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ILLINOIS
MAJORITY WHIP

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

United States Senate
WASHINGTON, DC 20510-1304

February 15, 2023

Dr. Robert Califf
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Califf:

Exactly one year ago today, you were confirmed by the Senate to once again serve as Commissioner of the Food and Drug Administration (FDA). After numerous meetings and calls about the urgency of addressing youth tobacco use, I voted in favor of your confirmation. I took that leap of faith because I hoped you—unlike your predecessors—would take swift, decisive action to protect our children from a lifetime of nicotine addiction. One year later, I realize I was wrong.

FDA is responsible for regulating e-cigarette products. Under the law, FDA is required to review applications from these tobacco product manufacturers and determine whether each product is "appropriate for the protection of the public health" *before* entry onto the market. To my dismay, and contradicting federal law, FDA has allowed unauthorized e-cigarette products to enter and remain on the market for years. And just recently, on your watch, FDA stated that it will not finish review of applications for the most popular e-cigarettes until December 31, 2023—more than two years past a court-ordered deadline to finalize review of these products. That is stunning.

Each day that these products remain on the market absent FDA authorization, more children pick up vaping—ask any teacher, parent, or student across the country. We can estimate that between now and FDA's projected timeline, up to one million children are at risk of starting to use e-cigarettes. I have called on FDA repeatedly to end its dangerous decision to grant enforcement discretion to these unauthorized products. Put simply: FDA should remove all unauthorized e-cigarette products from the market unless/until these products receive FDA authorization. This is what the law requires, and it is the responsible thing to do to protect children's health.

Your lack of urgency to address this situation is creating serious public health harm. Therefore, I would like to invite you to join me in visiting one of the many vape shops located in the District of Columbia. Perhaps you would have a greater appreciation for the seriousness and scope of FDA's failed enforcement if you could see, with your own eyes, the sheer volume of unauthorized and flagrantly kid-friendly e-cigarette products that FDA is allowing to be sold to our children.

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For too long, FDA has turned a blind eye to its tobacco enforcement duties. I hope you will be willing to observe the consequences. Thank you.

Sincerely,

Richard J. Durbin
United States Senator