

United States Senate

WASHINGTON, DC 20510

October 2, 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:

On September 12, 2018, citing “an epidemic of e-cigarette use among teenagers,” the Food and Drug Administration (FDA) announced a number of important and long-overdue actions that represent a promising step toward addressing a public health crisis that is threatening an entire generation of children. We commend you for sending warning letters and issuing civil monetary penalties to retailers who have repeatedly violated the law by selling tobacco products to minors, but we are most encouraged by FDA’s apparent willingness to finally consider prohibiting kid-friendly e-cigarette flavorings in the near term and restricting online sales. Given the e-cigarette industry’s calculated decision to target children with dangerous and addictive flavored products—and given their success in these efforts—we strongly urge FDA to take decisive action and immediately ban kid-friendly e-cigarette flavorings.

As we have discussed with you many times, the fruit, candy, and other kid-friendly liquid nicotine flavorings—that FDA has knowingly allowed to proliferate on the market for years without regulation—have been driving this youth e-cigarette epidemic from day one. This has been proven time and again and affirmed in the U.S. Surgeon General’s Report on E-Cigarette Use Among Youth and Young Adults, by the Centers for Disease Control and Prevention, and even by the FDA itself—acknowledging that 81 percent of kids who ever use a tobacco products start with a flavored product, including 81 percent who have ever tried e-cigarettes and 65 percent who have ever tried cigars.

While it remains unclear whether e-cigarettes can actually help adults quit smoking cigarettes, it is abundantly clear that tobacco companies are developing and marketing e-cigarette flavors that appeal to, and addict, children. A recent search of the FDA’s own database reveals more than 1,000 results for scores of different flavored e-cigarette products—everything from mango to gummy bear; whipped cream to tutti fruttii; blue razz candy to chocolate cupcake. The e-cigarette industry’s efforts to hook kids have been overwhelmingly successful, as demonstrated by the reportedly 75 percent spike in e-cigarette use among high school students over the past year. Even prior to this spike, more than two million middle- and high-school students were using e-cigarettes, making them the most popular form of tobacco use among children.

Given the unparalleled scope of this youth tobacco epidemic, we introduced S. 3319, the Stopping Appealing Flavors in E-Cigarettes for Kids Act (or SAFE Kids Act). This bipartisan legislation would immediately ban the use of flavorings in cigars and would give tobacco companies one year to prove that their e-cigarette flavorings actually help adults quit smoking cigarettes, do not cause children to start smoking, and do not harm the user. Anything short of strong and decisive regulation of e-cigarette flavorings would not be in the best interest of our nation's children.

Last month, FDA sent letters to the five e-cigarette manufacturers that currently represent more than 95 of the e-cigarette market (JUUL, Vuse, MarkTen, blu e-cigs, and Logic), giving them 60 days to provide "robust plans" demonstrating how they will "convincingly address the widespread use of their e-cigarette products by children." While we are very encouraged by FDA's attention to this issue, we remain deeply skeptical that e-cigarette companies will adequately police themselves in a way that benefits the public health. After all, manufacturers have failed to adequately respond to longstanding concerns that flavors were making their products appealing to youth and continue to assert that they do not market their products to kids. As you yourself stated, these companies have treated youth use of their products as a "public relations challenge rather than seriously considering their legal obligations, the public health mandate, and the existential threat to these products." There is simply no reason to believe that e-cigarette companies will put children's health ahead of their bottom line—not today, not 60 days from now, not ten years from now. This request has been made to cigarette companies for decades and with e-cigarette companies before. Their response has always been more rhetoric but no meaningful change.

Further, while focusing on the five manufacturers with the largest market share is logical, it will not solve the problem. Just as a host of other manufacturers jumped in to copy JUUL's success, nothing would prevent other manufacturers from using kid-friendly flavors and marketing practices that appeal to youth. Other manufacturers also claim they do not market to kids even while their practices have contributed to the current problem. Voluntary action by manufacturers is no substitute for industry-wide action by FDA. It is critical that FDA step in and use the authority that Congress gave it to protect kids and the public health.

Under current law, FDA has a number of existing authorities at its disposal to get kid-friendly e-cigarette and cigar flavorings out of the hands of America's children. For example, as you have threatened, FDA could reverse the decision it made last year to delay a product review of e-cigarettes and cigars that were on the market on August 8, 2016. Because of this delay, thousands of flavored tobacco products are on the market today without a scientific review by FDA of their health risks and appeal to youth. Further, we do not see any evidence that FDA has enforced the current requirements that prohibit manufacturers from introducing products that were not "commercially marketed" prior to August 8, 2016, or that were modified after that date, without first undergoing a review and receiving authorization from FDA. For certain, products that now deliver nicotine using nicotine salts modelled after JUUL fit that definition. FDA should also quickly promulgate regulations to more aggressively restrict online sales of e-cigarettes and cigars to youth instead of relying on enforcement actions against individual retailers and could take other steps to keep these products out of the hands of young people.

We urge you to take the strongest action possible to protect our children from a lifetime of nicotine addiction, and to offer our continued Congressional assistance in whatever way would be helpful in your efforts. Thank you.

Sincerely,

A handwritten signature in blue ink that reads "Dick Durbin". The signature is fluid and cursive, with a horizontal line underneath the name.

Richard J. Durbin
United States Senator

A handwritten signature in blue ink that reads "Lisa Murkowski". The signature is fluid and cursive, with a horizontal line underneath the name.

Lisa Murkowski
United States Senator