

March 30, 2026

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

Re: Docket No. FDA-2026-D-1817-0002, Flavored Electronic Nicotine Delivery Systems (ENDS) Premarket Applications – Considerations Related to Youth Risk

Dr. Makary, Dr. Koplow and Dr. Farrelly:

The Progressive Policy Institute (PPI) welcomes the opportunity to provide comments on the draft guidance for *Flavored Electronic Nicotine Delivery Systems (ENDS) Premarket Applications – Considerations Related to Youth Risk*. We appreciate that the draft guidance clarifies FDA’s position on flavored ENDS, including what the agency describes as a “sliding scale” regarding the evidentiary burden for various ENDS flavorings. Importantly, the draft guidance makes it clear that the agency does not have a *de facto* flavor ban for e-cigarettes. Despite this appreciation, the draft guidance fails to account for critical real-world factors that should inform FDA’s perspectives on the potential risks and benefits associated with flavored ENDS.

The draft guidance suggests “FDA’s current approach to PMTA review for determining whether a flavored ENDS product is ‘appropriate for the protection of the public health’ (APPH) includes evaluating the risks and benefits, *considering all relevant evidence and circumstances* associated with the new product to the population as a whole.” However, the draft guidance does not sufficiently acknowledge the following “relevant evidence and circumstances” or describe how these factors were considered when FDA conceptualized the evidentiary burden necessary to authorize flavored ENDS:

1. The agency fails to adequately acknowledge that youth ENDS use declined rapidly and dramatically while illicit flavored products were widely available.
2. The agency fails to acknowledge that existing FDA-authorized ENDS products do not sufficiently meet adult consumer demand, which sustains the illicit market for flavored ENDS.

By not adequately accounting for these factors, the proposed framework is likely to overestimate the risks flavored ENDS pose to youth, undervalue their potential benefits to adults who smoke cigarettes, and fall short in helping address the illicit ENDS marketplace. In the context of declining rates of youth use and growing public safety concerns with illicit tobacco products, FDA guidance should provide clear pathways that

are likely to accelerate the authorization of flavored ENDS products that benefit adult smokers, better meet adult consumer demand, and begin to draw consumers away from unregulated products and the illicit market.

### **Youth ENDS Use Has Declined Dramatically Despite Flavored Product Availability**

In the past six years, the overall rate of youth tobacco use has been cut by nearly two-thirds. Nationally, the percentage of teens reporting current use of any tobacco product dropped from 23 percent in 2019<sup>1</sup> to 8.1 percent in 2024<sup>2</sup>. Recently released data for 2025<sup>3</sup> show further reductions with only 7.5 percent of teens using any tobacco product.

Since its peak in 2019, youth use of e-cigarettes has been cut by nearly 75 percent and, today, only 5.2 percent of teens use e-cigarettes. Contrary to concerns that e-cigarettes may be a gateway to cigarette smoking, youth use of cigarettes has steadily declined. Today, fewer than 2 percent of teens use cigarettes.

Both the national public health response to youth vaping crisis and the near elimination of youth cigarette smoking should be celebrated as remarkable public health achievements. In fact, the U.S. has already surpassed its ambitious Healthy People 2030 goal for youth tobacco use.

The significant decline in youth e-cigarette use occurred during a period when illicit sweet-flavored products were available<sup>4</sup>. While youth report a preference for sweet-flavored products, **it is evident that the overall appeal of e-cigarettes among youth has declined substantially**. Between 2019 and 2024, the number of youth using e-cigarettes dropped from roughly 5.38 million to only 1.63 million, and data from the 2025 NYTS suggests use of e-cigarettes has declined even further.

The draft guidance fails to acknowledge the circumstances contributing to the dramatic reduction in youth e-cigarette use. Nationally, the response to the youth vaping crisis involved the efforts of many schools, public health and medical organizations. By all accounts, many of these public health and medical organizations will continue to prioritize youth prevention efforts. While increasing the legal purchase age to 21 and the FDA's public education campaigns<sup>5</sup> contributed to the decline in youth tobacco use, the agency must also acknowledge and account for a broad range of public health initiatives – many beyond the federal government's control – that are helping to reduce youth e-cigarette use.

