United States Senate

WASHINGTON, DC 20510

February 15, 2019

The Honorable Alex Azar
Secretary
Department of Health and Human Services
100 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Azar:

We write today to express our deep concern regarding the insufficient response of the Department of Health and Human Services (HHS) to the growing epidemic of e-cigarette use among youth. Though FDA Commissioner Scott Gottlieb recognized youth e-cigarette use as an epidemic in September of 2018, and has taken some measured steps to address this concerning trend,[1] and U.S. Surgeon General Jerome Adams echoed this sentiment with an official declaration of an epidemic in December of 2018,[2] we remain concerned that HHS has not adequately tackled the crisis at hand. HHS and its agencies must immediately respond to this epidemic on all fronts, by further educating the public on the dangers of youth tobacco use, researching treatments for youth already addicted to these pernicious products, and removing flavored e-cigarette products that attract kids from the market until or unless they have undergone a thorough FDA review that shows they are of benefit to the public health.

As you know, in 2017 FDA delayed the compliance deadlines for premarket review of e-cigarettes and other newly regulated products under the Deeming Rule.[3] As a result of this action, countless non-grandfathered tobacco products, including most e-cigarettes marketed today, can stay on the market for years to come without a comprehensive review of the public health implications of the e-cigarette, or e-cigarette flavor, by FDA. FDA's choice to delay premarket review for these products already on the market and new products entering the market has given JUUL and other e-cigarette manufacturers additional time to expose youth users to their products and hook the next generation of tobacco users. We are now working to respond to a public health epidemic that is has grown more severe as a result of FDA's decision not to heed the warnings of public health experts and physicians, and fully apply its regulatory authority.

Despite the continued warning signs and unacceptable behavior of the e-cigarette industry, including the promotion of flavors that attract kids, FDA is still slow to meaningfully regulate the industry. For example, despite publicity about JUUL's youth-centric advertising campaign, and most recently, the large investment in JUUL by Altria, a Big Tobacco giant, FDA has moved slowly to

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[1] U.S. Department of Health and Human Services, Food and Drug Administration, "Statement from FDA Commissioner Scott Gottlieb, M.D., on new steps to address epidemic of youth e-cigarette use," https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm620185.htm (Accessed February 14, 2019)

[2] U.S. Department of Health and Human Services, "Surgeon General releases advisory on E-cigarette epidemic among youth," https://www.hhs.gov/about/news/2018/12/18/surgeon-general-releases-advisory-e-cigarette-epidemic-among-youth.html (Accessed February 14, 2019)

[3] U.S. Department of Health and Human Services, Food and Drug Administration, "FDA Extends Future Deeming Rule Compliance Dates To All Tobacco Products," https://www.fda.gov/TobaccoProducts/NewsEvents/ucm556562.htm (Accessed February 14, 2019)

take actions against the company. Despite clear evidence flavors are a primary driver of youth initiation of e-cigarette use, FDA has thus far refused to reinstate earlier pre-market review requirements established in the Deeming Rule, and also has yet to propose rulemaking that would ban all flavored products until or unless they have undergone a thorough FDA review that shows they are of benefit to the public health. Neglecting to take either of these actions ensures such kid-friendly flavors will continue to hook our youth.[4] FDA is instead relying largely on voluntary action from JUUL and other manufacturers. FDA has not even implemented the restriction of flavored-e-cigarette sales to age-restricted, in-person locations or introduced the "enhanced age verification" processes for online sales it announced in November 2018. We do not understand why there is such a delay in moving forward with these proposals given the immediacy of the issue and the progressive increase in vaping rates.

This inaction has fueled an alarmingly rapid rise in rates of youth e-cigarette use. According to the National Youth Tobacco Survey, e-cigarette use among high school students increased by 78 percent in one year alone.[5] An estimated 3.6 million high school and middle school students are now current e-cigarette users. Unfortunately, many do not understand the risks: 63 percent of JUUL users said in a 2017 study that they did not know that the device contained nicotine,[6] despite the fact that a single JUUL pod often contains the same amount of nicotine as a full pack of cigarettes.[7] It is clear that regulatory delay has led to large numbers of kids becoming addicted to these products.

Parents are now struggling to understand how to help their children who have become addicted to e-cigarettes. Medical and research professionals have little information on how to treat the 3.7 million youth users of e-cigarettes, including 27 percent who are likely addicted,[8] . There are no nicotine replacement therapies (NRTs) currently approved for youth use. Previous trials have not included youth, or have not been successful with youth users.[9] The lack of understanding around the impacts of youth nicotine and e-cigarette dependence, combined with a lack of research on potential NRTs for youth indicates that we are woefully unprepared to handle this crisis.

