

United States Senate

WASHINGTON, DC 20510

March 9, 2022

Robert M. Califf, MD
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

Dear Commissioner Califf:

We are writing to express our deep concern that the Food and Drug Administration (FDA) is now six months overdue in fulfilling a court order to complete its premarket review of e-cigarettes and other deemed tobacco products. Because of this ongoing delay, the most popular e-cigarettes—including JUUL and other flavored products most responsible for addicting children—remain on the market.

This current six-month delay follows after the U.S. District Court for the District of Maryland found that FDA, “decided not to enforce the premarket review provisions at all...”. It is unacceptable that, despite having the authorities to regulate e-cigarettes, FDA has pursued a course of inaction that has fueled the youth vaping epidemic. We urge the agency to promptly complete its review of the remaining tobacco product applications, appropriately apply the statutory “appropriate for the protection of public health” standard to reject flavored products, and remove e-cigarette products that do not have an authorization from the market.

We recognize that FDA received a very large number of applications and commend the agency for completing work on the vast majority of them, including rejecting millions of flagrantly kid-friendly flavored e-cigarettes. But FDA has not completed its reviews by the court deadline of September 9, 2021, and is permitting unreviewed products to remain on the market, leaving children at risk of getting hooked on these e-cigarettes.

Contrary to its initial plan, FDA has not prioritized review of e-cigarettes with the largest market share and therefore greatest public health implication. Instead, it has deferred its decisions on the most critical applications—including for those products that are most popular with youth—to the end. As a result, six months after FDA was supposed to have completed its reviews, e-cigarettes that hold the greatest potential harm to public health remain unreviewed and on the market. In fact, FDA has not issued a marketing order or denial for any product since October!

Now that FDA is six months past the court deadline, these unreviewed products are only being permitted to stay on the market due to the agency exercising enforcement discretion. It makes no sense, and runs contrary to the Tobacco Control Act’s statutory framework, that products that have not been granted authorization are being allowed to stay on the market and attract new, young users. FDA has the authority and responsibility to halt

this grace period today and restore the statutory burden of proof on manufacturers to demonstrate their product is “appropriate for the protection of public health” prior to market entrance.

Flavored e-cigarettes remain unreviewed and on the market despite evidence that youth use e-cigarettes at high rates and that flavors are a primary reason why youth use e-cigarettes. The FDA’s and Centers for Disease Control and Prevention’s National Youth Tobacco Survey found that more than two million youth used e-cigarettes in 2021. The National Institute on Drug Abuse’s Monitoring the Future survey found that 19.6 percent of high school seniors used e-cigarettes last year. Flavors are a major reason. Approximately 85 percent of youth e-cigarette users report using flavored products, and 70 percent of youth e-cigarette users say they use e-cigarettes “because they come in flavors I like.”

We are pleased that, so far, FDA has not authorized any e-cigarette with flavors other than tobacco. For the premarket reviews that FDA has completed, the agency has correctly recognized that flavored e-cigarettes appeal to youth and has appropriately required manufacturers that want to continue to sell flavored e-cigarettes to provide “robust and reliable evidence” demonstrating that their potential benefit to adult smokers outweighs the significant known risks to youth.

We hope FDA continues to apply this standard as it completes its review of other flavored e-cigarettes, including menthol-flavored e-cigarettes. We are concerned that if FDA were to authorize one or more flavored e-cigarettes, youth would simply switch to those products. This is not a theoretical concern. When FDA removed certain flavored e-cigarettes from the market in 2020, youth migrated to those flavored products that remained on the market. FDA’s game of whack-a-mole does not work.

After being sworn in as FDA’s new Commissioner, you identified tobacco regulation as one of your priorities. There are a number of steps you can take that will protect kids from the dangers of e-cigarettes. We urge you to do the following:

- Promptly complete review of all pending e-cigarette applications, including products with the largest market share and those most popular with youth;
- Continue to rigorously apply the statutory standard for authorizing any e-cigarette and issue denial orders for all flavored products, including menthol-flavored e-cigarettes;
- Cease FDA’s illogical discretion and immediately prioritize enforcement against the flavored e-cigarettes with the largest market share and those most popular with youth that continue to be sold without authorization, including those with pending applications; and
- Ensure that all e-cigarettes receiving denial orders are quickly removed from the market.

Thank you for your attention to this matter. Many of us raised these issues in our meetings with you prior to your confirmation. It is our hope and expectation that you can bring a new approach and commitment to using all of FDA's tools and prioritizing public health to protect youth from the harms of tobacco and nicotine.

Sincerely,



Richard J. Durbin
United States Senator



Mitt Romney
United States Senator



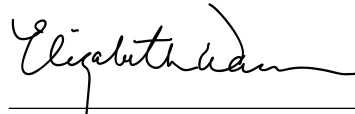
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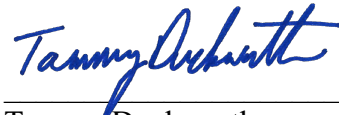
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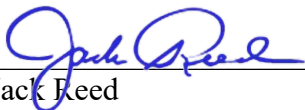
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