MITT ROMNEY
UTAH

COMMITTEES
FOREIGN RELATIONS
HEALTH, EDUCATION, LABOR, AND PENSIONS
HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS
SMALL BUSINESS AND ENTREPRENEURSHIP

United States Senate

SR-124
RUSSELL BUILDING
WASHINGTON, DC 20510

125 S. STATE STREET
#8402
SALT LAKE CITY, UT 84138

February 13, 2020

Mr. Mitch Zeller
Director
Center for Tobacco Products
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Director Zeller,

We appreciate the Food and Drug Administration's and the Center for Tobacco Products' effort to address the national youth vaping epidemic. However, the Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization, ("January Guidance") falls short of the Agency's responsibility to protect the public health and to reduce tobacco use by minors.

Data from the 2019 National Youth Tobacco Survey, which the Guidance heavily relies on, shows roughly 5 million young people tried e-cigarettes in the past 30 days, and an increasing number of middle- and high-schoolers are becoming regular users. Yet, despite mounting evidence that flavors are a key driver of youth ENDS use, the January Guidance has glaring policy gaps that keep kids addicted to flavored products.

As FDA is in the early stages of implementing the January Guidance, we write to express our deep concerns on devices, flavor requirements, and the Premarket Tobacco Product Applications process, and urgently request answers to the following questions.

Devices.

The January Guidance prohibits the sale of flavors in any *cartridge-based* electronic nicotine delivery system product, except tobacco and menthol. The Guidance cites the design attributes of cartridge-based ENDS as a reason for youth appeal, including a "relatively small size that allows for easy concealability, and intuitive and convenient features that facilitate ease of use."[1] Further, FDA finds small products may allow youth to use the product in circumstances where the use of tobacco products is prohibited, such as school.[2]

However, these attributes are not exclusive to cartridge-based ENDS products, as shown in Exhibits A and B (see: Appendix), and, it's devices such as Exhibits A and B that are gaining popularity with young people. The January Guidance is limited to one out of 14 ENDS products FDA lists on its website (Exhibit C).

---

[1] Food and Drug Administration. "Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization." Available at https://www.fda.gov/media/133880/download. P. 16-17.
[2] Ibid.

Additionally, the January Guidance relies heavily on two data-limited surveys the: National Youth Tobacco Survey and Monitoring the Future. NYTS did not ask about disposable ENDS until 2019; and MTF does not ask at all about disposable ENDS. Yet our state departments of health and constituents find youth use of disposable products and sleek e-liquid-based pens is growing in popularity.

Flavors.

The January Guidance exempts tobacco- and menthol-flavored products from the temporary flavor ban, and it does not temporarily ban any flavors for disposables or e-liquids.

In a November 13, 2019 Health, Education, Labor & Pensions Committee Hearing on rising youth e-cigarette use, Centers for Disease Control & Prevention Principal Deputy Director Dr. Anne Schuchat testified the use of mint/menthol flavored products increased after JUUL removed candy flavors from the market. CDC believes youth are likely to use whatever flavor is left on the market. Further, CDC does not know if kids are even able to differentiate between menthol and mint flavors.[3]

A 2019 FDA/CDC study of e-Cigarette Use Among Youth in the United States tracked flavor trends for high school students, and found a significant increase in the use of mint or menthol flavored products since 2017. Conversely, fruit declined since 2018 and candy/dessert, and chocolate declined since 2017.[4]

The Federal Food Drug & Cosmetic Act provides FDA authority to establish tobacco product standards, if the Secretary finds a tobacco product standard is appropriate for the protection of public health, including, where appropriate, provisions for nicotine yields.[5] FDA acknowledges recent data show an alarming increase in youth use of ENDS products in the past two years, particularly flavored ENDS.

It is critical to the protection of youth health and safety that we prepare for their migration to menthol-flavored ENDS. We encourage FDA to add menthol-flavored ENDS to the temporary flavor ban for cartridge-based ENDS and apply the temporary flavor ban, including menthol, to disposables and e-liquids.

May 12, 2020, Deadline for Premarket Tobacco Product Applications (PMTA).

We have significant concerns about the limitations of the January Guidance after the May 12, 2020 submission deadline.

The PMTA process allows for the possibility that an ENDS manufacturer may submit an application for a non-tobacco non-menthol flavored product, and that FDA may approve that application, which would allow flavors back on the market.

