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

United States Senate
WASHINGTON, DC 20510-1304

December 9, 2021

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

Dear Acting Commissioner Woodcock:

Today marks THREE MONTHS past a deadline set by a U.S. District Court Judge for Maryland for the Food and Drug Administration (FDA) to complete its review and action on premarket tobacco product applications (PMTAs) for the millions of e-cigarette products that collectively have fueled the youth vaping epidemic. The overwhelming majority of these products had illegally entered the market without FDA review. Worse yet, these kid-friendly vaping products have remained on the market due to the agency's years-long failure to begin applying its regulatory oversight.

Over the past few months, I have been pleased to see the agency finally right its wrongs by beginning to use its authorities under the Tobacco Control Act to police the market of dangerous, addictive, and flagrantly kid-friendly e-cigarettes. Notably, FDA has rejected the applications of millions of products for failing to meet the public health requirements set out in the law and FDA's regulations.

However, FDA has failed to act on the vaping products with the largest market share and greatest appeal to children—a troubling and entirely perplexing delay given assurances by Center for Tobacco Products Director, Mitch Zeller, that these very PMTAs would be prioritized for review. Each day these flavored, kid-friendly e-cigarettes remain on the market, more children are at risk of picking up a dangerous nicotine addiction.

FDA finalized the deeming rule in 2016 to assert its authority over e-cigarettes, a time of promise for public health. Since then, tobacco and vaping companies have preyed upon and hooked millions of children. The Surgeon General and Centers for Disease Control and Prevention have found that these products, especially flavored e-cigarettes, are undeniably and overwhelmingly used by children, not adults. How many more deadlines does FDA need to blow past to finally wake up to its public health duty and do the right thing?

Sincerely,

Dick Durbin

Richard J. Durbin
United States Senator

CC: Mitch Zeller, Director, Center for Tobacco Products, FDA
CC: Dr. Robert Califf, nominee to serve as FDA Commissioner

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