United States Senate
WASHINGTON, DC 20510

May 15, 2026

Kyle Diamantas
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

Dear Mr. Diamantas,

We are deeply concerned by the Food and Drug Administration's (FDA) shortsighted and reckless decision to authorize flavored e-cigarette products that appeal to children. By authorizing fruit flavors, FDA is once again exacerbating the risk of chronic disease and death for a new generation. We urge FDA to rescind this decision immediately.

While the U.S. has made significant progress in reducing youth e-cigarette use, according to the 2025 Youth Tobacco Survey, over 1.4 million middle and high school students still use e-cigarettes.[1] There is no scientific consensus that flavors provide a benefit to adults who want to quit using tobacco products, but there is clear data that proves flavored products draw in young people and that the tobacco industry intentionally markets flavored products to young people. According to FDA's own figures, nearly all youth who use e-cigarettes report using flavored products, and fruit flavors are the most popular.[2] A 2024 report from the Senate Permanent Subcommittee on Investigations detailed FDA's failure to regulate flavored e-cigarettes when manufacturers first put them on the market, which led to soaring rates of vaping among high school and middle school students, undoing decades of progress in reducing youth tobacco use.[3]

Media reports suggest that FDA was pressured by the White House to make this decision—effectively abandoning its scientific integrity to help the President score political points. It is no secret that during his 2024 campaign, President Trump promised to "save vaping",[4] risking the health of American children in favor of his political donors.[5] Just last month, *The Wall Street*

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[1]National Youth Tobacco Survey. U.S. Food and Drug Administration. March, 4th 2026. https://www.fda.gov/tobacco-products/youth-and-tobacco/national-youth-tobacco-survey-nyts

[2]Ibid.

[3]"The Youth Vaping Epidemic: Federal Regulation of E-cigarettes and the Rise of JUUL and Puff Bar." February 29, 2024. https://www.hsgac.senate.gov/wp-content/uploads/2024-02-29-PSI-E-cig-Report-Final.pdf

[4]Ventura, Juliann. "Trump vows to 'save vaping' despite previous support for ban." The Hill. September 21, 2024. https://thehill.com/policy/healthcare/4892387-trump-vaping-ban-post/

[5]Durkee, Alison. "This Tobacco Giant Was The Biggest Corporate Donor to the 2024 Presdiential Race." Forbes. December 27, 2024. https://www.forbes.com/sites/alisondurkee/2024/12/27/this-tobacco-giant-was-the-biggest-corporate-donor-to-the-2024-presidential-race/

Journal reported on internal documents showing that former FDA Commissioner Makary had concerns about the public health risks of authorizing flavored products that appeal to children.[6] Further, the *New York Times* recently reported that Dr. Makary "ultimately resigned over concerns about the administration's decision to authorize fruit-flavored e-cigarettes, an action he opposed."[7] This adds to the mounting evidence that potential political conflicts of interest led FDA to approve these dangerous products rather than impartial science and public health considerations, as required by the law. Trust is a key component of public health, and these actions erode public trust—threatening lives and risking Americans' confidence in our public health agencies.

FDA justified its approval of these dangerous products by claiming that the use of "device access restriction (DAR) technology" will mitigate the risk to young people. However, just two months ago, FDA issued draft guidance stating that there is a "current lack of real-world experience regarding use of DAR to prevent or sufficiently mitigate the risk of youth use."[8] Relying on unproven technology – technology that FDA itself said is likely insufficient to protect children – in justifying its approval of these products[9] is not just hypocritical, but foolish and extremely dangerous.

The harmful impact of this decision is compounded by President Trump's efforts to dismantle tobacco prevention and cessation programs. This includes attempts to eliminate the Centers for Disease Control and Prevention's (CDC) Office on Smoking and Health (OSH), which is essential to preventing youth tobacco use[10] and a key source of federal funding for state quitlines[11] and the Tips From Former Smokers educational campaign that help adult tobacco users with cessation,[12] causing an upheaval at FDA's Center for Tobacco Products by terminating —and then later reinstating—staff responsible for levying fines on retailers that sold tobacco to minors,[13]and cutting research at the National Institutes of Health, including a grant that sought to determine the most effective messages to persuade teenagers not to vape.[14] Taken together, these

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[6]Essley Whyte, Liz. "White House Pushes for Flavored Vapes Blocked by FDA Head." The Wall Street Journal. April 17, 2026. https://www.wsj.com/politics/policy/white-house-pushes-for-flavored-vapes-blocked-by-fda-head-2f8f0138?mod=article_inline

[7]Jewett, Christina. "F.D.A. Commissioner Marty Makary Resigns After Weeks of Pressure." The New York Times. May 12, 2026. https://www.nytimes.com/2026/05/12/us/politics/trump-fires-fda-commissioner-makary.html