Unlike 2017 to 2019 when youth e-cigarette use escalated, there is a comprehensive and ongoing youth vaping prevention campaign underway. When weighing the potential benefits of flavored ENDS to adult smokers against the risks of youth initiation and use,

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<sup>1</sup> <https://www.cdc.gov/mmwr/volumes/68/ss/ss6812a1.htm>

<sup>2</sup> [www.cdc.gov/mmwr/volumes/73/wr/mm7341a2.htm](https://www.cdc.gov/mmwr/volumes/73/wr/mm7341a2.htm)

<sup>3</sup> <https://www.fda.gov/tobacco-products/youth-and-tobacco/national-youth-tobacco-survey-nyts>

<sup>4</sup> <https://www.fda.gov/news-events/press-announcements/justice-department-and-fda-announce-federal-multi-agency-task-force-curb-distribution-and-sale>

<sup>5</sup> <https://www.fda.gov/tobacco-products/public-health-education-campaigns/real-cost-campaign>

FDA must account for the real-world evidence and circumstances regarding youth use, including the efficacy of youth prevention efforts not directed by the agency. By not sufficiently accounting for factors associated with the decline in youth e-cigarette use, FDA will likely overestimate the risks that flavored ENDS pose to youth which, in turn, will undermine their potential public health benefit for adult smokers.

We also encourage FDA to acknowledge the role of postmarket surveillance, which allows for monitoring and risk mitigation of any authorized tobacco product. Through postmarket surveillance, FDA can determine whether youth use of any flavored ENDS exceeds acceptable thresholds and, if so, it can establish additional product-specific marketing restrictions or withdraw a product's marketing granted order.

### **The Limited Array of Authorized ENDS Products Sustains the Illicit Market**

In addition to these trends in youth usage, the draft guidance also fails to account for dynamics in the adult market. Surprisingly, the draft guidance does not even mention the illicit market for flavored ENDS or the circumstances under which it developed. The Tobacco Control Act requires FDA to approach regulation in ways that “will benefit the health of the *population as a whole*, taking into account both users of tobacco products and persons who do not currently use tobacco products.” Arguably, the health of the “population as a whole” is being harmed by a vast market of illicit ENDS products. The FDA must better account for the potential population benefits associated with products that would help draw adult consumers away from unregulated products and the illicit market.

It is essential for FDA to consider the circumstances under which the illicit ENDS market emerged and has expanded. Today's illicit ENDS market can be traced to the development of adult consumer preferences between 2016, when FDA gained regulatory authority over ENDS, and 2023 when the agency completed most ENDS PMTA reviews. During this seven-year period, flavored ENDS were widely available, including many products that FDA allowed to remain on the market through its enforcement discretion policy. By 2023, when greater clarity emerged regarding the legally authorized ENDS marketplace, 6.5% of American adults – roughly 17 million people – were using e-cigarettes<sup>6</sup>.

Although FDA has authorized certain products that meet its public health standard, the current range of authorized products clearly fails to meet established adult consumer preferences. Millions of adults with a preference for sweet-flavored ENDS were not simply going to stop using them because FDA did not authorize them. It is not surprising that strong adult consumer demand for flavored ENDS created incentives for a wide range of actors to manufacture and sell illicit products.

Unfortunately, the illicit market for flavored ENDS products is expanding<sup>7</sup> and posing significant enforcement challenges for federal, state and local authorities. At least half of

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<sup>6</sup> <https://www.cdc.gov/nchs/products/databriefs/db524.htm>

<sup>7</sup> <https://www.reuters.com/business/retail-consumer/illegal-us-vape-sales-worth-least-24-billion-2024-data-shows-2025-02-24/>

all ENDS products sold in the U.S. are illegal products that lack FDA authorization. National estimates regarding the percentage of ENDS sales for illegal, unauthorized products include 54% by FDA<sup>8</sup>, 70% by Altria<sup>9</sup>, and 86% by the Truth Initiative<sup>10</sup>.

