

United States Senate

WASHINGTON, DC 20510

January 13, 2020

The Honorable Stephen M. Hahn, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Dear Commissioner Hahn,

We are deeply disappointed with the Trump Administration's stark reversal from its September 11, 2019 commitment to clear the market of all non-tobacco flavored e-cigarettes.¹ On January 2, 2020, the U.S. Food and Drug Administration (FDA) announced it intends to leave all tobacco- and menthol-flavored electronic nicotine delivery systems (ENDS) and all flavors of e-liquids for "open tank" ENDS on the market. These products have not undergone a scientific review by FDA of their impact on public health. Leaving them on the market will place millions of children at risk of addiction.² As the newly confirmed FDA Commissioner, you have the opportunity – and the obligation – to take meaningful action to address the ongoing youth vaping crisis. FDA's recently announced compliance policy fails to prioritize children, families, and the public health ahead of industry objections. We strongly urge you to abandon this policy and instead implement the proposal President Trump and his Administration promised in September.

E-cigarettes pose a serious health risk to youth. Nicotine is highly addictive and can harm adolescent brain development as well as young lungs, and children who use e-cigarettes are more likely than non-vaping peers to end up using traditional tobacco products. E-cigarettes have been the most popular nicotine product among American teens since 2014, and youth use continues to skyrocket. The appeal of flavors such as fruit, candy, and menthol or mint have largely fueled the skyrocketing rate of use by children of e-cigarettes.³

In recognizing this crisis, the Trump Administration announced on September 11, 2019 that FDA would prioritize enforcement of premarket authorization requirements under the Family Smoking Prevention and Tobacco Control Act for all non-tobacco flavored e-cigarettes, including mint and menthol. In announcing the policy, Health and Human Services (HHS) Secretary Alex Azar said, "the Trump Administration is making it clear that we intend 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. We will not stand idly by as these products become

¹ <https://www.hhs.gov/about/news/2019/09/11/trump-administration-combating-epidemic-youth-ecigarette-use-plan-clear-market.html>

² <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-priorities-electronic-nicotine-delivery-system-ends-and-other-deemed-products-market>

³ <https://jamanetwork.com/journals/jama/fullarticle/2755265?resultClick=1>;
https://www.cdc.gov/mmwr/volumes/67/wr/mm6745a5.htm?s_cid=mm6745a5_w;
<https://www.hhs.gov/about/news/2019/09/11/trump-administration-combating-epidemic-youth-ecigarette-use-plan-clear-market.html>

an on-ramp to combustible cigarettes or nicotine addiction for a generation of youth.”⁴ At your confirmation hearing before the Senate Committee on Health, Education, Labor, and Pensions, you agreed you “do not want to see another generation of Americans become addicted to tobacco and nicotine” and called for “aggressive action” to prevent addiction.⁵ Those of us who have long advocated for strong action were encouraged the Administration had finally decided to take meaningful steps to protect kids.

Public health organizations and families across the country have repeatedly urged the Administration to implement a reasonable, effective policy to clear the market of flavored tobacco products that have not undergone FDA review. Nonetheless, in one of FDA’s first major actions under your leadership, the Trump Administration once again bowed to industry pressure at the expense of public health. The newly announced e-cigarette flavors policy, which represents an alarming reversal from what the Administration promised, is weak and unlikely to have a meaningful impact on e-cigarette use by youth. Under your finalized policy, FDA will enforce the premarket review requirements only for cartridge-based ENDS (such as JUUL products) that are a flavor other than tobacco or menthol. In other words, FDA will continue to allow all menthol-flavored e-cigarettes and all flavored e-liquids used in “open tank” e-cigarettes, including those in fruit and candy flavors, as well as single-use products, to remain on the market even though these products have not undergone an FDA review.

In proposing this approach, you appear to accept the vaping industry’s unsubstantiated claims that flavored e-cigarettes are necessary to reduce harm among adult smokers and ignore the known risk of leaving flavors on the market. In 2018, the National Academies of Sciences, Engineering, and Medicine found “there is general agreement that the number, size, and quality of studies for judging the effectiveness of e-cigarettes as cessation aids in comparison with cessation aids of proven efficacy are limited, and therefore there is insufficient evidence to permit a definitive conclusion at this time.”⁶ At the recent White House meeting President Trump hosted on vaping, Secretary Azar echoed this finding, saying, “[a] lot of statements have been made about e-cigarettes and those as harm-reduction devices. There has been no evidence presented to the FDA to that fact.”⁷ Despite the lack of data showing flavors play a role in reducing harm among adult smokers, and the overwhelming data showing flavors do play a significant role in the current youth epidemic, you have allowed those products to remain on the market. The FDA’s decision to ignore these findings is particularly concerning in light of the fact that, in comments on December 31, the President said the new policy would “protect the industry.”⁸

