March 17, 2026

To: Food and Drug Administration, HHS
Re: Flavored Nicotine Delivery Systems (ENDS) Premarket Applications-Considerations Related to Youth Risk; Draft Guidance for Industry

Docket No.: FDA-2026-D1817

My name is Jeffrey A. Singer. I am a Senior Fellow in Health Policy Studies at the Cato Institute. I am also a medical doctor specializing in general surgery and have been practicing that specialty in Phoenix, Arizona, for over 40 years. The Cato Institute is a 501(c)(3) non-partisan, non-profit, tax-exempt educational foundation dedicated to the principles of individual liberty, limited government, free markets, and peace. Cato scholars conduct independent research on a wide range of policy issues. To maintain its independence, the Cato Institute accepts no government funding. Cato receives approximately 80 percent of its funding through tax-deductible contributions from individuals. The remainder of its support comes from foundations, corporations, and the sale of books and other publications. The Cato Institute does not take positions on legislation.

I write to share my thoughts on the draft guidance for industry on premarket applications-considerations for youth risk.

The draft guidance effectively sets an asymmetric evidentiary bar—requiring flavored products to demonstrate large, product-specific cessation benefits while presuming youth risk based on broad category-level data—and, despite recent CDC data showing teen vaping has fallen to its lowest level in a decade, this approach functions less as a neutral public health balancing test and more as a de facto ban standard.[1]

The guidance imposes an unrealistic evidentiary burden by expecting applicants to provide robust, product-specific evidence that flavored ENDS outperform tobacco-flavored products in promoting smoking cessation. In practice, this would require large-scale randomized controlled trials and long-term switching data—forms of evidence that are costly, time-consuming, and often infeasible, particularly for smaller manufacturers. At the same time, there is real-world evidence indicating that adult smokers often prefer non-tobacco flavors and are more likely to use

flavored ENDS when attempting to quit or reduce cigarette consumption.[2] Yet the agency is effectively demanding pharmaceutical-grade evidence for consumer products while discounting observational data and broader population-level trends showing substitution away from combustible cigarettes. As a clinician, I would note that in medicine we routinely make decisions based on imperfect but converging evidence when the alternative is continued exposure to a more dangerous product. In this case, setting an evidentiary bar that ignores real-world substitution risks impeding access to lower-risk alternatives while leaving combustible cigarette use—the most harmful form of nicotine delivery—unchallenged.

This imbalance becomes even clearer in how the guidance weighs competing public health risks.

The guidance emphasizes the risk of youth uptake of flavored ENDS, but it does not equally consider the well-known and ongoing dangers of combustible cigarettes or the public health benefits that can occur when adult smokers switch to lower-risk options. This imbalance creates a risk-avoidance bias that effectively maintains the cigarette market by making it harder for smokers to switch away from it. A policy that limits access to potentially less harmful alternatives to reduce youth vaping is not neutral—it implicitly favors one type of harm over another, despite the much higher morbidity and mortality linked to combustible tobacco use.

At the same time, the guidance reflects an internal inconsistency regarding the role of flavors. FDA acknowledges that adult smokers often prefer non-tobacco flavors and that these flavors may facilitate switching or reduction in cigarette use. Yet it imposes a near-prohibitive evidentiary burden on those very products. **This creates a logical contradiction**: the feature that may make ENDS more effective as a harm-reduction tool for adults is treated as a disqualifying risk factor. In effect, the agency recognizes that flavors may help smokers quit, but then regulates those same flavors as if their only function were to attract youth.

Furthermore, the guidance relies heavily on youth preference data—such as survey findings that adolescents favor fruit or sweet flavors—without adequately distinguishing between preference and causation. Youth access to ENDS is often driven less by product characteristics than by social sourcing, enforcement gaps, and the persistence of illicit or gray markets. By focusing primarily on flavors rather than these access pathways, the guidance risks addressing the symptom rather than the underlying cause. **The central issue is not that flavors exist, but**

that age-restriction enforcement is inconsistent and easily circumvented. A more effective approach would target access directly rather than broadly restricting product characteristics that may play an important role in helping adult smokers move away from combustible cigarettes.