Public health data clearly indicates that the growth of the ENDS market is being fueled by adult consumers. Between 2017 and 2023, the number of U.S. adults who report exclusively use of c-cigarettes increased by 7.2 million, from roughly 2.9 to 10.1 million people<sup>11</sup>. On the other hand, as previously noted, between 2019 and 2024 the number of U.S. teens who used e-cigarettes dropped by 3.75 million. By clearly acknowledging the evidence that adult consumers are drawn to the illicit market, FDA can ensure its regulatory decisions better meet adult consumer demand and reduce adult interest in illicit products.

In addition, authorizing a wider range of flavored ENDS will expand the availability of more appealing, lower-risk alternatives in retail outlets where adults typically buy cigarettes. In the U.S., most cigarettes are sold in convenience stores<sup>12</sup> with lower sales in tobacco specialty and vape shops. To maximize switching, adults who smoke cigarettes should encounter a wider array of FDA-authorized alternatives in the stores where they typically purchase cigarettes. This reflects a familiar public health principle: making the healthier choice the easier choice.

FDA should adopt a more pragmatic view of adult consumer preferences and prioritize better meeting the needs of adults who smoke cigarettes and would benefit from a wider range of lower-risk alternatives in the stores where they typically shop. Further, the agency must acknowledge that any effective, long-term solution to the illicit market requires a wider range of legally authorized ENDS products that meet adult consumer demand and help draw consumers away from unregulated products and the illicit market.

In conclusion, FDA has taken an important step in considering the evidentiary requirements for authorizing a wider range of flavored ENDS products. However, the draft guidance fails to fully account for the full range of relevant evidence and circumstances that help determine whether any ENDS product – flavored or not – is appropriate for the protection of public health.

Youth e-cigarette use has dropped by 75% in an environment where a range of illicit flavored products were available. FDA must account for this and ensure its interpretation of the public health standard does not overestimate the risks that flavored ENDS pose to

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<sup>8</sup> <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-marty-makary-md-mph-encouraging-retailers-stop-selling-illegal-vapes>

<sup>9</sup> [https://edge.sitecorecloud.io/altriaclien9c5f-altriaclien2f33-prod0b41-3d12/media/Project/Altria/Altria/Investors/events-and-presentations/2026/2026-CAGNY/2026-CAGNY-Presentation.pdf?sc\\_lang=en](https://edge.sitecorecloud.io/altriaclien9c5f-altriaclien2f33-prod0b41-3d12/media/Project/Altria/Altria/Investors/events-and-presentations/2026/2026-CAGNY/2026-CAGNY-Presentation.pdf?sc_lang=en)

<sup>10</sup> <https://truthinitiative.org/research-resources/tobacco-industry-marketing/us-retail-sales-data-show-86-e-cigarette-sales-are>

<sup>11</sup> <https://www.cdc.gov/mmwr/volumes/74/wr/mm7407a3.htm>

<sup>12</sup> <https://www.nacsmagazine.com/Issues/December-2023/Cigarettes-Are-Still-Powering-Sales>

youth. In addition, the majority of the ENDS market consists of illicit products that are not authorized by FDA. To better address the illicit market, FDA must acknowledge the importance of adult consumer preferences and quickly take the steps necessary to expand the range of legally authorized flavored ENDS products.

By more directly accounting for these real-world factors, FDA can more accurately assess the potential benefits and risks associated with flavored ENDS products to better achieve the two primary public health objectives in the Tobacco Control Act<sup>13</sup> – addressing the use of tobacco by young people and promoting cessation to reduce disease risk and social costs associated with tobacco.

Respectfully submitted,

Progressive Policy Institute

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<sup>13</sup> <https://www.fda.gov/tobacco-products/rules-regulations-and-guidance-related-tobacco-products/family-smoking-prevention-and-tobacco-control-act-table-contents>