Moreover, the evidence shows that youth will seek out different flavored e-liquids when their preferred flavor is no longer available. A recent study found that youth use of mint and menthol

⁴ <https://www.hhs.gov/about/news/2019/09/11/trump-administration-combating-epidemic-youth-ecigarette-use-plan-clear-market.html>

⁵ <https://www.help.senate.gov/hearings/nomination-of-stephen-m-hahn-md-to-serve-as-commissioner-of-food-and-drugs>

⁶ National Academies of Sciences, Engineering, and Medicine (2018). *Public Health Consequence of E-Cigarettes* at 579. Washington, DC: The National Academies Press. <https://doi.org/10.17226/24952>.

⁷ <https://www.whitehouse.gov/briefings-statements/remarks-president-trump-listening-session-youth-vaping-electronic-cigarette-epidemic/>

⁸ <https://www.cnn.com/2019/12/31/health/e-cigarette-flavor-ban-fda-trump-bn/index.html>

e-cigarettes rose dramatically after other flavors became unavailable.⁹ Furthermore, there does not appear to be anything stopping manufacturers from rebranding mint flavors as menthol flavors.¹⁰

In your testimony, you assured Congress that you would elevate data-driven decision making above all else; this policy is at odds with that commitment. To better understand the basis for FDA's January 2 announcement, we request answers to the following questions no later than January 27, 2020:

1. In the January 2 announcement, you promised to “closely monitor the use rates of all e-cigarette products and take additional steps to address youth use as necessary.”
 - a. How are you monitoring whether the newly announced policy is reducing rates of e-cigarette use among youth?
 - b. When do you expect to have data on whether the policy is reducing rates of e-cigarette use among youth?
 - c. What additional steps is FDA considering?
2. At a November 13, 2019 hearing before the Senate Committee on Health, Education, Labor, and Pensions, Centers for Disease Control and Prevention (CDC) Principal Deputy Director Anne Schuchat testified that a policy like the one announced January 2 – one that clears the market of some flavors while allowing the sale of others to continue – would likely result in young people simply switching to whatever flavored products remain on the market. Do you agree with Dr. Schuchat's testimony? If not, why not?
3. Menthol remains a popular flavor choice for youth: the 2019 National Youth Tobacco Survey found that 57 percent of high school students and 31 percent of middle school students who are currently using e-cigarettes use menthol and mint flavored e-cigarettes.¹¹ JUUL, the manufacturer of the most popular mint-flavored e-cigarette, is reportedly considering rebranding its mint-flavored pods as a menthol variant.
 - a. How is FDA defining mint and menthol under the January 2 policy?
 - b. Does FDA plan to take action against manufacturers to prevent the relabeling of mint products as menthol?
4. At the recent White House meeting on vaping, Secretary Azar said, “there has been no evidence presented to the FDA” to prove e-cigarettes' effectiveness as harm-reduction devices. Does FDA have any data supporting the claim that e-cigarettes are effective as harm-reduction devices? Please share all data on harm reduction FDA used to inform the January 2 policy.

⁹ https://jamanetwork.com/journals/jama/fullarticle/2755264?guestAccessKey=6cd13a73-46aa-460e-95c7-0cb2d9b666fdf&utm_source=For_The_Media&utm_medium=referral&utm_campaign=ftm_links&utm_content=tf1&utm_term=110519


¹⁰ <https://www.wsj.com/articles/juul-debates-pushing-back-on-e-cigarette-ban-11568327978>

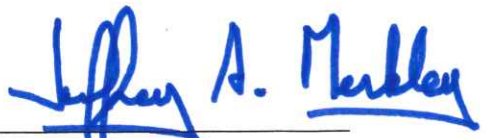
¹¹ <https://www.bloomberg.com/news/articles/2019-11-05/menthol-mint-popular-with-young-vapers-as-white-house-may-ban>

5. Does FDA have any data showing youth will not switch to flavored e-liquids for use with "open tank" ENDS or to menthol-flavored cartridge-based ENDS if their preferred products are no longer available? If so, please share that data.
6. Disposable ENDS come in an array of flavors that appeal to youth. In a footnote, the final guidance states that "completely self-contained, disposable products" are not covered by the guidance's definition of cartridge-based ENDS. What is FDA's rationale for not prohibiting flavors for disposable ENDS?

Thank you in advance for your attention to this matter. If you have any questions, please contact Andi Lipstein Fristedt with Senator Murray's HELP Committee Staff at 202-224-7675.