On January 18, 2019, FDA held a public hearing entitled, "Eliminating Youth Electronic Cigarette and Other Tobacco Product Use: The Role for Drug Therapies."[10] While we were pleased to see FDA take steps to acknowledge the gap in effective cessation therapies for youth use, we were disturbed to see the inclusion of organizations representing the vaping industry. It is unconscionable that at this point, long after e-cigarette use has become pervasive among youth and long after the Surgeon General and the FDA's own Commissioner declared vaping a public health epidemic, the

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[4] Truth Initiative, "4 Marketing Tactics E-cigarette Companies Use to Target Youth," August 09, 2018, https://truthinitiative.org/news/4-marketing-tactics-e-cigarette-companies-use-target-youth.

[5] U.S. Department of Health and Human Services, Food and Drug Administration, "Results from 2018 National Youth Tobacco Survey show dramatic increase in e-cigarette use among youth over past year," https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm625917.htm (Accessed February 14, 2019)

[6] Sarah Shank, "63% of Youth Are Unaware That JUUL E-cigarettes Contain Nicotine," Truth Initiative, June 26, 2018, https://truthinitiative.org/news/juul-e-cigarettes-gain-popularity-among-youth.

[7] Truth Initiative, "6 Important Facts about JUUL," Truth Initiative, August 29, 2018, https://truthinitiative.org/news/6-important-facts-about-juul.

[8] Laura Bach, "ELECTRONIC CIGARETTES AND YOUTH," *Campaign for Tobacco-Free* Kids, December 18, 2018 https://www.tobaccofreekids.org/assets/factsheets/0382.pdf

[9] Natalia Thomas, U.S. Department of Health and Human Services, Food And Drug Administration, "FDA Approach to Evaluating Nicotine Replacement Therapies," Public Hearing, Capital Reporting Company https://www.fda.gov/downloads/NewsEvents/MeetingsConferencesWorkshops/UCM596699.pdf

[10] U.S. Department of Health and Human Services, Food And Drug Administration, "FDA's Eliminating Youth Electronic Cigarette and Other Tobacco Product Use: The Role for Drug Therapies," https://www.fda.gov/downloads/NewsEvents/MeetingsConferencesWorkshops/UCM629495.pdf (Accessed February 14, 2019)

FDA would choose to allow presentations entitled, "Still No Evidence of a Youth Nicotine Vaping Epidemic" and "Youth Vaping Epidemic? What is best for public health?" at their public hearing.[11] This choice by FDA reinforces our concerns that FDA is not prioritizing public health concerns over concerns from e-cigarette manufacturers.

Due to these concerns, we ask that you, or the appropriate officials at CDC, FDA, or NIH, answer the following questions regarding your plans and your commitment to tackling the public health crisis of youth e-cigarette use:

1. Though research, education, and cessation technology are important, the best way to tackle the epidemic at hand is by preventing youth usage of e-cigarettes prior to addiction. When does FDA expect to have their comprehensive tobacco plan fully in place?
    a. When will FDA reverse its decision to delay compliance deadlines under the Deeming Rule and require premarket authorization for all e-cigarettes sold in the United States, including those that are currently on the market without FDA review? Please be as specific as possible.
    b. When will FDA establish and implement its definition for products that were "on the market" as of August 8, 2016, which will finally enable FDA to enforce pre-market review on products that are currently available and entering the market illegally?
    c. Will the FDA take steps to ban all flavored e-cigarettes, including mint and menthol, regardless of where the products are sold, until or unless they have undergone a thorough FDA review that shows they are of benefit to the public health?
    d. When will the Center for Tobacco Products (CTP) issue guidance setting out the necessary features of the "heightened age verification processes" it seeks to require for online sales of certain flavored e-cigarette products?
    e. What will the "enhanced" online verification as outlined by the FDA look like? How can you ensure that consumers will not abuse the new system as they have previously done?

2. FDA continues to see issues with retailers selling to minors. Just last week, the Agency took action against specific Walgreens and Circle K stores. Does FDA have any plan to increase inspection of these retailers and/or increase civil money penalties? In addition, how does the Agency conduct oversight of the contractors who routinely conduct these inspections to be sure the contractors are following enforcement protocol and complying with federal law?

3. What does the CDC's Office on Smoking and Health (OSH) currently do to prevent youth uptake of e-cigarettes and/or educate teens and adults on the dangers of using vaping products, like JUUL? Does OSH have any plans to expand these activities?

