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COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY
COMMITTEE ON APPROPRIATIONS
COMMITTEE ON THE JUDICIARY
COMMITTEE ON RULES AND ADMINISTRATION

July 25, 2019

The Honorable Norman E. "Ned" Sharpless, M.D.
Acting Commissioner
United States Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

Dear Acting Commissioner Sharpless:

It is my strong belief that any person leading the Food and Drug Administration (FDA)—the federal agency tasked with ensuring the safety of food on our tables and medicine in our cabinets, as well as regulating the tobacco industry—must feel a deep sense of responsibility to protect the health and well-being of all Americans, especially our nation's children. Unfortunately, to date, your noncommittal statements and inaction as Acting FDA Commissioner regarding youth use of e-cigarettes have cast serious doubt on whether you are the appropriate, long-term leader for this agency.

The most impactful and commonsense first step you can take would be to immediately and unequivocally comply with the May 15 District Court ruling and July 12 remedy order, thereby ending FDA's needless delay of commonsense e-cigarette regulation. Then-Commissioner Gottlieb's unilateral and illegal action in 2017 to delay FDA regulation of flavored e-cigarettes and cigars from 2018 to 2022 ensured that kid-friendly e-cigarettes and flavors—such as cotton candy, fruit medley, gummy bear, and chocolate cupcake—were given years of excess time to proliferate on the market, virtually unregulated. As a result, over the last year alone, our nation saw a 78 percent increase in the number of high-school children using e-cigarettes, and a 48 percent increase in the number of middle-school children using these insidious, addictive products. Today, nearly four million children are vaping.

Thankfully, U.S. District Court Judge Paul Grimm recently stepped in to do what FDA has, thus far, refused to do: end the senseless delay of e-cigarette regulation. Judge Grimm's order directed FDA to set a 10-month deadline of May 12, 2020, for e-cigarette manufacturers to submit their products for FDA's public health review if they wish to remain on the market. Further, the order provides FDA with no longer than one year to review the applications. It is my strong hope that you will accept the Judge's ruling without further delay or appeal. Anything less is simply unacceptable and an abdication of your responsibility to our nation's children.

Next, you should effectuate immediate and robust enforcement of the "deeming rule's" prohibition on any new e-cigarette product from coming to market after August 8, 2016, without FDA approval. As you are well aware, new products are coming to market seemingly daily without FDA approval, in complete and total violation of the "deeming rule." And yet, to my knowledge, FDA has only ordered the removal of a handful of products for this violation.

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According to JUUL's own social media posts, their popular mango and "cool cucumber" flavors did not come to market until 2017, and they did so without FDA approval. The market is also filled with numerous JUUL look-a-like products and JUUL-compatible products. Since JUUL's popularity did not take off until after August 2016, it seems highly unlikely that all of these products were commercially available on the market as of August 8, 2016. Based upon numerous inquiries to JUUL and FDA, I am not aware of any credible proof that such products were commercially available before that deadline.

Finally, you must stop JUUL from illegally claiming to be a smoking cessation device. JUUL's current marketing campaign urges smokers to "make the switch" from cigarettes. This is, unmistakably, a smoking cessation claim from JUUL—a product that FDA has found to be largely responsible for the current epidemic of youth use of addictive e-cigarettes and which has never been approved by FDA as a smoking cessation device. In fact, JUUL has conducted zero clinical trials in the United States, proving their products help adults quit smoking cigarettes. You even recently admitted that, "most e-cigarette users continue to smoke cigarettes." Such dual use is corroborated by epidemiological data from the FDA, the Centers for Disease Control and Prevention (CDC), and the National Institutes of Health (NIH). JUUL should not be making a smoking cessation claim, and FDA has the authority and mandate to stop them.

In a recent blog post about e-cigarettes and youth use, you wrote, "After years of witnessing a steady decline in the use of tobacco products by children and young adults, we are now seeing a rapid resurgence of the use of tobacco products in these populations … I considered this topic as one of the leading issues facing American public health when I was leading the National Cancer Institute, and that view has not changed since I came to the FDA last April." If that indeed is the case, then further delay, excuses, and accommodations—all of which benefit e-cigarette companies like JUUL, while putting children at risk—cannot be an option. It is imperative that you remember your paramount duty is to serve the American consumer, not tobacco and e-cigarette manufacturers.

Should you be nominated to serve as Commissioner of the FDA, I will need more than words to support your confirmation.

Sincerely,

Richard J. Durbin
United States Senator