The guidance acknowledges the potential role of device access restrictions (DAR)—such as biometric verification, age-gated devices, and geofencing—but ultimately dismisses these tools as insufficient to mitigate youth use, particularly for flavored products. This approach risks prematurely foreclosing innovation that could meaningfully address youth access at the point of use. Rather than encouraging the development and refinement of such technologies, the guidance signals a preference for restricting product characteristics themselves. This reflects a broader pattern in which the agency appears more comfortable limiting product availability than allowing technological solutions to evolve and compete as tools for harm reduction and access control.

In addition, the guidance appears to rest on a static view of the marketplace—implicitly assuming that restricting flavored ENDS will directly translate into reduced youth use. In practice, markets are dynamic. When legal, regulated products are restricted, consumers—both adults and youth—often shift to alternatives, including illicit or gray-market products, disposable imports, or newly developed substances that may be less transparent and potentially more harmful. This pattern is well documented across other areas of drug policy.

As experience has repeatedly shown, when regulators apply pressure to one segment of a market, innovation does not disappear—it adapts. Products evolve, supply chains shift, and activity often migrates to less regulated channels where oversight is weaker and risks may be greater. A regulatory framework that does not account for these substitution effects risks not only failing to achieve its intended public health goals but also inadvertently driving consumers toward products that are less safe and more difficult to monitor.

The guidance gives little weight to international experience with vaping as a harm-reduction strategy. Countries such as the United Kingdom have taken a more permissive, public-health–oriented approach—encouraging adult smokers to switch to e-cigarettes—and have seen meaningful declines in cigarette use. While policy contexts differ, these real-world outcomes offer valuable comparative evidence about how ENDS can function as a substitute for combustible tobacco. By largely discounting this body of experience, the FDA risks operating in a regulatory silo, limiting its analysis to domestic concerns without fully considering

how alternative policy frameworks have performed in practice. More broadly, public policy for adults should not be dictated by what minors might do. If that were the governing principle, we would be compelled to revive alcohol prohibition and consider banning non–self-driving vehicles—an approach that sacrifices adult autonomy without effectively addressing youth behavior.

The guidance also introduces a "risk-proportionate" sliding scale for evaluating flavored ENDS, but provides no clear thresholds or objective criteria for how much evidence is sufficient at different levels of perceived youth risk. This leaves applicants navigating a highly discretionary process with uncertain endpoints. The result is regulatory ambiguity that can function as a de facto barrier to entry, as firms are unable to predict what will satisfy the standard. A sliding scale without defined endpoints is not a standard—it is a moving target, and one that risks discouraging innovation and investment while failing to provide transparent, consistent decision-making.

In summary, the FDA's new guidance on flavored e-cigarettes reflects a familiar pattern in public health regulation: when faced with uncertainty, regulators default to restriction. But in doing so, the agency risks undermining one of the most promising harm-reduction tools available to smokers. By setting an evidentiary bar that few products can meet, relying on broad assumptions about youth behavior, and discounting both real-world data and technological innovation, the FDA is not so much balancing risks and benefits as preemptively deciding the outcome. The result may be fewer flavored vaping products on the legal market—but not necessarily fewer risks, and possibly more.

Respectfully submitted,

Jeffrey A. Singer, MD, FACS

Senior Fellow, Department of Health Policy Studies

Cato Institute

[1] https://www.cdc.gov/media/releases/2024/p0905-youth-ecigarette.html#:~:text=This%20decline%20was%20largely%20driven,disposable%20and%20cartridge%2Dbased%20products.

[2] https://pmc.ncbi.nlm.nih.gov/articles/PMC7275248/ ;
https://pmc.ncbi.nlm.nih.gov/articles/PMC10576309/ ; and
https://pmc.ncbi.nlm.nih.gov/articles/PMC8500174/