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

United States Senate

WASHINGTON, DC 20510-1304

September 9, 2023

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

Dear Commissioner Califf:

Happy second anniversary. It's been two years. Today marks the two-year anniversary of a federal court-ordered deadline for the Food and Drug Administration (FDA) to complete its long-overdue review of pre-market tobacco product applications (PMTAs) from e-cigarette manufacturers. The failure of FDA to meet this court-ordered deadline jeopardizes public health and raises significant legal questions about the agency's compliance with the *Tobacco Control Act*. Based on published research, retail sales data, and public health surveys, an estimate of approximately two million children may have picked up vaping in the time since FDA missed its September 9, 2021, deadline. It is unacceptable for a federal agency to be so delinquent in complying with a federal court order, especially given the inexcusable harm it has caused to America's children.

Since FDA missed the court's deadline two years ago, I have sent eight letters raising key questions about FDA's regulatory review process and enforcement actions. You and I have met and spoken by phone several times. And a July 26, 2023, letter from public health leaders representing 24 of the nation's largest cities pleaded with FDA to shut down domestic distribution of unauthorized e-cigarettes that are filling store shelves across the country. Despite these efforts, FDA has failed to meaningfully act. It is unclear what—if anything—will finally prompt FDA to get its act together and take more seriously the risk of the tobacco industry addicting a new generation of kids.

While I commend FDA for processing millions of PMTAs—including rejecting thousands of flagrantly kid-friendly flavored products—the failure to police the market fully has rendered FDA's regulatory review almost meaningless. Under the *Tobacco Control Act,* manufacturers are required to demonstrate their product is "appropriate for the protection of public health" prior to entering the market. This has not happened. Despite the clear requirements under the law, thousands of unauthorized and addictive e-cigarettes currently are peddled to children every day because FDA refuses to enforce violations of the law.

A scathing independent report from the Reagan-Udall Foundation in December 2022 found that FDA's "failure to take timely enforcement action jeopardizes public health and undermines credibility and effectiveness in tobacco product regulation," and that "the Agency has not been transparent regarding the reasons it has failed to clear the market of illegal

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products." Following this report, FDA announced on February 24, 2023, its plan to hold a joint "summit" with the Department of Justice (DOJ) and other stakeholders to improve enforcement actions. If any such summit has even been scheduled or taken place, I am not aware of any readout, outcomes, or even participant list.

I have written to DOJ and spoken directly with Attorney General Garland about these enforcement failures and the need for enhanced interagency collaboration. An encouraging example was FDA's recent import alert for Elf Bar and Esco Bars, subjecting these e-cigarettes, which are unauthorized and extremely popular among children, to detention without physical examination at the time of entry. And while FDA, together with DOJ, has now used its civil monetary penalty (CMP) and injunction authorities in some two-dozen limited circumstances, it simply is not credible to suggest that this makes a dent in the flagrantly illegal products being sold to children.

My office has investigated FDA's public data files to identify e-cigarette manufacturers who have received both marketing denial orders and warning letters yet continue to sell unauthorized products, in order to assess FDA's effectiveness in taking enforcement action against some of the most obviously defiant examples. Our examination found at least 22 vaping products that currently appear to be sold online by the manufacturer—in violation of the law—and in defiance of repeated enforcement actions by FDA. In addition to those products sold online by the manufacturer, several other such products remain available for purchase from third-party retailers. This includes Breeze Smoke, which was found by the Centers for Disease Control and Prevention (CDC) to be among the top-five highest selling e-cigarettes in America. These products we identified are only the tip of the iceberg—our review excluded products that have a pending PMTA, that have a PMTA that FDA refused to file or accept, that never submitted PMTAs, or are sold exclusively in brick and mortar stores.

These appear to be flagrant examples of e-cigarette companies flouting FDA rules that are ripe for additional penalties, and yet FDA has not acted. In response to my March 16, 2023, inquiry, DOJ stated that, "FDA is not required to give notice to or receive approval from the Department before issuing such warning letters or civil monetary penalties." It is not clear why in these instances FDA has not used its authority to issue CMPs. In the continued absence of FDA action, my office has referred these cases to DOJ for review and potential enforcement action.

Further, my investigation found that FDA has only issued "closeout letters" to 10 percent of the 685 tobacco warning letters it has issued since January 1, 2021. A closeout letter indicates that FDA has verified that corrective action has taken place to address the violations contained in the warning letter. The fact that such a small percentage of warning letters have received closeout letters indicates that these violations have not been remedied adequately, and that the public health threat persists. It also appears to run contrary to FDA's claims that "many [companies] come into compliance after receiving a warning letter."

When FDA sounded the alarm in 2021 about new synthetic nicotine vaping products that were utilizing a regulatory loophole to evade FDA regulation, I led the swift, bipartisan effort to pass a law to subject these products to FDA's authority. Any synthetic nicotine vape that failed

to receive authorization by July 13, 2022, is now considered to be on the market illegally. That deadline was more than one year ago. Yet, despite obtaining new authority to regulate these vaping products, FDA has not fulfilled its duty—leaving some of the most popular e-cigarettes among children on the market without authorization. That is unacceptable and, frankly, infuriating.

With these synthetic nicotine products—as with other e-cigarettes—the question of whether or not a product has a pending PMTA should have no bearing on FDA's enforcement. For all unauthorized e-cigarettes on store shelves in 2023, the *Tobacco Control Act* does not provide a safe harbor for the mere fact that a PMTA is pending. The law sets forth a clear premarket framework. DOJ has stated to me that the "Department has no formal policy regarding enforcement discretion with respect to e-cigarette companies that have not obtained marketing authorization." These products are on the market illegally and pose a significant public health threat, yet FDA has repeatedly and inexplicably shied away from using its full arsenal of enforcement tools granted to the agency by Congress.

For years, you and FDA leadership have sought to distract from or justify your failures to protect children from being preyed upon by Big Tobacco by touting something around the corner: needing to close the synthetic loophole; a Reagan-Udall review; a summit with DOJ; time for a new Center for Tobacco Products Director to get acclimated. Meanwhile, FDA has missed a federal court deadline by two years, and the problem has only grown worse: the CDC found a 46 percent increase in the number of e-cigarette brands on the market between 2020 and 2022. If you are unwilling to meet this moment, perhaps FDA requires new leadership.

Sincerely,

Richard J. Durbin
United States Senator

cc: Dr. Brian King, Director, Center for Tobacco Products, FDA
cc: The Honorable Merrick Garland, Attorney General, DOJ