

United States Senate

WASHINGTON, DC 20510

October 29, 2018

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

Dear Commissioner Gottlieb,

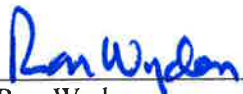
We support your recent statement expressing a willingness to revisit the Food and Drug Administration's (FDA) decision to delay the agency's review of some electronic cigarettes (or e-cigarettes), given the dramatic increase in youth use of these addictive nicotine products. While we were encouraged that FDA sent letters to the five largest e-cigarette manufacturers asking for the development of "robust plans" to reduce youth use of these products, we remain unconvinced that voluntary, self-policing by e-cigarette companies will be sufficient for addressing this burgeoning public health epidemic. It is imperative that FDA exercise its existing authority and take immediate, strong action to protect our nation's youth from a lifetime of addiction. We write today to urge FDA to require manufacturers to remove all kid-appealing flavored e-cigarette products from the market unless or until manufacturers can demonstrate that these flavors will benefit public health and will not attract children to begin using these addictive products.

Today, more than two million middle and high-schoolers are using e-cigarettes, making them the most popular form of tobacco product among youth. Partially due to FDA's decision in July 2017 to delay its review of e-cigarette products that were on the market prior to August 2016 by four years, some of these devices have been on the market for upwards of a decade without an evaluation of their net public health impact. The extended regulatory compliance period—combined with FDA's insufficient policing of new products coming to market after the August 2016 deadline—is putting a new generation of children at risk of tobacco use and addiction, including cigarette use. As you acknowledged, flavors are "one of the principal drivers of the youth appeal of these products"—with 81 percent of kids who have ever tried an e-cigarette starting with a flavored product.

The FDA has the tools it needs to take swift action. Under the 2016 "deeming rule," the authority of the Family Smoking Prevention and Tobacco Control Act was extended to e-cigarettes and other tobacco products that were not being overseen by the agency. For a product that delivers highly addictive nicotine, the burden of proof should lie with the manufacturer to demonstrate to FDA its appropriateness for public health and the marketplace. And yet rather than conducting clinical trials, the e-cigarette companies have developed kid-appealing flavors and sleek devices and devoted resources to marketing their products to youth. As a result of its inaction, FDA has placed a cohort of teens at risk for a lifelong addiction, as well as put them at increased risk for using cigarettes. The FDA needs to take action, and fast.

We urge FDA to immediately require manufacturers to remove kid-appealing flavored e-cigarettes from the market, and further request that FDA make public the responses it receives from the five e-cigarette manufacturers in response to FDA's September 12 request letters.

Sincerely,



Ron Wyden
United States Senator



Richard J. Durbin
United States Senator



Patty Murray
United States Senator



Sheldon Whitehouse
United States Senator



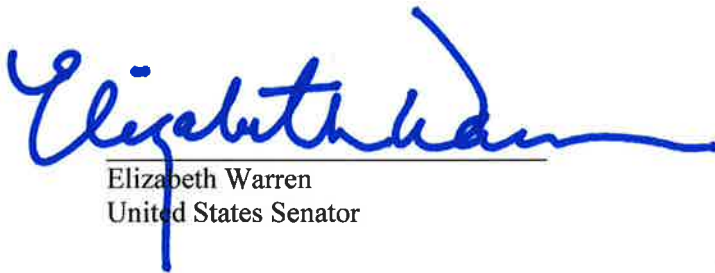
Richard Blumenthal
United States Senator



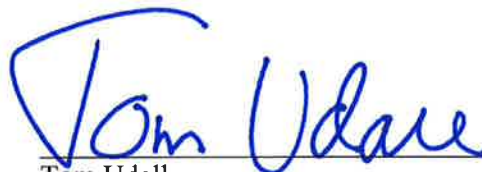
Sherrod Brown
United States Senator



Maggie Hassan
Margaret Wood Hassan
United States Senator



Elizabeth Warren
United States Senator



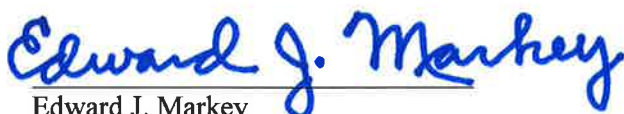
Tom Udall
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United States Senator

Kirsten Gillibrand

Kirsten Gillibrand
United States Senator

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United States Senator