

United States Senate

WASHINGTON, DC 20510

May 19, 2017

Dr. Scott Gottlieb
Commissioner, Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20857

Dear Dr. Gottlieb:

Given your recent confirmation as Commissioner of the Food and Drug Administration (FDA), we write to encourage you to prioritize agency efforts to prevent tobacco-related disease and keep tobacco products out of the hands of children. We have serious concerns regarding the recent decision by FDA to delay all upcoming compliance deadlines under the final tobacco deeming rule, reflected by the May 10, 2017 guidance titled Three-Month Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule. We urge the Administration to stand up to special interests and reconsider its decision to delay all compliance deadlines set forth in the tobacco deeming rule; such delays will have dangerous consequences and hamper the ability of FDA to carry out its mandate to protect the public's health.

On May 10, 2016, nearly seven years after passage of the bipartisan Family Smoking Prevention and Tobacco Control Act of 2009 (TCA) giving the agency such authority, FDA finalized the tobacco deeming rule to establish jurisdiction over categories of tobacco products, including electronic cigarettes (e-cigarettes), cigars, hookah, and pipe tobacco. This oversight was long overdue. The booming, previously unregulated e-cigarette industry was often described as a "wild west" of consumer products and in recent years has increasingly and deliberately targeted children. E-cigarette manufacturers regularly use candy and fruit flavors—such as cotton candy and cookies and cream—as well as other marketing strategies to attract children and teens and have been effective in doing so. In December 2016, the U.S. Surgeon General published a report revealing that e-cigarettes are the most commonly used tobacco product among teens, surpassing conventional cigarettes. Further studies have found that more than 85 percent of current youth e-cigarette users use flavored e-cigarettes and that flavors are the leading cause of initiation.

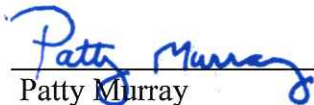
While more research is needed, evidence from several longitudinal studies suggests that e-cigarette use is "strongly associated" with the use of other tobacco products among youth and young adults, including conventional cigarettes. E-cigarettes can expose users to harmful chemicals, including nicotine, which is highly addictive and can have adverse effects on the developing adolescent brain, such as lowering impulse control and affecting learning and attention. E-cigarettes are not the only newly deemed tobacco product that pose a threat to young people; high school boys now smoke cigars at a higher rate than regular cigarettes.


In the final rule, FDA states "that completely switching from combusted cigarettes to [e-cigarettes] may reduce the risk of tobacco-related disease for individuals currently using


combusted tobacco products.” Any potential public health benefit of these products, however, will only be realized if e-cigarettes lead current smokers to quit using combustible tobacco and if they do not attract new tobacco users. For these reasons and more, consistent with statute, FDA carefully crafted the deeming rule to protect the public health while establishing a regulatory scheme for all newly deemed tobacco products. To accomplish this goal, FDA set forth a series of deadlines to give manufacturers a reasonable window of time to come into compliance with the requirements of the rule. These include adding warning statements to products with nicotine, listing ingredients, and submitting all products to FDA for review. We believe the rule should have gone further and banned flavors and marketing practices that are known to attract children and teens. For many of the requirements put forth in the final rule, manufacturers have been given two full years to comply. We see no evidence to indicate that additional time is necessary or warranted, and urge you to stand strong against industry pushback and fully enforce the FDA rule as written.


Your new role as FDA Commissioner comes with enormous responsibility to protect the public health. Given the public health threat posed by youth e-cigarette use, it is imperative that the FDA commit to the original compliance deadlines for the tobacco deeming rule. Every day that these products stay on the market with no assessment of their risks, we continue to put America’s youth in harm’s way.

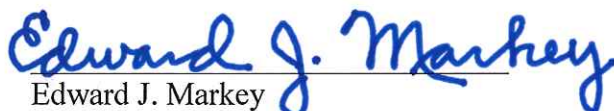
Sincerely,


Patty Murray
United States Senator


Jeffrey A. Merkley
United States Senator


Sherrod Brown
United States Senator


Tom Udall
United States Senator


Edward J. Markey
United States Senator


Sheldon Whitehouse
United States Senator



Jack Reed
United States Senator



Elizabeth Warren
United States Senator



Richard J. Durbin
United States Senator



Richard Blumenthal
United States Senator



Al Franken
United States Senator