United States Senate

WASHINGTON, DC 20510

September 24, 2021

Dr. Janet Woodcock
Acting Commissioner of Food and Drugs
United States Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993, United States

Dear Commissioner Woodcock,

We write you to express concern about the recent actions taken by the Food and Drug Administration (FDA) regarding electronic nicotine delivery system (ENDS) products. While we applaud the decision to pull more than 5 million of these products from shelves, we are dismayed at the delay in issuing a decision on Premarket Tobacco Product Applications (PMTAs) representing companies with the largest market shares.[1] The FDA has also failed to provide clear guidance on menthol-flavored ENDS products, which make up an increasingly large share of e-cigarette sales.[2] We request a staff briefing and ask that you provide a timeline for issuing decisions on the remaining PMTAs and guidance on the sale of menthol-flavored ENDS products.

Studies have clearly demonstrated the risk that ENDS products pose to young people, including increasing the likelihood of future consumption of cigarettes.[3] In response to this risk, your agency was given one year to determine whether these products provided more public health benefit than harm to youth, including whether they were safe for smokers and unappealing

[1] U.S. Food and Drug Administration (FDA). FDA Statement. FDA Makes Significant Progress in Science-Based Public Health Application Review, Taking Action on Over 90% of More Than 6.5 Million 'Deemed' New Tobacco Products Submitted. (September 9, 2021) https://www.fda.gov/news-events/press-announcements/fda-makes-significant-progress-science-based-public-health-application-review-taking-action-over-90 ; Richtel, Matt. New York Times. F.D.A. Delays Decision on Juul's E-Cigarettes but Orders Others Off the Market. (September 9, 2021) https://www.nytimes.com/2021/09/09/health/fda-e-cigarettes-vaping.html

[2] Diaz, Megan et al. Tobacco Control. Menthol e-cigarette sales rise following 2020 FDA guidance. (September 23, 2020) https://tobaccocontrol.bmj.com/content/early/2020/09/23/tobaccocontrol-2020-056053

[3] Centers for Disease Control and Prevention (CDC). Quick Facts on the Risks of E-cigarettes for Kids, Teens, and Young Adults. https://www.cdc.gov/tobacco/basic_information/e-cigarettes/Quick-Facts-on-the-Risks-of-E-cigarettes-for-Kids-Teens-and-Young-Adults.html; U.S. Department of Health and Human Services (HHS). Office of the Surgeon General. E-Cigarette Use Among Youth and Young Adults: A Report of the Surgeon General. (2016) https://www.cdc.gov/tobacco/data_statistics/sgr/e-cigarettes/pdfs/2016_sgr_entire_report_508.pdf

to children.[4] Despite reassurances that the FDA would prioritize firms with the largest market share,[5] your agency failed to meet its court-ordered deadline and delayed action on PMTAs from several companies associated with the youth e-cigarette epidemic.[6]

Further, your agency has yet to provide clear guidance on menthol-flavored e-cigarettes. After the FDA's harmful decision to exclude menthol-flavored e-cigarettes from restrictions on flavoring in 2020,[7] the sale of these products increased drastically.[8] In a recent announcement, the FDA stated that the scientific review of menthol-flavored ENDS products raised "unique considerations," [9] and we are concerned that the FDA will continue to overlook the risk of these products to youth. The April 2021 decision to issue product standards to ban menthol as a characterizing flavor in cigarettes and cigars is a step in the right direction.[10] The FDA must also take strong action on menthol flavoring in ENDS products in order to curb the youth vaping epidemic.

Your agency's failure to issue a timely decision on all PMTAs and its failure to provide clarity on menthol ENDS products have placed young people at continued risk of exposure to harmful products and dangerous marketing techniques. In fact, in 2020, nearly 20% of high school students and 5% of middle school students reported using e-cigarettes, with mint and menthol flavors being consumed by 56% and 37% of young flavored e-cigarette users, respectively.[11] To increase transparency on the agency's progress towards removing these harmful products from the market, we request a staff briefing and a response to the following questions by October 8, 2021:

1) What is FDA's timeline for issuing decisions on the remaining PMTAs for ENDS products? Please provide an outline of the plan.
2) How does the FDA plan to evaluate the PMTAs for menthol-flavored ENDS products given their harmful impact on youth?

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[4] Foley, Katherine Ellen. Politico. FDA says more than 5 million electronic cigarettes must be taken off the market. (September 9, 2021) https://www.politico.com/news/2021/09/09/fda-electronic-cigarettes-off-market-510967
[5] Id.
[6] Vallone, Donna et al. JAMA Pediatrics. Electronic Cigarette and JUUL Use Among Adolescents and Young Adults. (January 21, 2020). https://jamanetwork.com/journals/jamapediatrics/fullarticle/2759022
[7] FDA. FDA News Release. FDA finalizes enforcement policy on unauthorized flavored cartridge-based e-cigarettes that appeal to children, including fruit and mint. (January 2, 2020) https://www.fda.gov/news-events/press-announcements/fda-finalizes-enforcement-policy-unauthorized-flavored-cartridge-based-e-cigarettes-appeal-children
[8] Diaz, Megan et al. Tobacco Control. Menthol e-cigarette sales rise following 2020 FDA guidance.
[9] FDA. FDA Statement. FDA Denies Marketing Applications for About 55,000 Flavored E-Cigarette Products for Failing to Provide Evidence They Appropriately Protect Public Health. (August 26, 2021) https://www.fda.gov/news-events/press-announcements/fda-denies-marketing-applications-about-55000-flavored-e-cigarette-products-failing-provide-evidence
[10] FDA. FDA News Release. FDA Commits to Evidence-Based Actions Aimed at Saving Lives and Preventing Future Generations of Smokers. (April 29, 2021). https://www.fda.gov/news-events/press-announcements/fda-commits-evidence-based-actions-aimed-saving-lives-and-preventing-future-generations-smokers
[11] CDC. Morbidity and Mortality Weekly Report (MMWR). E-cigarette Use Among Middle and High School Students — United States, 2020. (September 18, 2020) https://www.cdc.gov/mmwr/volumes/69/wr/mm6937e1.htm

3) How will the FDA ensure that products not authorized for sale are not marketed unlawfully?
    a. In particular, what will you do to enforce the removal of new products on the market without the statutorily required premarket authorization?
    b. How will you ensure the removal of products that received Marketing Denial Orders (MDOs)?

Thank you for your continued efforts to protect youth from harmful ENDS products, and we look forward to your timely response.

Sincerely,

Tim Kaine
United States Senator

Mitt Romney
United States Senator