United States Senate

WASHINGTON, DC 20510

July 28, 2025

Martin A. Makary, MD, MPH
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

Dear Commissioner Makary:

We write with alarm over the FDA's marketing granted orders to JUUL's e-cigarettes, including its menthol-flavored vaping pods. As you know, JUUL is the e-cigarette brand that ignited the youth vaping "epidemic"—as it was characterized by Dr. Scott Gottlieb, your predecessor in the first Trump Administration—and is responsible for addicting millions of children to nicotine, many of whom would have never picked up a cigarette.

The *Family Smoking Prevention and Tobacco Control Act* (TCA) sets a high bar for authorizing a premarket tobacco product application (PMTA) for a new tobacco product, by placing the burden on manufacturers to demonstrate that the product is "appropriate for the protection of public health." This statutory standard precludes FDA from authorizing a PMTA for a new tobacco product unless the manufacturer can prove such product will help current tobacco users to quit and that those benefits exceed the risks of youth initiation and harm.

For years, on a bipartisan basis, United States Senators have urged FDA to consider in its PMTA review: a tobacco product's history of addicting children, use of flavors to appeal to youth, perceptions among youth, and the role of nicotine in increasing risk of addiction. JUUL's shameful history and evidence of its appeal to youth over the past decade should have been disqualifying. Perhaps you are unaware of JUUL's history of targeting children with deceptive marketing to addict them on vaping products, but families across America know the harms.

JUUL has a documented history of lying about the addictiveness of their e-cigarette products and targeting children, including through outrageous programs under which JUUL paid local schools to offer so-called vaping education programs—with no teachers present—and falsely telling students that e-cigarettes were "totally safe." JUUL has reached settlement agreements with states totaling more than $1.1 billion over these misleading promotions, including a $438.5 million settlement in 2022 with 32 states and Puerto Rico, and a $462 million settlement in 2023 with six states and the District of Columbia.

FDA denied JUUL's PMTA in 2022, before staying that denial and placing it back into scientific review in June 2024. All that time, JUUL continued to unlawfully sell its product to children, despite FDA stating in an answer to a Question for the Record from the June 12, 2024, Judiciary Committee hearing entitled "*Combatting the Youth Vaping Epidemic by Enhancing Enforcement Against Illegal E-Cigarettes*," that, "The Agency's continued review does not constitute authorization to market, sell, or ship JUUL products." Yet, according to the 2024

National Youth Tobacco Survey, JUUL remains among the top five most popular e-cigarette products among children.

Related to this reversal, we are deeply troubled by the appearance of conflicts of interest between the Trump Administration and the e-cigarette industry in the United States. For example, President Trump's former counselor for public health and science now leads JUUL's federal lobbying operation. Beyond JUUL, tobacco companies Swisher International and Reynolds American—the nation's second-largest tobacco company—were both clients of White House Chief of Staff Susie Wiles' lobbying firm. The *Washington Post* ran a headline in September 2024 stating, "Trump vows to save vaping after private meeting with vaping lobbyist." After the meeting, Trump issued a statement claiming that he, "saved flavored vaping in 2019…[and] I'll save vaping again."

Similarly, Department of Health and Human Services Secretary Kennedy recently testified that, "U.S. vaping companies, in my view, are acting very responsibly… putting chips in their vapes that make sure young people could not use them." JUUL submitted an application in December 2023 to FDA for a product with similar such age-related technology. There is no FDA-validated evidence of the effectiveness of JUUL's age-related technology, which remains pending in a separate application. However, in addition to celebrating a product that is not legally sold in the United States, Secretary Kennedy's statement could have been interpreted to be putting his thumb on the scale for JUUL's pending application.

Based upon this troubling history and the risk to public health from this recent FDA decision, we request responses to the following questions by August 22, 2025. Given this Administration's stated priority of "radical transparency", we trust that detailed and complete responses will be provided.

1. FDA issued a marketing denial order to JUUL on June 23, 2022, for its premarket tobacco product application, on the basis that it "lacked sufficient evidence" to demonstrate that the company's e-cigarette was appropriate for the protection of public health. Please explain in detail how JUUL remedied its PMTA such that it merited authorization.

2. Did FDA consider the history of youth use associated with JUUL's e-cigarette products (including based upon historical National Youth Tobacco Survey data) in the agency's evaluation of whether the product met the appropriate for the protection of public health standard?
    a. If so, please explain how, given this history—including JUUL having been the most popular brand e-cigarette used by children—FDA reached the conclusion that authorization was appropriate for the protection of public health.

3. Did FDA consider the history of misleading promotion of JUUL's e-cigarette products (as documented in settlements involving 48 states, territories, and Washington, DC), including the repository of internal JUUL documents made available through such state investigations and settlements, in the agency's evaluation of JUUL's marketing plans as

it relates to whether the product met the appropriate for the protection of public health standard?

   a. If so, please explain how, given this history, FDA reached the conclusion that authorization was appropriate for the protection of public health.

4. Did FDA consider the history of its prior enforcement action against JUUL, through its September 2019 warning letter for marketing unauthorized modified risk tobacco products, including in outreach to youth, in the agency's evaluation of whether JUUL's product met the appropriate for the protection of public health standard?
   a. If so, please explain how, given this history, FDA reached the conclusion that authorization was appropriate for the protection of public health.

5. In its decision memo, FDA states that, "advertising and promotion restrictions … cannot mitigate the substantial risk to youth from flavored ENDS sufficiently to reduce the magnitude of adult benefit required to demonstrate APPH. Rather, for flavored ENDS, only the most stringent mitigation measures – specifically device access restrictions – have such mitigation potential. These PMTAs do not propose device access restrictions." Because JUUL's menthol-flavored pod lacks device access restrictions, which the agency concluded are necessary to overcome the role of flavors (including menthol) in addicting children, how did FDA justify authorizing JUUL's menthol-flavored pod?

6. To the extent permissible by law, please provide all correspondence between JUUL, any of its representatives, and FDA between January 20, 2025, and July 17, 2025.

7. Please provide all studies, scientific materials, and marketing information submitted by JUUL, and any of its representatives, redacted as appropriate by law, to FDA between January 20, 2025, and July 17, 2025.

8. Please provide a de-identified list with the number of all FDA employees in the Center for Tobacco Products, Office of the Chief Counsel, and Office of the Commissioner who have ever worked on JUUL's application in any capacity and have separated from the agency (through any mechanism) after January 20, 2025. For each such de-identified individual counted, please note their job function, the date of their separation, and the manner through which they departed the agency.

Thank you for your attention to this matter. We look forward to your timely response.

Sincerely,

Richard J. Durbin
United States Senator

Richard Blumenthal
United States Senator

Tammy Baldwin
United States Senator

Edward J. Markey
United States Senator

Jeffrey A. Merkley
United States Senator

Jack Reed
United States Senator

Ron Wyden
United States Senator

Elizabeth Warren
United States Senator