[8]"Flavored Electronic Nicotine Delivery Systems (ENDS) Premarket Applications – Considerations Related to Youth Risk." Draft Guidance for Industry. U.S. Food and Drug Administration. March 2026. https://www.fda.gov/media/191455/download

[9]"FDA Expands Market Access, Authorizes New ENDS Products." U.S. Food and Drug Administration. May 5, 2026. https://www.fda.gov/news-events/press-announcements/fda-expands-market-access-authorizes-new-ends-products

[10]Dale, Jill. "New Report Details Devastating Impact of Federal Cuts on Lifesaving Tobacco Prevention and Quit Programs. American Lung Association. May 28, 2025. https://www.lung.org/media/press-releases/new-report-details-devastating-impact-of-federal-c

[11]Todd, Sarah. "Why CDC cuts are being called "the greatest gift to tobacco industry in the last half century." STAT News. April 14, 2025. https://www.statnews.com/2025/04/14/cdc-closing-office-smoking-health-called-gift-to-big-tobacco-by-former-osh-director/

[12] "Tips From Former Smokers." U.S. Centers for Disease Control and Prevention. March 31, 2025. https://www.cdc.gov/tobacco/campaign/tips/index.html

[13]Cancryn, Adam and Gardner, Lauren. "The FDA fired its tobacco enforcers. Now it wants them back." POLITICO. April 14, 2025. https://www.politico.com/news/2025/04/14/fda-fired-tobacco-enforcers-asked-return-00289985

[14]Jewett, Christina. "Trump Budget Cuts Hobble Antismoking Programs." The New York Times. May 15, 2025. https://www.nytimes.com/2025/05/15/health/trump-budget-cuts-anti-smoking-tobacco.html

actions significantly impair the ability to protect youth from Big Tobacco's predatory practices and will likely lead to a renewed surge in youth use of flavored tobacco products.

In order to protect public health and restore faith in the scientific integrity of the FDA, we request responses to the following questions by June 1, 2026:

1. Please provide a detailed description of policies at the Center for Tobacco Products regarding the ability of political appointees to modify or overrule the conclusions of career scientists regarding the approval of new product applications.
2. Please provide a list of all political appointees at the agency who were involved in the decision to approve Glas, Inc.'s application for flavored e-cigarettes.
3. Please describe agency practices for the involvement of career agency employees who form part of a new product review team at the Center for Tobacco Products are part of final approval decisions for that product. Were any career agency employees who were part of the review team for the Glas, Inc. application but subsequently excluded from the final approval decision?
4. What evidence convinced the agency that the benefits of authorizing mango- and blueberry-flavored products outweighed the risk of addicting more children? What evidence came to light after former Commissioner Makary blocked the authorization of fruit flavored vapes as reported by *The Wall Street Journal* in April?
    a. Will FDA make public the marketing granted orders (MGOs) and Technical Project Lead Review decision summaries for the GLAS, Inc. authorizations, as it has done for other authorized products?
5. Does FDA still believe fruit-flavored e-cigarettes require a heightened evidentiary burden because of their appeal to youth? Please provide a detailed description of the ways the application from Glas, Inc. differed from those of flavored e-cigarette applications the agency had recently rejected.
6. Did FDA consider other youth mitigation factors in addition to the device access restriction (DAR) technology when authorizing two fruit-flavored e-cigarette products?
    a. In March 2026, FDA issued draft flavored e-cigarette PMTA guidance acknowledging that there is little real-world evidence demonstrating that DAR technology works at scale, particularly for products with high youth appeal. Please provide a detailed explanation for why DAR technology is adequate for the approved products of Glas Inc. but inadequate for other previously rejected flavored products.
    b. What specifically is FDA's post-market surveillance plan for these products and this DAR technology?

c. How frequently will FDA publicly release post-market surveillance data so Congress, public health experts, and parents can evaluate whether these products are in fact meeting public health standards?

7. Why did FDA choose to authorize these Glas Inc. products before finalizing its flavored e-cigarette PMTA guidance?

8. FDA has repeatedly suggested that authorizing e-cigarettes is about giving adults who smoke cigarettes alternatives, but FDA has never approved any e-cigarettes as a smoking cessation product. Dual use of both e-cigarettes and cigarettes has not been proven to meaningfully reduce one's risk of tobacco-related disease and may in fact result in greater exposure to toxins and worse respiratory health outcomes than using either product alone. What evidence does FDA have that these products help people to quit smoking completely, rather than leading to long-term dual use?

Thank you. We look forward to your response.

Sincerely,

Richard Blumenthal
United States Senator

Jeffrey A. Merkley
United States Senator

Edward J. Markey
United States Senator

Tammy Baldwin
United States Senator

Richard J. Durbin
United States Senator

Mazie K. Hirono
United States Senator

Jack Reed
United States Senator

Elizabeth Warren
United States Senator

Tammy Duckworth
United States Senator

Cory A. Booker
United States Senator