

United States Senate

WASHINGTON, DC 20510

October 29, 2019

The Honorable Alex M. Azar II
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Azar,

We write with significant concerns about the continued delay by the Trump Administration in issuing a compliance policy to address the terrible epidemic of e-cigarette use among children. After years of delay and inaction, which fueled this epidemic, the Trump Administration announced on September 11, 2019, that the U.S. Food and Drug Administration (FDA) intended to “finalize a compliance policy in the coming weeks that would prioritize the agency’s enforcement of the premarket authorization requirements for non-tobacco flavored e-cigarettes, including mint and menthol, clearing the market of unauthorized, non-tobacco flavored e-cigarette products.”¹ We have long advocated for this action and were encouraged that the Administration had finally decided to act. As of today, however, the FDA has neither finalized nor announced when it will finalize the compliance policy and is reportedly considering significantly weakening this policy by exempting mint and menthol products, which your agency’s own data have demonstrated are incredibly popular among children.² While the Administration continues to permit the sale of unauthorized, non-tobacco flavored e-cigarette products, each day more children are becoming e-cigarette users – driven primarily by flavors.³ We strongly urge the Administration to fulfill its promise to clear the market of all unauthorized, non-tobacco flavored e-cigarettes – including mint and menthol flavors – immediately.

It is imperative that the Administration promptly finalize the compliance policy. E-cigarette use among children continues to rise at an alarming rate. Approximately 20 percent of high school students reported using e-cigarettes in 2018, which is more than a 75 percent

¹ “Trump Administration Combating Epidemic of Youth E-Cigarette Use with Plan to Clear Market of Unauthorized, Non-Tobacco-Flavored E-Cigarette Products,” Sept. 11, 2019, <https://www.hhs.gov/about/news/2019/09/11/trump-administration-combating-epidemic-youth-ecigarette-use-plan-clear-market.html>.

² “Trump Administration Combating Epidemic of Youth E-Cigarette Use with Plan to Clear Market of Unauthorized, Non-Tobacco-Flavored E-Cigarette Products,” Sept. 11, 2019, <https://www.hhs.gov/about/news/2019/09/11/trump-administration-combating-epidemic-youth-ecigarette-use-plan-clear-market.html>.

³ “Quick Facts on the Risks of E-cigarettes for Kids, Teens, and Young Adults,” *Centers for Disease Control and Prevention*, March 11, 2019, https://www.cdc.gov/tobacco/basic_information/e-cigarettes/Quick-Facts-on-the-Risks-of-E-cigarettes-for-Kids-Teens-and-Young-Adults.html.

increase in use from 2017.⁴ Furthermore, high school students who used e-cigarettes reported using them more often in 2018 than in 2017. E-cigarette use among middle school students increased nearly 50 percent from 2017 to 2018.⁵ This appetite for e-cigarette use by children has been largely fueled by the appeal of non-tobacco flavors such as fruit, candy, and menthol or mint.⁶ There are no recent signs that e-cigarette use by children is decreasing: preliminary data from the 2019 National Youth Tobacco Survey shows a continued rise in youth e-cigarette use.⁷

Although the full scope of the dangers remains uncertain, it is well-known that e-cigarettes pose a serious health risk to youth. On October 11, 2018, the Washington Post published an op-ed by you and then-FDA Commissioner Scott Gottlieb. In it, you acknowledged that “the steps we have taken thus far are not enough,” noting that e-cigarettes have been the most popular nicotine product among American teenagers since 2014; nicotine is highly addictive and can harm brain development; and children who start on e-cigarettes are more likely than non-smoking peers to end up using traditional tobacco products.⁸ You stated you were “actively reconsidering our policy under which certain e-cigarettes — particularly the products with flavors that might appeal to children — can remain on the market”⁹ In the year since, the epidemic has worsened, and we have learned that e-cigarettes are associated with a nationwide outbreak of lung illnesses, some of which have resulted in death.

