United States Senate
WASHINGTON, DC 20510

February 13, 2020

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

Dear Commissioner Hahn:

In fulfilling the public health mission of the Food and Drug Administration (FDA), one of the most pressing agenda items should be addressing our nation's escalating youth e-cigarette epidemic. Specifically, we urge you to bring much-needed public health oversight to these unregulated, addictive, and kid-friendly tobacco products. Three months from now, e-cigarette manufacturers will be required to submit premarket tobacco product applications (PMTAs) to the FDA. We want FDA to succeed in carrying out its statutory mandate to regulate tobacco products, but are concerned based upon past oversight activities that FDA will not deny a PMTA application for a tobacco product that is not appropriate for the protection of public health.

Moreover, when recently announcing the FDA's final enforcement guidance on e-cigarettes, President Trump, stated, "We have to protect our families. At the same time, it's a big industry. We want to protect the industry." As head of the FDA, your responsibility is to the American public, including, and most important, our nation's children.

The Family Smoking Prevention and Tobacco Control Act (TCA) prohibits any new tobacco products, including e-cigarettes, from entering the U.S. market unless the FDA determines that there is "a showing that permitting such tobacco product to be marketed would be appropriate for the protection of the public health." The statute is clear that the burden to demonstrate such public health benefit lies with e-cigarette product manufacturers. In carrying out this product review requirement, we urge the FDA to conduct a thorough and science-based analysis and require companies to submit high-quality research studies, clinical and medical evidence, and sales data.

Many of the products that FDA will begin reviewing by May 12 have been on the market for years, including those responsible for fueling the current epidemic of youth e-cigarette use. For these products, FDA must incorporate information about the product's experience on the market into its review of the product, including the demographic characteristics of who has been using the product (including youth use), how the product has been used (including frequency, flavor use, and dual use), how the product has been marketed and perceptions of the product (including by youth), the risk of addiction for those who have been using the product, misuse of the product, and any other adverse health information from the time it has been on the market. We call on you to keep the commitment you made in your Congressional testimony to be guided by "science, data, and the law," by evaluating how a certain e-cigarette product has been used by children in the time preceding the May 12 submission.

Further, in carrying out the PMTA requirement to assess the risks and benefits to the population as a whole, FDA must take into account whether these products will increase the likelihood of cessation among current tobacco users and increase the likelihood of youth initiation to nicotine or tobacco products. It is clear that, in recent years, FDA leadership has prioritized the possibility that e-cigarettes might provide some potential, but yet unproven, cessation value to smokers, which has undermined its ability to meaningfully address the alarming increase in youth use of e-cigarettes. Since your confirmation, the U.S. Surgeon General issued a report which found that there is "inadequate evidence to conclude that e-cigarettes, in general, increase smoking cessation." Given the abundance of existing public health surveillance data, medical literature, and the Surgeon General's findings about smoking cessation and youth use of e-cigarettes, we do not believe that a product that has increased or is likely to increase youth use of nicotine or tobacco can meet the public health standard required under the TCA.

Finally, we urge FDA to act quickly and decisively to remove from the market all new tobacco products that are out of compliance with its January 2 guidance or the May 12 deadline, including products that do not submit PMTAs, flavored cartridge-based products, and products that appeal to or are targeted to minors. Despite our urging, FDA has inadequately enforced the deeming rule requirement that prohibits manufacturers from introducing an e-cigarette to the market after August 8, 2016, without first receiving a marketing order. When looking at the changing e-cigarette marketplace, including the proliferation of products that use nicotine salts, JUUL-like products, and disposable flavored products, it is virtually certain that many products have entered illegally. FDA will have failed to uphold its responsibility to protect public health if the May 12 deadline is enforced in the same manner as the deeming rule.

As you know, five million children are now vaping, including one in four high school students—an increase of 135 percent over the past two years alone. To adequately address this youth vaping epidemic, we urge FDA to fully enforce and implement its May 12 deadline with a science-based review that holds industry accountable and prioritizes public health.

Sincerely,

Richard J. Durbin
United States Senator

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United States Senator

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United States Senator

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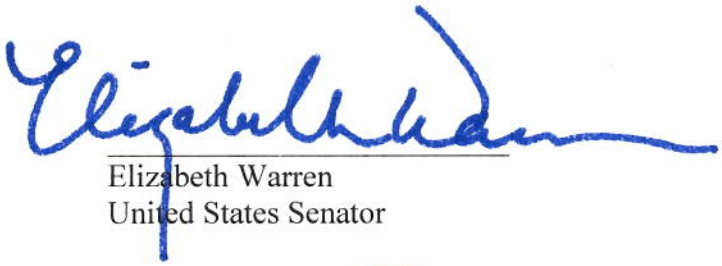

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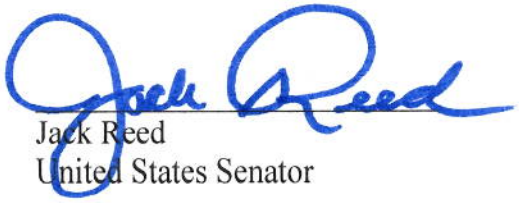

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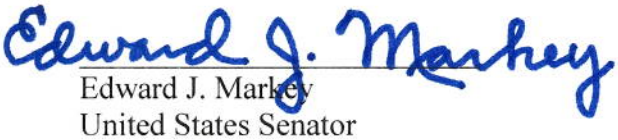

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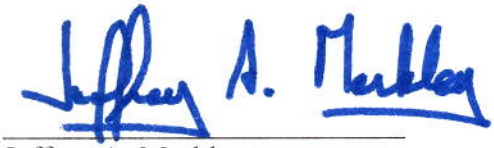

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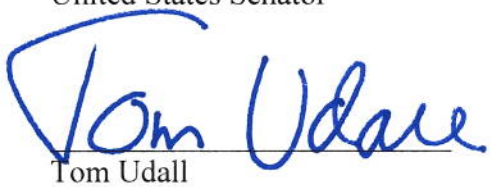

Tom Udall
United States Senator