---

[3] Health, Education, Labor & Pensions Committee Hearing. Examining the Response to Lung Illness and Rising Youth Electronic Cigarette Use. Accessible at https://www.help.senate.gov/hearings/examining-the-response-to-lung-illnesses-and-rising-youth-electronic-cigarette-use

[4] Cullen, KA, Gentzke AS, Sawdey MD, et al. e-Cigarette Use Among Youth in the United States, 2019. *JAMA*. 2019.Accessible at doi:10.1001/jama.2019.18387.

[5] 21 U.S.C. § 378g. Accessible at https://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title21-section387g&num=0&edition=prelim

Additionally, there has been no indication from FDA whether a public list will be available beginning May 13, 2020 indicating which manufacturers have complied with the May 12 application submission deadline. We urge FDA to publish a list of deadline-compliant manufacturers so that the public can be informed about which products are legally allowed to remain on the market until product applications have been reviewed.

FDA should report to Congress and to the public any new findings related to these questions, and other matters regarding the youth vaping epidemic. We appreciate your attention and look forward to your prompt response to the following questions:

1. Why does the January Guidance exclude disposables and e-liquid ENDS products from the temporary flavor ban?

2. Did FDA consider temporarily banning flavors for disposables and small-milliliter e-liquids for vape pens, which meet FDA's own characterization of the types of products that appeal to youth?

3. What supplemental data is required to implement a temporary flavor ban for disposables and small-milliliter e-liquids, which appeal to youth?

4. How will FDA monitor product migration from cartridge-based ENDS to disposables and/or small e-liquid ENDS, where kids can maintain a flavor fix?

5. How will FDA monitor flavor migration to menthol from mint in cartridge-based ENDS? If data depict a flavor migration, will FDA consider a temporary menthol ban?

6. Has FDA considered issuing product standards that significantly limit or remove nicotine yields in flavored products, particularly for the most youth-appealing products?

7. Will FDA conduct additional surveys, or release quarterly updates, of either the NYTS or MTF survey? Will the 2020 surveys account for rapidly changing preferences of young people?

8. Has FDA considered extending January Guidance temporary flavor ban through at least one full year of NYTS and/or MTF survey data, irrespective of the PMTA process?

9. In reviewing PMTAs, how will FDA balance "safe and appropriate for the protection of public health" with manufacturer-derived data on flavor safety?

10. Will FDA triage and prioritize reviewing PMTAs of products known to appeal to youth, including disposables and smaller e-liquid-based ENDS products?

Sincerely,

Mitt Romney
United States Senator

Margaret Wood Hassan
United States Senator

Lisa Murkowski
United States Senator

Tom Udall
United States Senator

Susan M. Collins
United States Senator

Jeffrey A. Merkley
United States Senator

Appendix

Exhibit A. Puff disposable vape pens, sleek, easy to conceal, flavors permitted.[6]

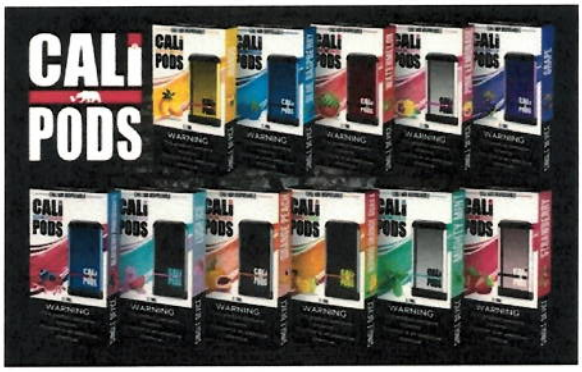

Exhibit B. Innokin Endura vape pens, small-milliliter e-liquid capacity, flavors permitted.[7]

Exhibit C. FDA's profile of types of ENDS products.[8]

[6] Puff, Cali Pods Air Disposable Pod Device. Accessible at: https://puffecig.com/cali-pods-air-disposable-pod-device/#description
[7] Element Vape, Innokin Endura T18 II Starter Kit. Accessible at: https://www.elementvape.com/innokin-endura-t18-ii-starter-kit
[8] Food and Drug Administration, Tobacco Products. Available at https://www.fda.gov/tobacco-products/products-ingredients-components/vaporizers-e-cigarettes-and-other-electronic-nicotine-delivery-systems-ends