

United States Senate

WASHINGTON, DC 20510

April 18, 2018

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

Dear Commissioner Gottlieb:

In 2009, Congress granted the Food and Drug Administration (FDA) the authority to regulate the manufacture, distribution, and marketing of tobacco products. In the years since, the FDA has taken a number of important steps to protect the public health and create a healthier future for all Americans by better educating the public about the risks of smoking, cracking down on deceptive practices of big tobacco companies, and considering lowering nicotine levels in cigarettes. We commend the FDA for initiating many of these efforts—including those commenced under your leadership—which have, and will, save lives. However, we write today to share our deep concern that the significant progress we have made in reducing tobacco use among our nation's youth is at serious risk of being reversed because of the FDA's failure to take swift action against specific products that clearly appeal to youth and threaten to hook a generation of children onto tobacco products.

From aggressively marketing cigarettes and tobacco products near primary and secondary schools, to shamelessly using cartoon characters to shill their products to children, to making their tobacco products available in kid-friendly candy and fruit flavors, it is no secret that big tobacco companies will stop at nothing to hook young people on their addictive and dangerous products. The good news is that, thanks to enhanced prevention and awareness policies, cigarette smoking among high school students is at record lows—dropping from 28 percent in 2000 to 8 percent in 2016. The bad news is that, much to our dismay, these gains are being jeopardized because of non-cigarette tobacco products—especially cigars and e-cigarettes with kid-appealing flavors, including the JUUL vaping device.

An April 2, 2018, article in *The New York Times*, entitled "'I Can't Stop': Schools Struggle With Vaping Explosion," details the alarming explosion of vaping, and specifically JUUL use, among high school and middle school students across the country. Between 2011 and 2015, the use of e-cigarettes among high school students increased more than ten-fold—from 1.5 percent to 16 percent. While e-cigarette use by high school students declined to 11.3 percent in 2016, e-cigarettes remain the most popular form of tobacco use among youth. According to the U.S. Surgeon General's Report on E-Cigarette Use Among Youth and Young Adults, much of the popularity associated with youth use of e-cigarettes can be attributed to the appealing candy and fruit flavorings that accompany these devices—flavors such as gummy bear, cotton candy, peanut butter cup, and cookies 'n cream. No one with a straight-face could ever argue that these flavorings are not meant to appeal to children.

The *Family Smoking Prevention and Tobacco Control Act of 2009* gave the FDA immediate authority over cigarettes, cigarette tobacco, smokeless tobacco, and roll-your-own tobacco and authorized the agency to expand its jurisdiction to other tobacco products. In May 2016, the FDA finally did so—issuing a rule (the “deeming rule”), which established the agency’s authority to regulate e-cigarettes and cigars in order to protect the public health and prevent use youth of these products. And yet—nearly a decade after this law was enacted and two years after the FDA asserted their ability to regulate e-cigarettes—these products and their kid-friendly flavorings are proliferating on the market without adequate FDA oversight.

While we were pleased that the FDA finally took an initial step to regulate flavorings in e-cigarettes and other tobacco products—issuing an advance notice of proposed rulemaking (ANPRM) on March 21, 2018—we remain very concerned that, by announcing in July 2017 a delay of critical, commonsense e-cigarette regulations until 2022, the FDA is not acting quickly enough to protect our nation’s youth from becoming addicted to these dangerous products. As the FDA has itself acknowledged, 81 percent of kids who have ever used tobacco products started with a flavored product, including 81 percent who have ever tried e-cigarettes and 65 percent who have ever tried cigars. Big tobacco companies are actively peddling e-cigarettes and kid-friendly flavorings in an attempt to hook an entirely new generation of children on nicotine and tobacco products, and yet the FDA has decided to suspend, for four more years, the requirement that these products undergo a scientific review by the FDA to determine their effect on kids and public health. This is unacceptable.

While it remains an open question whether e-cigarettes can play a role in helping adult smokers to quit cigarettes, there is certainly no role for them to play in our nation’s classrooms—and yet that is exactly where they are turning up. It is imperative that the FDA take immediate steps to remove kid-friendly e-cigarette and cigar flavorings from the market. If companies want to use flavors, they should be required to demonstrate to the FDA that use of flavors will benefit public health. If we wait four more years to act, we will have doomed countless more children to addiction and adverse health consequences at the hands of big tobacco companies.

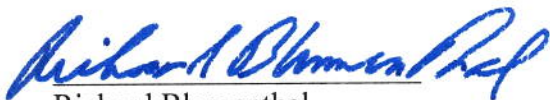
Sincerely,



Richard J. Durbin
United States Senator



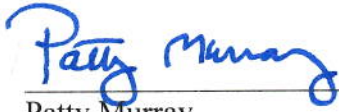
Sherrod Brown
United States Senator



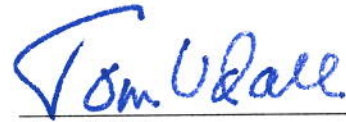
Richard Blumenthal
United States Senator



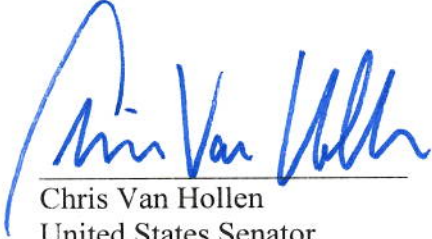
Charles E. Schumer
United States Senator



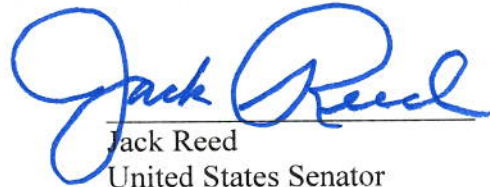
Patty Murray
United States Senator



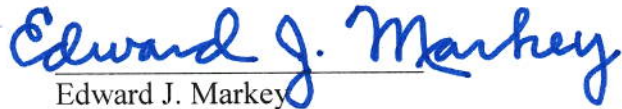
Tom Udall
United States Senator



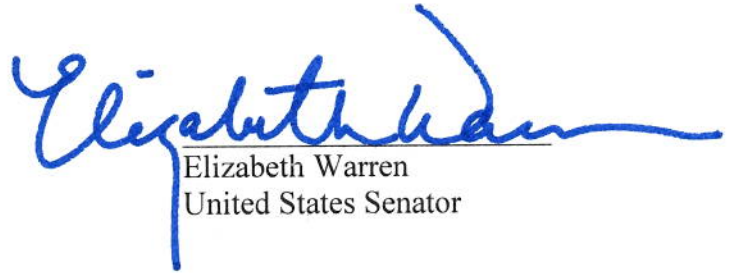
Chris Van Hollen
United States Senator



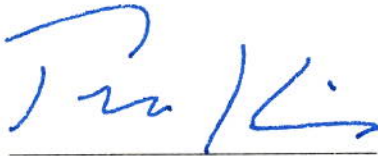
Jack Reed
United States Senator



Edward J. Markey
United States Senator



Elizabeth Warren
United States Senator



Tim Kaine
United States Senator