United States Senate
WASHINGTON, DC 20510

January 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:

We are pleased that e-cigarettes and other tobacco products were finally required to submit premarket review applications to the Food and Drug Administration (FDA) on September 9, 2020, following an order from the U.S. District Court of Maryland. To fulfill FDA's public health mission and comply with the requirements of the Family Smoking Prevention and Tobacco Control Act (TCA), we urge FDA as part of its review of premarket tobacco product applications (PMTAs) to reject any product that will increase the number of youth who use tobacco products, will increase the risk of nicotine addiction among youth, will disproportionally harm vulnerable populations, or that does not reduce the harm to public health.

For years, delays by FDA to enforce the premarket review requirements of the TCA for all new tobacco products enabled thousands of products to be marketed without undergoing a scientific review by FDA, including a wide array of flavored, high-nicotine e-cigarettes targeted to youth. If implemented properly, the long-overdue PMTA review can protect public health and halt our nation's epidemic of youth e-cigarette use.

The TCA appropriately sets a high bar for authorizing a PMTA for a new tobacco product, by placing the burden on manufacturers to demonstrate that the product is "appropriate for the protection of the public health" (APPH). This standard prevents FDA from authorizing a PMTA for a new tobacco product unless the manufacturer can prove such product does not lead to youth tobacco initiation and will reduce the risk of harm. Accordingly, we write to set forth a non-exhaustive list of principles that should guide FDA's review of PMTAs and application of the APPH standard, to remind you of the urgent need to enforce the premarket application requirements, and to ask you what the agency has done so far to comply with the September 9 deadline.

Principles That Should Guide FDA's Review of PMTAs

First, FDA should not authorize a PMTA that fails to show the product will not lead youth to start using tobacco products or to continue using tobacco products. Manufacturers have a history of designing tobacco products to make them more appealing to non-tobacco users, particularly young people. Blocking products that appeal to youth is especially important since almost all tobacco use begins during adolescence and youth are particularly vulnerable to the harmful effects of nicotine. Yet, to date, FDA has not required manufacturers to provide data on whether youth in the United States are more likely to use a tobacco product as part of their PMTAs. Meanwhile, the evidence shows that flavored tobacco products lead youth to start using tobacco products.

Thus, FDA should not authorize a PMTA for any flavored tobacco products. Flavored e-cigarettes and cigars have been on the market for years and have proven to be especially attractive to youth. Flavors reduce the harshness and increase the appeal of these products, making them dangerous as ideal starter products for youth. Studies from the FDA, National Institutes of Health (NIH) and Centers for Disease Control and Prevention (CDC) have found that 83 percent of youth who use e-cigarettes report using a flavored product and 70 percent say they use e-cigarettes "because they come in flavors I like." Given the lack of compelling evidence that flavors are necessary to help smokers stop using cigarettes—coupled with the abundant data about the link between flavors and youth use—FDA should refuse to authorize PMTAs for all non-tobacco flavored products, including mint and menthol.

Second, FDA should not authorize a PMTA that fails to show the product will not deliver a level of nicotine that increases the risk of addiction. Some e-cigarettes deliver as much nicotine as, if not more than, an entire pack of cigarettes. In recent years, e-cigarette manufacturers have begun using nicotine salts, which allow users to inhale higher levels of nicotine with less irritation than other forms of nicotine. As a result, more youth report using e-cigarettes frequently, a troubling sign that many are at risk for, or have already become, addicted. FDA should reject products that deliver a level of nicotine that places more youth at risk for a lifetime addiction.

Finally, FDA should not authorize a PMTA that fails to show the product will result in reduced harm to the public health, including for vulnerable populations. To that end, the PMTA for an e-cigarette must show, among other things, that the e-cigarette presents a lower risk than combustible cigarettes, will be used as a substitute for cigarettes, will be used only by adults who would otherwise continue to smoke, will not disproportionately harm populations (including African Americans, LGBTQ people, and Native Americans) with historic inequities in tobacco use, and will not delay or prevent a tobacco user from stopping altogether.

Enforcement of the September 9 Premarket Application Deadline

It is important for FDA to develop and implement a rigorous plan for enforcing the September 9 application deadline. Many of us have expressed to you and previous Commissioners our disappointment in FDA's refusal to prevent manufacturers from marketing e-cigarettes without FDA's authorization. Although we are encouraged by the effectuation of the application deadline, we are concerned that e-cigarette manufacturers that did not submit applications by September 9 will continue to sell their products and that FDA will not take adequate enforcement action to stop them. Continued sale of unauthorized new tobacco products renders the PMTA requirement meaningless and is detrimental to the public health. Accordingly, FDA must take appropriate enforcement action, which includes removing all unauthorized new tobacco products from the market. FDA must also follow through on its commitment to publishing a list of marketed e-cigarettes that are the subject of premarket applications filed by the deadline. FDA should act quickly to provide transparency and to take enforcement action against unauthorized new tobacco products and their manufacturers.

Questions Regarding FDA's Implementation of the PMTA Requirement for E-cigarettes

The premarket review requirement should be applied in a manner that, first and foremost, protects youth and other vulnerable groups from nicotine addiction and tobacco-caused disease and benefits the population as a whole. We request a response from FDA to the following questions by February 19, 2021.

1. Has FDA developed criteria to assess whether a new tobacco product is "appropriate for the protection of the public health"? If yes, please provide that criteria and framework. If no, please explain why it has not.

2. Does FDA believe that a manufacturer must clearly demonstrate in its PMTA for a new tobacco product that the product:

    a. Will not lead more people, particularly youth, to start using nicotine and tobacco?

    b. Does not contain any flavors (other than tobacco)?

    c. Will not deliver levels of nicotine that will increase the risk of addiction among youth?

    d. Is less harmful than other tobacco products?

    e. Will be used as a substitute for combustible cigarettes and will be used only by adults who would otherwise continue to smoke?

3. Has FDA developed a plan for monitoring the marketplace and enforcing the September 9 application deadline, including the removal of new tobacco products that did meet the deadline? If yes, please describe that plan. If no, please explain why it has not.

Thank you for your attention to this important matter. We look forward to the continued partnership to protect youth from e-cigarette addiction through effective FDA regulation.

Sincerely,

Richard J. Durbin
United States Senator

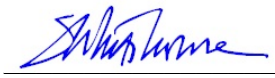
Lisa Murkowski
United States Senator

Patty Murray
United States Senator

Sherrod Brown
United States Senator

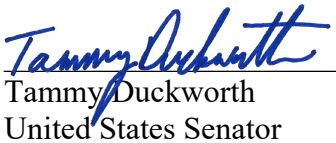
Richard Blumenthal
United States Senator

Jeanne Shaheen
United States Senator

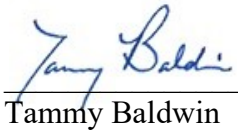


Sheldon Whitehouse
United States Senator

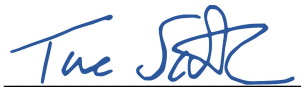
/s/ Jack Reed
United States Senator



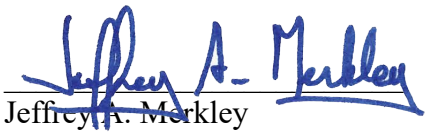
Tammy Duckworth
United States Senator



Tammy Baldwin
United States Senator



Tina Smith
United States Senator



Jeffrey A. Merkley
United States Senator