On September 11, 2019, you joined President Trump, First Lady Melania Trump, and Acting FDA Commissioner Norman Sharpless in the Oval Office to announce your intent to finalize the compliance policy removing unauthorized, non-tobacco flavored e-cigarettes from the market.¹⁰ You stated the Administration’s intent to “clear the market of flavored e-cigarettes to reverse the deeply concerning epidemic of youth e-cigarette use that is impacting children, families, schools and communities,” and Acting Commissioner Sharpless noted that “finalization

⁴ “CDC Vital Signs, Youth Tobacco Use Is Rising: E-cigarettes are the main reason,” Centers for Disease Control and Prevention, Feb. 21, 2019, <https://www.cdc.gov/vitalsigns/youth-tobacco-use/>; “Youth Tobacco Use: Results from the National Youth Tobacco Survey,” U.S. Food and Drug Administration, Center for Tobacco Products, Oct. 8, 2019, <https://www.fda.gov/tobacco-products/youth-and-tobacco/youth-tobacco-use-results-national-youth-tobacco-survey>.

⁵ “Youth Tobacco Use: Results from the National Youth Tobacco Survey,” U.S. Food and Drug Administration, Center for Tobacco Products, Oct. 8, 2019, <https://www.fda.gov/tobacco-products/youth-and-tobacco/youth-tobacco-use-results-national-youth-tobacco-survey>.

⁶ “Trump Administration Combating Epidemic of Youth E-Cigarette Use with Plan to Clear Market of Unauthorized, Non-Tobacco-Flavored E-Cigarette Products,” Sept. 11, 2019, <https://www.hhs.gov/about/news/2019/09/11/trump-administration-combating-epidemic-youth-ecigarette-use-plan-clear-market.html>; “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*, November 16, 2018, https://www.cdc.gov/mmwr/volumes/67/wr/mm6745a5.htm?s_cid=mm6745a5_w.

⁷ “Trump Administration Combating Epidemic of Youth E-Cigarette Use with Plan to Clear Market of Unauthorized, Non-Tobacco-Flavored E-Cigarette Products,” Sept. 11, 2019, <https://www.hhs.gov/about/news/2019/09/11/trump-administration-combating-epidemic-youth-ecigarette-use-plan-clear-market.html>.

⁸ “We cannot let e-cigarettes become an on-ramp for teenage addiction,” *The Washington Post*, October 11, 2018, https://www.washingtonpost.com/opinions/we-cannot-let-e-cigarettes-become-an-on-ramp-for-teenage-addiction/2018/10/11/55ce424e-ccc6-11e8-a360-85875bac0b1f_story.html.

⁹ *Id.*

¹⁰ “Trump Administration Plans to Ban Flavored E-Cigarettes,” *The New York Times*, September 11, 2019, <https://www.nytimes.com/2019/09/11/health/trump-vaping.html>.

of the compliance policy will be an important step in ongoing work to ensure e-cigarettes are not marketed to, sold to, or used by kids.”¹¹

With each day, more children continue to be lured to e-cigarettes by flavors such as fruit, candy, and mint or menthol. We are therefore deeply troubled that there is no final compliance policy more than six weeks after the Oval Office announcement. Instead, the FDA provides assurances that the agency is working “as quickly as possible” to finalize a compliance policy.¹² It is increasingly unclear what the FDA’s final compliance policy will look like.

The Trump Administration is reportedly considering allowing mint and menthol flavors to remain on the market even if and when the FDA does finalize a compliance policy, despite nearly two-thirds of kids who use e-cigarettes using mint and menthol flavored products.¹³ This is unacceptable. The Administration has already delayed action for far too long to address this public health crisis.

Further fueling our concerns, on October 25, 2019, news reports indicated that this reconsideration follows warnings from President Trump’s campaign manager, Brad Parscale, that a policy removing flavored e-cigarettes from the market “could backfire in the 2020 election” and that “Trump supporters who use e-cigarettes could abandon the president if he follows through on a ban.”¹⁴ We are outraged that the President appears to be playing politics with children’s health.

Because of the ever-increasing epidemic of youth e-cigarette use that has been fueled by flavors that include mint and menthol, we implore the Administration to finalize a compliance policy removing all unauthorized, non-tobacco flavored e-cigarettes from the market immediately. It must not bow to industry or political pressure at the expense of the public health. If you have any questions regarding this letter, please contact Andi Lipstein Fristedt with the HELP Committee Staff at (202) 224-7675.

