouch Applications (Sept. 18, 2025), https://tinyurl.com/3ewznkhs.

[118] *See* Emma Rumney & Patrick Wingrove, *Exclusive: US Nicotine Pouch Fast-Track Scheme Slowed by Worries Over Youth, New Users*, Reuters (Apr. 1, 2026), https://tinyurl.com/ym8rzwms; Christina Smith, *FDA's Nicotine Pouch Delay Undermines Adult Smokers*, RealClearHealth (Apr. 3, 2026).

decision out quickly."[119] Reynolds agrees. But those words ring hollow when American vape manufacturers have waited years for decisions on products that could save lives. If cutting idle time is a national priority for other products, it should be a national priority for the less-risky products that could help 28 million American smokers quit smoking.

C. FDA should combat youth usage of ENDS by significantly increasing enforcement against illicit ENDS.

FDA's treatment of the illicit market is derelict. The vapes youth actually use are illegal disposables[120]—overwhelmingly from China. The draft guidance barely mentions enforcement. Writing about youth risk from flavored vapes while ignoring the illegal products kids actually use is like writing a car-safety plan that obsesses over the color of stop signs while ignoring drunk driving.

FDA itself recently conceded that it "lacks the resources to pursue enforcement against every product" that has not received authorization.[121] Given that FDA's resources are so limited, the Agency must direct its limited enforcement capacity toward the illicit Chinese products that actually endanger youth—not toward imposing unworkable authorization standards on responsible manufacturers that have submitted applications and are cooperating with the regulatory process. FDA must commit—with real resources, real consequences, and real political will—to an all-out enforcement war against illegal vapes, in three ways:

First, CTP should increase and intensify its enforcement campaign against illicit disposable ENDS, which FDA recently acknowledged are the products most often used by youth.[122] Dedicate the resources necessary to remove illicit disposable products from the market, quickly and at scale.

Second, FDA should conduct inspection "blitzes" involving at least 200 unannounced inspections of tobacco retailers and distributors annually across the country—including at least one such inspection in each of the 50 states—designed to crack down on illegal sales of popular disposable ENDS. Concentrated, high-visibility enforcement actions send a clear signal to retailers and distributors that the sale of illicit products will not be tolerated and will carry meaningful consequences.

Third, FDA should develop an enhanced retailer inspection program to ensure that inspectors are properly trained to observe and account for all potential violations during an inspection, including violations related to products sold in violation of the Act's premarket authorization requirements. When violations are found, the Agency should conduct ongoing

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[119] Dr. Martin Makary, FDA Commissioner, *Remarks at the Food and Drug Law Institute Conference*, Washington, D.C. (May 6, 2026) (video recording at 31:30).

[120] *See* FDA, Results from the Annual National Youth Tobacco Survey, https://tinyurl.com/p4jurpc8 (Jan. 22, 2025).

[121] Enforcement Guidance at 4.

[122] *Id.* at 4 n.11.

surveillance to ensure that subsequent violations are observed within the relevant timeframe and impose the maximum statutory penalties for any such subsequent violation.

D. FDA should provide adults with accurate information regarding tobacco harm reduction.

Americans are being misinformed—by omission and by propaganda—about information that could save their lives. Less than 3% of adults know that vapes are much less harmful than cigarettes.[123] Nearly 80% think nicotine causes cancer.[124] Every smoker who believes vapes are just as dangerous as cigarettes will never switch.

Even the *New England Journal of Medicine* is saying what FDA will not: "U.S. public health agencies and professional medical societies should reconsider their cautious positions on e-cigarettes for smoking cessation. The evidence has brought e-cigarettes to a tipping point. The burden of tobacco-related disease is too big for potential solutions such as e-cigarettes to be ignored."[125]

Public fear of vapes skyrocketed after the 2019 EVALI outbreak—which was caused by illegal THC products,[126] not nicotine vaping. Perceptions of vapes as more harmful than cigarettes "increased sharply" between 2019 and 2020.[127] FDA let these misperceptions stand uncorrected.

Doctors are misinformed too.[128] Nearly 80% of doctors worldwide think nicotine causes lung cancer.[129] Doctors are the frontline for helping smokers—and they are working with wrong information. Manufacturers cannot fix this. FDA must step in and address the problem.

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[123] *See Insider Q&A: FDA Officials on Vaping's "Promise or Peril,"* Associated Press (Sept. 26, 2022).

[124] *See Health Information National Trends Survey*, Nat'l Cancer Inst.

[125] Sandro Galea & Catherine K. Ettman, *E-Cigarettes and Smoking Cessation—At the Tipping Point?*, 390 New Eng. J. Med. 664, 665 (2024), https://tinyurl.com/5hb4aps9.

[126] Pesko et al., *United States Public Health Officials Need to Correct E-Cigarette Health Misinformation*, 118 Addiction 785, 785 (2023).

[127] Priti Bandi et al., *Relative Harm Perceptions of E-Cigarettes Versus Cigarettes, U.S. Adults*, 63 Am. J. Prev. Med. 186 (2022).

[128] *See* Modesta Alobawone, *Rutgers-Led National Survey Uncovers Doctors' Misconceptions About Nicotine Risks*, Rutgers (Sept. 8, 2020), https://tinyurl.com/bdfctawx; Michael Steinberg et al., *Nicotine Risk Misperception Among US Physicians*, 36 J. Gen. Int'l Med. 3888 (2021).

