

United States Senate

WASHINGTON, DC 20510

May 5, 2026

Martin A. Makary, M.D., M.P.H.
Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

Dear Commissioner Makary:

We are writing to share our concerns about the Food and Drug Administration (FDA)'s draft guidance document, *Flavored Electronic Nicotine Delivery Systems (ENDS) Premarket Applications – Considerations Related to Youth Risk*. While we commend the agency for its efforts to clarify and enforce the premarket authorization requirements, we believe that this draft guidance could risk the health of children by increasing the number of flavored e-cigarettes that FDA authorizes.

FDA must be careful to avoid changes that could jeopardize recent progress in reducing the number of youth who use e-cigarettes. Tobacco use often begins during adolescence, when people are more vulnerable to nicotine addiction and less aware of the risks of tobacco use. Nicotine can harm the parts of the adolescent brain responsible for attention, learning, mood, and impulse control and can prime the brain for addiction to other drugs. In its guidance, FDA acknowledges that it has “determined that the evidence shows that flavored ENDS products pose a substantial risk to youth, and they pose a greater risk to youth than tobacco-flavored ENDS.” Nine in 10 youth who vape report using flavored e-cigarettes, which appeal to children and mask the harsh taste. If young people remain tobacco-free into their early twenties, they are unlikely to ever start using a tobacco product.

We appreciate FDA's recognition that the products that most egregiously target kids would face a “correspondingly high evidentiary burden to demonstrate that the benefits to adult smokers... outweigh the risks of youth initiation.” As sponsors of the *Family Smoking Prevention and Tobacco Control Act* (P.L. 111-31), we intended FDA's premarket review of new tobacco products to be utilized as an important tool to prevent new products from entering the market that are likely to increase youth use of tobacco.

This draft guidance will increase the number of flavored e-cigarettes that FDA authorizes. For flavors characterized as less risky to youth by FDA, the agency is suggesting it would require a product to show a relatively small benefit to adults compared to tobacco-flavored products to be “appropriate for the protection of the public health.” It is unclear how FDA is identifying and justifying the relative risk profile of certain flavors, given that the flavors that FDA seeks to categorize as less risky to youth (e.g. mint, menthol, coffee, and spice) are still attractive to youth and often used by them.

For example, the 2024 National Youth Tobacco Survey found that 28 percent of high school students who use e-cigarettes reported using mint-flavored e-cigarettes. When some flavored e-cigarettes were removed from the market several years ago, youth switched to those flavored products that remained on the market, including mint- and menthol-flavored e-cigarettes. Given the sheer volume of illicit products with inappropriate flavorings available to kids, the fact that other unauthorized flavors hold a smaller market share should not be misconstrued as evidence of a lower risk to youth.

We are concerned that the draft guidance, if finalized in its current form, would create more risk than benefit to public health and should be reconsidered. Given the importance of preventing youth use of all tobacco products and the strong evidence that flavors increase the appeal and use of e-cigarettes by youth, FDA should not ignore the basic reality that kids are drawn to what flavors are most available to them, particularly since FDA recognizes the underlying risk of flavors to youth.

Finally, we appreciate and support FDA's assessment of the role of device access restrictions in preventing underage use of tobacco products. Specifically, we agree that while such technologies may be a component of a comprehensive youth prevention strategy, they might not alone propel a kid-friendly, flavored e-cigarette to satisfy the especially high evidentiary burden.

We request a timely response that addresses the concerns we have about the new draft guidance. Thank you for your attention to this matter, we look forward to working with you to protect America's children.

Sincerely,



Susan M. Collins
United States Senator



Richard J. Durbin
United States Senator