

United States Senate
WASHINGTON, DC 20510

December 5, 2018

The Honorable Scott Gottlieb, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Gottlieb,

We write in response to your November 15, 2018 announcement on steps the Food and Drug Administration (FDA) is taking to combat youth tobacco use. We appreciate the steps FDA announced to reduce youth access to some flavored e-cigarettes, but we urge the agency to take additional, stronger steps to prevent and reduce e-cigarette use among youth. We also applaud the decision to pursue a ban on flavored cigars and menthol cigarettes, products that we know disproportionately impact youth, and urge FDA to act swiftly to undergo and complete a rulemaking process to remove these products from the market.

The evidence is clear that flavored e-cigarettes are having a dramatic and harmful impact on our youth. The recent rise in the use of e-cigarette products has reversed years of progress made by youth smoking prevention efforts.¹ New findings from the Centers for Disease Control and Prevention's (CDC) and FDA's National Youth Tobacco Survey (NYTS) showed that the number of current e-cigarette users increased a staggering 78 percent among high school students and 48 percent among middle school students between 2017 and 2018.² In 2018, 3.6 million middle and high school students are considered users of e-cigarette products, and one in five high school students reported using an e-cigarette product in the past 30 days.³ Of high school e-cigarette users, nearly 68 percent use flavored products.⁴ And the number of high school students who use e-cigarettes regularly (e.g., 20 or more times a month) is growing, raising concerns that more youth are becoming addicted to nicotine.⁵

The November 15 announcement outlined steps FDA intends to take to limit the sale of most flavored e-cigarettes to age-restricted retail settings and websites with "heightened" age

¹ Wang, Teresa W et al. "Tobacco Product Use Among Middle and High School Students - United States, 2011-2017" *MMWR. Morbidity and mortality weekly report* vol. 67,22 629-633. 8 Jun. 2018, doi:10.15585/mmwr.mm6722a3

² Cullen KA, Ambrose BK, Gentzke AS, Apelberg BJ, Jamal A, King BA. *Notes from the Field: Use of Electronic Cigarettes and Any Tobacco Product Among Middle and High School Students — United States, 2011–2018.* *MMWR Morb Mortal Wkly Rep* 2018;67:1276–1277. DOI: <http://dx.doi.org/10.15585/mmwr.mm6745a5>.

³ *ibid*

⁴ *ibid*

⁵ *ibid*

verification practices and combat the marketing of e-cigarettes to kids. This announcement comes more than a year after FDA delayed key compliance deadlines for e-cigarettes, cigars, hookah, and pipe tobacco, including for products that contain kid-appealing flavors and are actively marketed to children. While we are glad you acknowledge that changes must be made to counter the epidemic of youth e-cigarette use, we are concerned that the recently announced steps are insufficient to turn the tide on the extreme increase in youth use of e-cigarettes or the impacts of the agency's previous delays. In particular, we are concerned that by excluding mint and menthol products – which are used by more than half of youth e-cigarette users – the updated policy overlooks two popular flavors used by youth.⁶ We are also concerned by the lack of detail regarding the age restrictions that physical and online retailers will be required to follow and FDA's plan for assessing whether these requirements are truly preventing youth from accessing the restricted products.

We are encouraged by FDA's decision to seek a ban on menthol cigarettes and flavored cigars; it is an important step that has the potential to save countless lives and protect youth across the country. These products clearly appeal to youth – more than half of youth smokers ages 12 to 17 smoke menthol cigarettes.⁷ As indicated in the November 15 statement, menthol flavoring “serves to mask some of the unattractive features of smoking that might otherwise discourage a child from smoking.”⁸ Similarly, flavored cigars present a grave threat to young people. Data from 2014 indicate that, of middle and high school students who smoked cigars, 63.5 percent smoked flavored products.⁹ It is well past time to end the marketing of products that so clearly impact the health of our youth, and we urge the agency to act quickly to make good on its commitment to take them off the market once and for all.

It is clear flavored tobacco products are leading to a new generation of youth becoming addicted to nicotine, and we have repeatedly urged the FDA to act swiftly and strongly to end the scourge of youth tobacco use. While the agency's planned actions on menthol cigarettes and flavored cigars would generate substantial public health improvements, we remain concerned the new steps do not go far enough, especially with regard to e-cigarettes. We therefore urge FDA to move quickly to not only ban flavored cigars and menthol cigarettes, but also to end the marketing of all tobacco products to youth and remove all flavored tobacco products, including e-cigarettes, from the market until or unless they have undergone a thorough FDA review that shows they are of benefit to the public health.

⁶ *ibid*

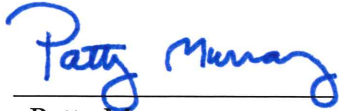
⁷ Villanti AC, Mowery PD, Delnevo CD, *et al.* Changes in the prevalence and correlates of menthol cigarette use in the USA, 2004–2014. *Tobacco Control* 2016;25:ii14-ii20. https://tobaccocontrol.bmj.com/content/25/Suppl_2/ii14

⁸ Statement from FDA Commissioner Scott Gottlieb, M.D., on proposed new steps to protect youth by preventing access to flavored tobacco products and banning menthol in cigarettes, November 15, 2018. <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm625884.htm>

⁹ Centers for Disease Control and Prevention. Flavored Tobacco Product Use Among Middle and High School Students—United States, 2014. *Morbidity and Mortality Weekly Report* 2015;64(38):1066–70 [accessed 2015 Oct 19].