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[11] U.S. Department of Health and Human Services, Food And Drug Administration, "FDA's Eliminating Youth Electronic Cigarette and Other Tobacco Product Use: The Role for Drug Therapies," https://www.fda.gov/downloads/NewsEvents/MeetingsConferencesWorkshops/UCM629495.pdf (Accessed February 14, 2019)

4. Does the NIH have any proposed, planned, or ongoing research opportunities to examine the extent and impact of e-cigarette/nicotine dependence in youth?

5. Do any HHS agencies have plans to fund research, or facilitate private-sector research, on NRTs and other drug therapies to assess whether they would be safe and effective for youth?
    a. If so, will FDA use incentives and requirements provided by the Best Pharmaceuticals for Children Act (BPCA) and the Pediatric Research Equity Act (PREA) to encourage the development of drug therapies in this area?

6. Do any HHS agencies have plans to research the impact of non-pharmacological therapies, like breathing techniques and behavioral counseling, for youth e-cigarette cessation?
    a. If so, will such research examine the impact of combination therapy using both NRT and other methods on youth cessation?

7. Will FDA expand its "Real Cost Campaign" on e-cigarettes to go beyond limited geo-targeting of youth users so that more youth see these ads, including in rural areas or for youth who do not have smartphones? Will FDA also continue to develop new campaigns and education initiatives, as a part of the Youth Tobacco Prevention Plan, to educate youth and adults on the impact of e-cigarette use?
    a. If so, what will these campaigns entail?

8. How will FDA use the information presented by provider, public health, and patient groups at the January 18th hearing to help youth already addicted to nicotine through JUUL and other products going forward?

Please provide answers to our questions by March 1, 2019.

Sincerely,

RICHARD BLUMENTHAL
United States Senate

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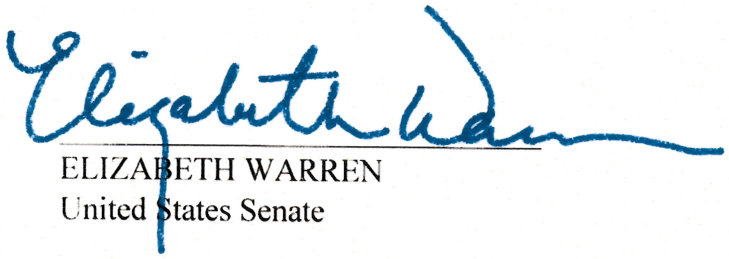

ELIZABETH WARREN
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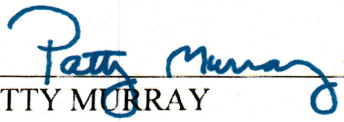

PATTY MURRAY
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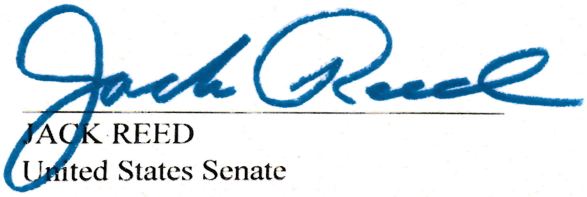

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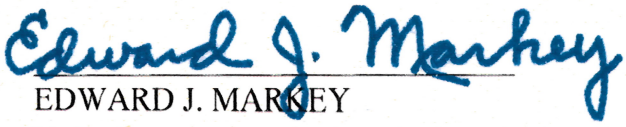

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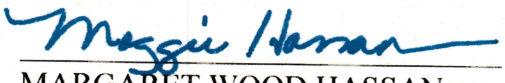

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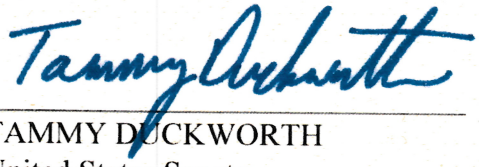

TAMMY DUCKWORTH
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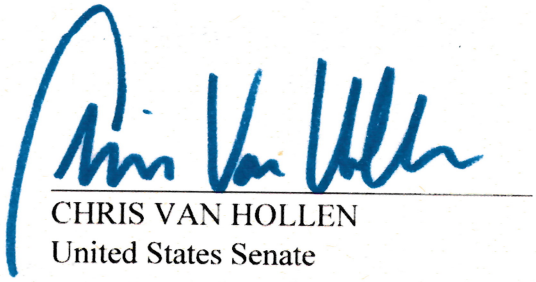

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CC:
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FDA Commissioner Scott Gottlieb, M.D.
NIH Director Francis Collins, M.D., Ph.D.