¹¹ “Trump Administration Combating Epidemic of Youth E-Cigarette Use with Plan to Clear Market of Unauthorized, Non-Tobacco-Flavored E-Cigarette Products,” Sept. 11, 2019, <https://www.hhs.gov/about/news/2019/09/11/trump-administration-combating-epidemic-youth-ecigarette-use-plan-clear-market.html>.

¹² “FDA working ‘as quickly as possible’ on e-cigarette flavor ban,” *The Hill*, Oct. 25, 2019, <https://thehill.com/policy/healthcare/467469-fda-working-as-quickly-as-possible-on-e-cigarette-flavor-ban>.

¹³ *Id.*; “Trump Considers Retreat From Ban of Mint and Menthol Vaping Flavors,” *Bloomberg*, Oct. 25, 2019, <https://www.bloomberg.com/news/articles/2019-10-25/trump-considers-retreat-from-ban-of-mint-menthol-vaping-flavors>; “Trump Administration Combating Epidemic of Youth E-Cigarette Use with Plan to Clear Market of Unauthorized, Non-Tobacco-Flavored E-Cigarette Products,” Sept. 11, 2019, <https://www.hhs.gov/about/news/2019/09/11/trump-administration-combating-epidemic-youth-ecigarette-use-plan-clear-market.html>.

¹⁴ “Trump campaign urges White House to soften proposed flavored vape ban,” *The Washington Post*, Oct. 25, 2019, https://www.washingtonpost.com/politics/trump-campaign-urges-white-house-to-soften-proposed-flavored-vape-ban/2019/10/25/5d39dbae-f733-11e9-a285-882a8e386a96_story.html.

Sincerely,



Patty Murray
United States Senator



Richard J. Durbin
United States Senator



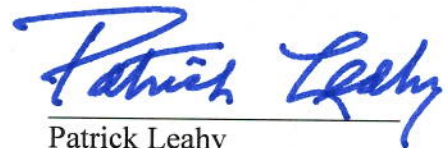
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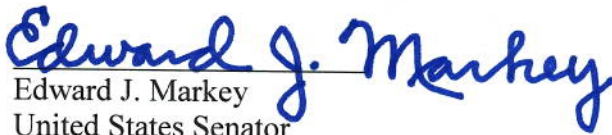
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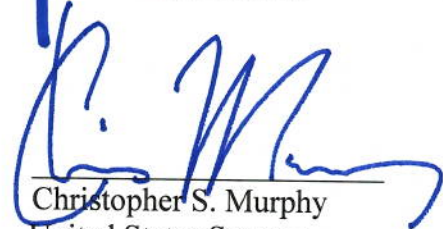
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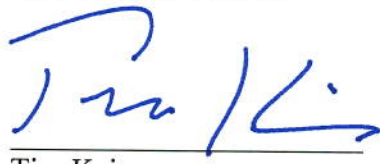



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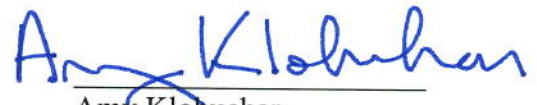

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United States Senator

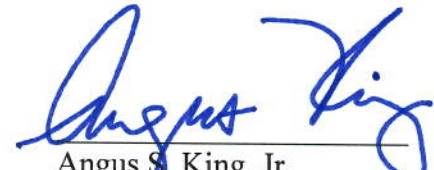

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United States Senator



Tim Kaine
United States Senator

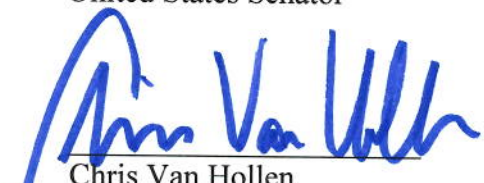

Cory A. Booker
United States Senator

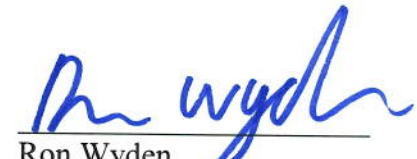

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Mazie K. Hirono
United States Senator

CC: Norman E. Sharpless, MD
Acting Commissioner
Food and Drug Administration