We know we all share the goal of keeping our nation's children safe and healthy, and we look forward to working with you to end youth tobacco use.

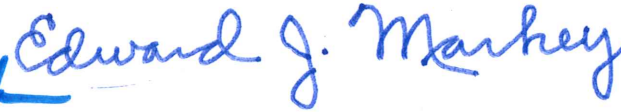
Sincerely,



Patty Murray
United States Senator



Richard J. Durbin
United States Senator



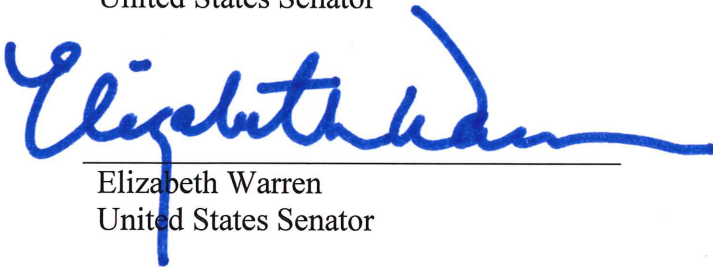
Edward J. Markey
United States Senator



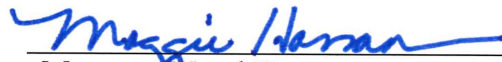
Sheldon Whitehouse
United States Senator



Richard Blumenthal
United States Senator



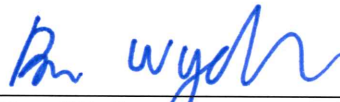
Elizabeth Warren
United States Senator



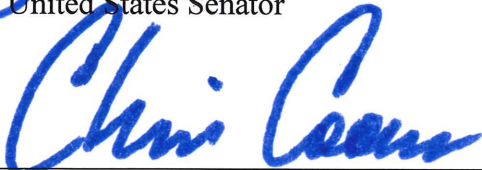
Margaret Wood Hassan
United States Senator



Jack Reed
United States Senator



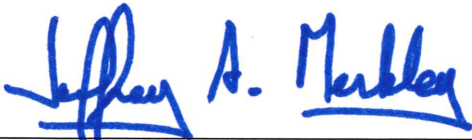
Ron Wyden
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Christopher A. Coons
United States Senator



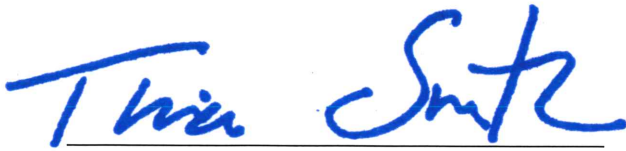
Sherrod Brown
United States Senator



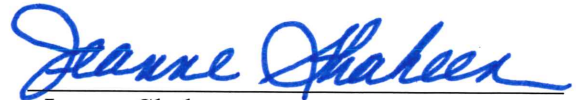
Jeffrey A. Merkley
United States Senator



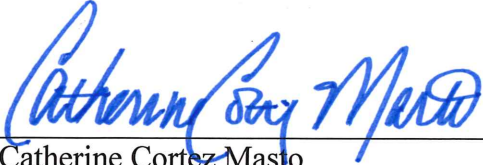
Kirsten Gillibrand
United States Senator



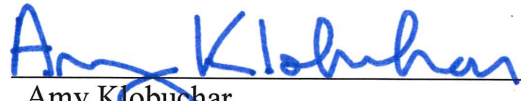
Tina Smith
United States Senator



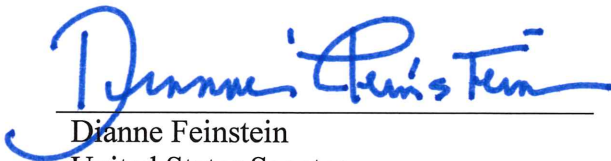
Jeanne Shaheen
United States Senator



Catherine Cortez Masto
United States Senator



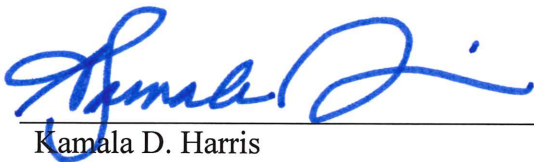
Amy Klobuchar
United States Senator



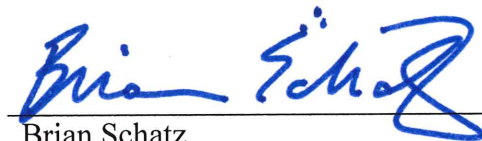
Dianne Feinstein
United States Senator



Tom Udall
United States Senator



Kamala D. Harris
United States Senator



Brian Schatz
United States Senator