[129] *See* Found. for a Smoke-Free World, *Nearly 80% Of Doctors Worldwide Mistakenly Believe Nicotine Causes Lung Cancer, Thwarting Efforts To Help One Billion Smokers Quit*, Cision (July 20, 2023), https://tinyurl.com/yc3ec4vz (announcing results from survey of more than 15,000 physicians in 11 countries, which found among other things that, "[o]n average, nearly 77% of doctors mistakenly believe nicotine causes lung cancer and 78% believe it causes atherosclerosis"); *Medical Professionals Recognize a Spectrum of Risk Exists for Tobacco and*

These widespread misperceptions have devastating, measurable public health consequences. Research has demonstrated that misperceptions of the relative risk of ENDS directly deter adult smokers who do not want to quit using nicotine products altogether from choosing less risky alternatives to combusted cigarettes.[130] Every day that these misperceptions go uncorrected, adult smokers who might otherwise have switched to ENDS instead continue smoking risky combustible cigarettes. The resulting information vacuum does not merely undermine the policy of tobacco harm reduction that FDA has adopted—it actively sabotages it, leaving millions of adult smokers without the information they need to make an informed choice that could save their lives.

Despite awareness of these longstanding and widespread public and clinician misperceptions, FDA has done little to correct them notwithstanding the scientific record that misperceptions negatively impact adults' ability to successfully switch to ENDS products. Instead, FDA inexplicably runs campaigns that *exacerbate* these problems—such as a scare-tactic video that depicts vapes as worms attacking a person's face and brain:[131]

Nicotine-Containing Products, Philip Morris Int'l ("Only one-third (34%) of medical professionals in the survey correctly disagree with the statement 'Nicotine, on its own, is a carcinogen and causes cancer,' with two-thirds either incorrectly agreeing with the statement (47%) or giving a 'neutral' response (19%).").

[130] *See* Sooyong Kim et al., *US Adult Smokers' Perceived Relative Risk on ENDS and its Effects on Their Transitions Between Cigarettes and ENDS*, 22 BMC Pub. Health 1 (2022); Leonie S. Brose et al., *Perceived Relative Harm of Electronic Cigarettes Over Time and Impact on Subsequent Use*, 157 Drug & Alcohol Dependence 106 (2015).

[131] *See Vaping Is An Epidemic*, The Real Cost, YouTube, https://tinyurl.com/3udrx959.

Even FDA's current webpage on relative risk is misleading: It describes the rigorous review of authorized products but obscures the fact that the vast majority of ENDS products in the United States are evading FDA regulation entirely.[132] None of this supports the TCA's goal of reducing smoking-related disease in a well-regulated marketplace.

Reynolds therefore urges CTP to do more to educate adult smokers who do not want to quit using nicotine products altogether about the health benefits of switching to new nicotine categories and to educate health care providers in primary care settings who play a key role in delivering this information to patients. Specifically, Reynolds recommends that CTP adopt the following approach to tobacco harm reduction.

First, CTP should create educational materials about the continuum of risk for categories of tobacco products and address common misconceptions about the health effects of nicotine and should distribute such educational materials to health care providers. FDA has long recognized that health risks for tobacco products exist on a spectrum and translating that recognition into actionable information for both clinicians and consumers is essential for the promise of tobacco harm reduction to be realized.

Second, CTP should initiate a public education campaign to inform adult smokers about tobacco harm reduction. Such a campaign should clearly communicate to adult smokers that noncombusted products such as ENDS and nicotine pouches are generally less risky than combustible cigarettes.

Third, CTP should annually allocate at least 2.5% of the budget for tobacco regulation activities to promoting tobacco harm reduction, including to fund the creation and distribution of the educational materials and the public education campaign described herein. Without dedicated funding, these risk-reducing initiatives remain aspirational rather than operational, and FDA's nascent commitment to tobacco harm reduction will remain unrealized in practice.

FDA is uniquely positioned to lead these educational efforts. Survey data confirms that 86% of medical professionals consider FDA to be a trusted source to learn more about tobacco and nicotine products and the science behind them.[133] Moreover, 93% of medical professionals believe FDA has an obligation to convey information to them if it finds that a certain product has less risk of cancer, cardiovascular disease, or COPD compared to continued smoking.[134] Among these professionals, nearly all (95%) say they would convey this information to their patients.[135] These findings underscore the significant weight FDA communications carry within the medical community and that science-based messaging from the Agency would reach adult smokers not only directly but also through their trusted healthcare providers.

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[132] *See, e.g.*, FDA, *The Relative Risks of Tobacco Products*, https://tinyurl.com/2v49zb5h.

[133] *Getting Smart on Reduced Harm*, White Paper, Philip Morris Int'l (Summer 2025) at 25, https://tinyurl.com/ts5y25yy.

[134] *Id.*

[135] *Id.*

CONCLUSION

FDA's draft guidance is built on a mistaken understanding: that flavors are driving youth vaping. FDA's own data proves otherwise. Ninety-three percent of kids do not use vapes—even though flavored products are everywhere on the illegal market. Only 1.5% of youth say flavors are a reason why they started. Youth vaping has been falling for years. Cigarette smoking among youth is at an all-time low. If flavors were the driver, none of this would be possible. The real driver of youth access is the illegal market that FDA's own failures created—a market flooded with unregulated Chinese products that deliberately target American children. FDA must stop punishing regulated products for a problem caused by illegal ones.

Flavored vapes are a powerful tool available to reduce the harm caused from cigarette smoking. FDA has a historic opportunity to Make America Healthy Again. Reynolds stands ready to work with FDA, the Administration, and every stakeholder who is serious about reducing smoking-related harms and encouraging smokers to switch to less risky ENDS.