Sincerely,



Patty Murray
United States Senator


Jeffrey A. Merkley
United States Senator


Edward J. Markey
United States Senator


Sherrod Brown
United States Senator



Richard Blumenthal
United States Senator

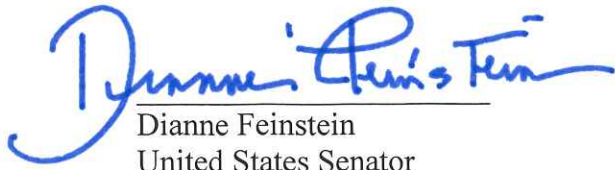

Tammy Baldwin
United States Senator



Kamala D. Harris
United States Senator


Mazie Hirono
United States Senator



Jack Reed
United States Senator

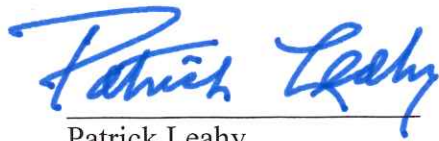

Benjamin L. Cardin
United States Senator



Dianne Feinstein
United States Senator


Sheldon Whitehouse
United States Senator

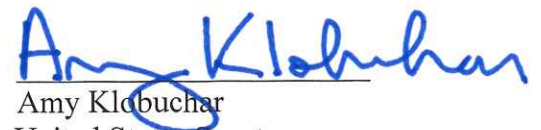

Maria Cantwell
United States Senator

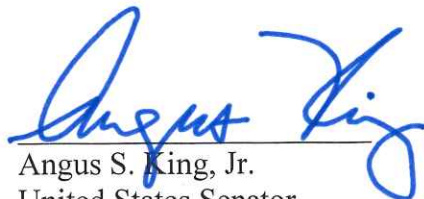

Margaret Wood Hassan
United States Senator

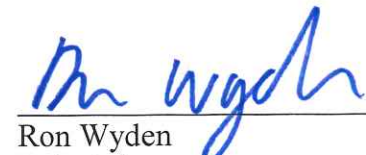

Patrick Leahy
United States Senator


Jeanne Shaheen
United States Senator


Richard J. Durbin
United States Senator

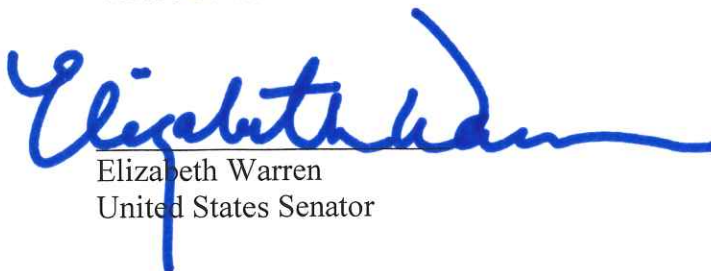

Amy Klobuchar
United States Senator


Angus S. King, Jr.
United States Senator


Ron Wyden
United States Senator


Tammy Duckworth
United States Senator

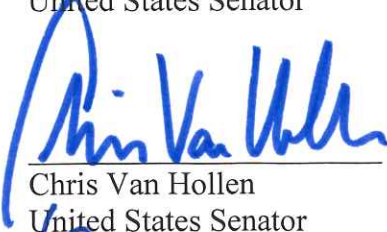

Thomas R. Carper
United States Senator


Elizabeth Warren
United States Senator

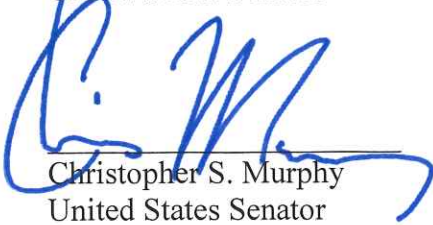

Brian Schatz
United States Senator



Tina Smith
United States Senator



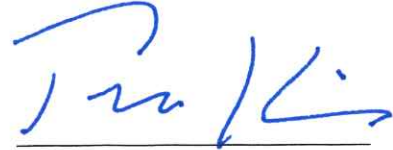
Chris Van Hollen
United States Senator



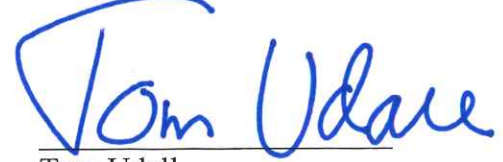
Christopher S. Murphy
United States Senator



Christopher A. Coons
United States Senator



Tim Kaine
United States Senator



Tom Udall
United States Senator