

United States Senate

WASHINGTON, DC 20510

August 4, 2017

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

Dear Commissioner Gottlieb:

We write with concern regarding the Food and Drug Administration's (FDA) recent tobacco regulatory announcement, specifically its plans on delaying implementation under the 2016 "deeming rule." There is no reason for the Agency to delay oversight of newly-regulated tobacco products, including electronic cigarettes (e-cigarettes) and cigars that contain kid-appealing flavors and are actively marketed to children. Furthermore, while we are encouraged by the components of the new tobacco plan that could lead to reduced nicotine levels in cigarettes, we are troubled by the potentially prolonged timeframe to implement such measures.

Many of us wrote to you in May urging you to steadfastly implement the FDA's deeming rule, which—for the first time ever—enacted oversight over e-cigarettes, cigars, and other tobacco products, helping to protect public health and prevent tobacco use by young people. Instead, last week's announcement indicates that you intend to delay implementation of key provisions of the deeming rule, giving e-cigarette and cigar manufacturers—including flavored products—a free pass to stay on the market for years with minimal oversight and restrictions. This is a step backwards and contradicts years of data demonstrating the danger these products pose to public health.

We are deeply concerned that by delaying deeming rule compliance deadlines for product review of e-cigarettes, cigars, hookah, and pipe tobacco, the FDA is failing in its commitment to safeguard public health, especially for children. The 2016 U.S. Surgeon General report on e-cigarettes found that e-cigarettes are marketed by promoting flavors that appeal to youth—including candy and fruit flavorings—and that such marketing has resulted in increased use of tobacco products among children and teens. When the FDA extended its regulatory authority to e-cigarettes and cigars, it specifically acknowledged the harms posed to youth by flavored tobacco products. Yet, FDA's recent announcement allows flavored products—that are clearly targeted to youth—to remain on the market until 2022.

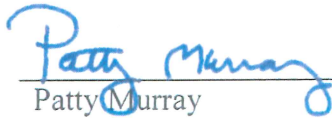
We are also concerned that last week's announcement indicates that your agency plans to re-examine the provision of the deeming rule pertaining to commonsense oversight of certain cigars. The FDA already determined that there is "no appropriate public health justification to exclude premium cigars" from FDA oversight. Furthermore, there is already sufficient evidence about the risks flavored tobacco products pose for youth initiation for FDA to issue a proposed rule to prohibit use of flavors and that removing cigarettes with menthol as a characterizing

flavor is appropriate for the protection of the public health. It is long past time for FDA to take action on flavored products.

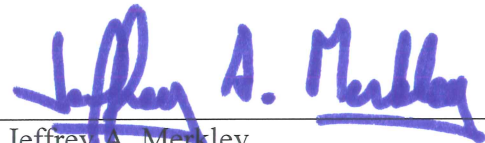
While we have serious concerns about FDA's announcement as it pertains to newly regulated tobacco products, we are encouraged by the agency's plans to examine lowering nicotine levels in cigarettes. As you stated in the announcement, tobacco is, "the only legal consumer product that, when used as intended, will kill half of all long-term users." We agree that the FDA should use all of the tools at its disposal under the Family Smoking Prevention and Tobacco Control Act (P.L. 111-31), including establishing product standards, to lower the nicotine content in combustible cigarettes. We urge FDA to develop a plan to do so quickly, including expeditiously issuing an Advance Notice of Proposed Rulemaking (ANPRM) and setting a timeframe for expected completion of a final rule. We will be continuing to monitor your agency's actions on this initiative to ensure that you hold to your commitment to reduce the addictiveness and harms from cigarettes.

While we saw a reduction in overall youth tobacco use and e-cigarette use last year, there are still far too many young people using tobacco products. Our nation is at a critical juncture in continuing to make progress against the harm caused by tobacco—now is not the time to abandon effective tobacco oversight policy.

Sincerely,



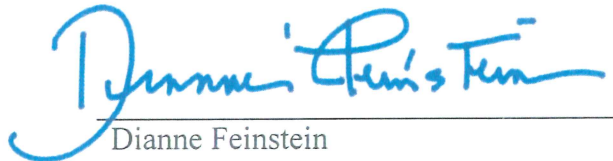
Patty Murray
United States Senator



Jeffrey A. Merkley
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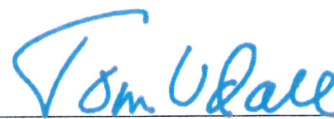
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United States Senator



Sherrod Brown
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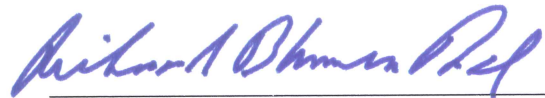
Sheldon Whitehouse
United States Senator



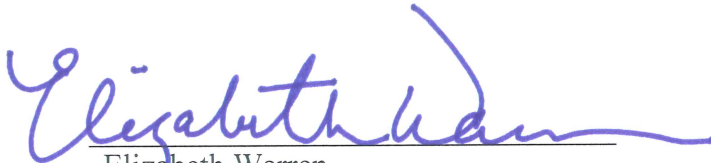
Tom Udall
United States Senator



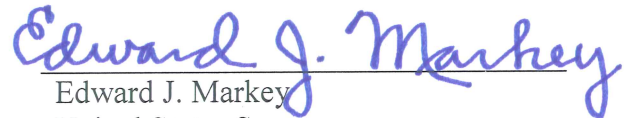
Al Franken
United States Senator



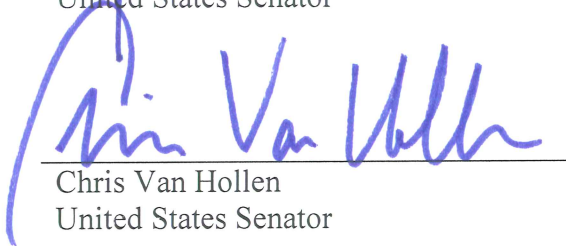
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