United States Senate

WASHINGTON, DC 20510

May 20, 2022

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

Dear Commissioner Califf:

Millions of children today are hooked on e-cigarettes promoted by some of the largest tobacco corporations in the country. After years of delay and inaction that allowed these products to proliferate and addict kids across America, the U.S. District Court of the District of Maryland ordered the Food and Drug Administration (FDA) to finally begin enforcing its own deeming rule to regulate these addictive, kid-friendly vaping products.

We recognize that FDA has finished its review of the majority of e-cigarette applications, including rejecting millions of flagrantly kid-friendly flavored e-cigarettes. However, we are disappointed that FDA has blown past the court-ordered deadline of September 9, 2021, for many of the e-cigarettes with the greatest market share. Notably, FDA still has not reviewed JUUL, the company arguably most responsible for causing the youth vaping epidemic—allowing unreviewed, unauthorized nicotine products to remain on the market, free to prey upon children.

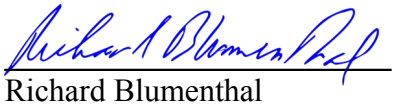
In a court filing on May 13, 2022, the FDA made an alarming admission and disclosed that it will not finish its premarket tobacco product application reviews until June 30, 2023. FDA is already more than eight months past the court-ordered deadline to finish reviewing e-cigarettes—now, the agency has revealed it may be nearly two years delayed before its work is done. This delay threatens public health.

The agency cannot sit back and allow its lengthy review period to provide a free pass for Big Tobacco to target kids with addictive, dangerous products. Yet e-cigarettes that are on store shelves today while under review, such as JUUL, only are permitted to stay on the market due to FDA exercising enforcement discretion. It runs contrary to the Tobacco Control Act that products that have not been granted authorization are allowed to be sold to new, young users. FDA has the authority and duty 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.

To protect public health, we urge you to cease FDA's enforcement discretion on unreviewed e-cigarettes by immediately removing these products from store shelves until their review is completed.

Sincerely,

Richard J. Durbin
United States Senator



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Sherrod Brown
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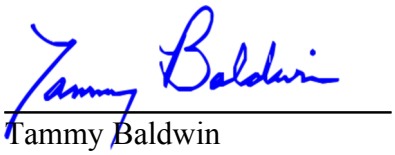

Tammy Baldwin
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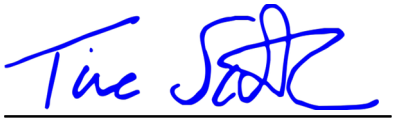

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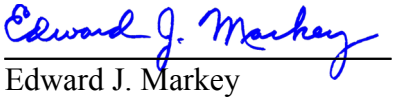

Edward J. Markey
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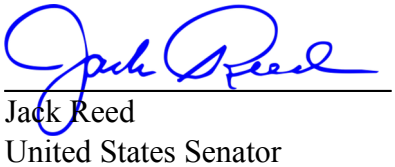

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