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August 30, 2021

Dr. Janet Woodcock
Acting Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Acting Commissioner Woodcock:

I am writing about the recent Food and Drug Administration (FDA) decision to bar the sale of certain flavored e-cigarette products.[1] This marks the first time that FDA has refused to approve a Premarket Tobacco Product Application (PMTA), which e-cigarette makers must receive in order to continue selling their products.

Your decision removes these several flavored products from the market and is a step in the right direction to protect American public health and curb the youth vaping epidemic.

In announcing your decision, however, you distinguished menthol from the other kid-friendly flavors, stating:

> The scientific review of menthol ENDS [Electronic Nicotine Delivery System], as compared to other non-tobacco-flavored ENDS products, raises unique considerations. Although menthol-flavored ENDS are not included in the decisions described above, the FDA notes that its reviews will similarly examine whether the evidence in the application demonstrates a benefit to existing adult users that outweighs the known youth use of such products.[2]

I hope that this statement is not an indication that FDA is still considering granting PMTAs for menthol-flavored e-cigarettes, a decision that would have a catastrophically negative impact on youth public health and safety. As you consider whether or not to approve the continued sale of any menthol-flavored product, I will respectfully remind you of your strong statements on the public record with respect to the harms of menthol-flavored e-cigarettes on teen use and addiction. On June 23, 2021, you testified before the Subcommittee, making it clear

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[1] Food and Drug Administration, *News Release: FDA Denies Marketing Applications for About 55,000 Flavored E-Cigarette Products for Failing to Provide Evidence They Appropriately Protect Public Health* (Aug. 26, 2021) (online at www.fda.gov/news-events/press-announcements/fda-denies-marketing-applications-about-55000-flavored-e-cigarette-products-failing-provide-evidence?utm_medium=email&utm_source=govdelivery).

[2] *Id.*

that any "unique consideration" related to menthol makes menthol *more dangerous* than other kid-friendly flavors. You testified that:

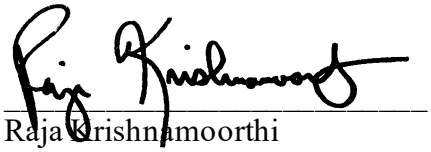
- using menthol in e-cigarettes is "like having a higher concentration of nicotine in your delivery system,"
- "menthol heightens the addictiveness of nicotine in e-cigarettes," and
- menthol "makes it harder to stop vaping."

And you agreed that "any flavor of e-cigarette left on the market is likely to encourage youth to start vaping."[3]

Your statements reflect an understanding of current science and the pernicious consequences flavored vaping products have on our nation's children. I urge FDA to heed the science and protect children. I look forward to reviewing your PMTA decisions in the days to come.

The Committee on Oversight and Reform is the principal oversight committee of the House of Representatives and has broad authority to investigate "any matter" at "any time" under House Rule X. If you have any questions regarding this request, please contact Subcommittee staff at (202) 225-5051.

Sincerely,



Raja Krishnamoorthi
Chairman
Subcommittee on Economic and Consumer Policy

cc: The Honorable Michael Cloud, Ranking Member
Subcommittee on Economic and Consumer Policy

[3] Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, *Press Release: Subcommittee Hearing Offers Insight into Future of E-Cigarette Regulation* (June 23, 2021) (online at https://oversight.house.gov/news/press-releases/subcommittee-hearing-offers-insight-into-future-of-e-cigarette-regulation).