United States Senate

WASHINGTON, DC 20510

February 1, 2023

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Ave, S.W.
Washington, D.C. 20201

Dear Secretary Becerra:

We write to once again draw your attention to the repeated failures of the Food and Drug Administration (FDA) to regulate the tobacco and e-cigarette market. While we understand the incredible pressures that FDA is under across its portfolio of regulated products, FDA's failures cannot be excused away by a heavy workload. For nearly a decade, the agency has neglected its duty under the law to regulate e-cigarettes, jeopardizing the health of millions of children. Now, after yet another delay in FDA's efforts to regulate the e-cigarette marketplace, it is now clear to us that FDA is adrift and lives are at risk.

To be clear, FDA's hapless e-cigarette oversight began when the prior administration made the decision in 2017 to delay implementation of the Deeming Rule, which had provided FDA with the authority to regulate vaping products. This delay led to millions of e-cigarettes illegally flooding the market without proper authorization as required under the *Tobacco Control Act*. These delays, coupled with aggressive and misleading advertising—targeted at children and pulled straight from Big Tobacco's playbook—helped to ignite the youth vaping epidemic. When FDA refused to act, a U.S. District Court thankfully stepped in, ordering FDA to follow the law and require submissions of premarket tobacco product applications (PMTAs) from all e-cigarette manufacturers by September 9, 2020.

Under the court order, FDA was supposed to complete its review of all e-cigarette PMTAs by September 9, 2021. This did not happen. In fact, FDA is still delinquent in this obligation—more than 16 months past the deadline set by the Court.

Last week, FDA submitted filings disclosing that it will take nearly another year for the FDA to complete its work—until December 31, 2023—for the e-cigarettes with the largest market share. We can project from retail sales and public health surveys that approximately one million children are at risk of newly picking up vaping in the intervening time that FDA misses the court order.

In the meantime, the agency has granted an unfathomable degree of deference to companies responsible for addicting children to nicotine. Some of the most popular e-cigarettes used by children today do not have market authorization but are on store shelves only because the FDA has granted a free pass and decided to exercise enforcement discretion. This grace period runs contrary to the *Tobacco Control Act's* requirement that manufacturers demonstrate their product is "appropriate for the protection of public health" prior to market entrance.

This enforcement discretion should have ended years ago. It must end today.

A scathing independent report from the Reagan-Udall Foundation found that FDA's, "failure to take timely enforcement action jeopardizes public health and undermines creditability and effectiveness in tobacco product regulation." It further stated that, "the Agency has not been transparent regarding the reasons it has failed to clear the market of illegal products." While we recognize the Department of Justice's (DOJ) key role in enforcement, and we plan to engage DOJ as well, this does not absolve FDA of culpability.

We recognize that FDA has received a 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 the reality is that too many addictive e-cigarettes continue to be peddled to children as FDA refuses to swiftly finalize applications and adequately enforce violations of the law's pre-market authorization requirement.

This is simply unacceptable. Each day that FDA fails to enforce against products illegally on the market, more children pick up vaping.

We need an FDA that stands on the side of public health and our children, rather than becoming mired in delays or cowering to Big Tobacco's lawyers. Together, we've made incredible progress in reducing the toll of death and suffering caused by tobacco and those who peddle that poison. But we are at a crossroads now. We ask you do everything in your power to right the ship and take meaningful action to fix FDA's persistent leadership failures and prevent youth from a lifetime of nicotine addiction.

Sincerely,

Richard J. Durbin
United States Senator

Mitt Romney
United States Senator

Jeffrey A. Merkley
United States Senator

Lisa Murkowski
United States Senator

Richard Blumenthal
United States Senator

Edward J. Markey
United States Senator

Tammy Baldwin
United States Senator

Jack Reed
United States Senator

Tammy Duckworth
United States Senator

Sherrod Brown
United States Senator

Elizabeth Warren
United States Senator

Sheldon Whitehouse
United States Senator

Jeanne Shaheen
United States Senator