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MAJORITY WHIP

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

United States Senate

WASHINGTON, DC 20510-1304

March 16, 2023

The Honorable Merrick Garland
Attorney General
U.S. Department of Justice
950 Pennsylvania Ave, NW
Washington, DC 20530

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

Dear Attorney General Garland and Commissioner Califf:

I write to express my concern that the Biden Administration has not taken more aggressive enforcement action to stop thousands of illegal e-cigarettes from flooding the market and addicting children. I urge you to enhance interagency coordination to address unlawfully marketed vaping products, and request more information about your enforcement efforts.

Under the *Tobacco Control Act* (TCA), the Food and Drug Administration (FDA) is responsible for regulating the tobacco and e-cigarette market to protect public health. But for years, the agency has failed to do its job—allowing millions of new vaping products to illegally enter the market. The wide availability of these unauthorized and addictive products—many of which are targeted at children with fruit and candy flavors—fueled a dramatic increase in youth use of e-cigarettes, jeopardizing the health of millions of children.

The Department of Justice (DOJ) also plays an important role in enforcement of the TCA, given FDA's lack of independent litigation authority. We commend DOJ for acting last fall, for the first time, to seek injunctions against six manufacturers of e-cigarettes that were selling products without authorization.

But make no mistake: there are more than six e-cigarette manufacturers selling without authorization on the market today. In fact, there are thousands of vaping products on the market in violation of the law. Under the TCA, no new e-cigarette is permitted onto the market unless its manufacturer first proves to FDA that the product is "appropriate for the protection of public health." Yet this statutory pre-market review requirement is not properly enforced by our federal agencies. While I applaud FDA's efforts to adjudicate 99 percent of the 26 million applications it has received, those regulatory efforts are undermined if FDA fails to police the market and permits even those rejected vaping products to continue to be sold. Every single day in America, children pick up vaping with unauthorized products that are on store shelves only because FDA has seemingly granted these illegal e-cigarettes a free pass.

A December 2022 report from the independent Reagan-Udall Foundation found that FDA's "failure to take timely enforcement action jeopardizes public health and undermines credibility 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

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products." The report describes how "the current process of bringing enforcement actions is cumbersome, and ultimate decisions on whether to take enforcement action rest with DOJ rather than FDA." Additionally, the report concluded that "FDA's tobacco cases must compete for DOJ resources with other issues that require DOJ attention" and that DOJ's procedures have created "a high bar for the Agency in bringing cases."

I commend FDA's announcement of its intention to convene a summit with DOJ related to tobacco enforcement. It was long overdue. It is important that DOJ and FDA improve collaboration to address the barriers to enforcement that jeopardize public health, especially as it relates to our children. As this interagency effort progresses, we request DOJ and FDA's responses to the following questions by April 7, 2023:

1. Why have FDA and DOJ not acted, as the law contemplates, to clear the market of all unauthorized e-cigarette products, including visibly child-oriented products, on store shelves today?

2. Does FDA or DOJ have a formal policy regarding enforcement discretion with respect to e-cigarettes that have not obtained marketing authorization? If yes, please provide the policy and the statutory and public health justification for it.

3. Does FDA communicate with, notify, obtain guidance, or receive approval from DOJ prior to issuing any warning letters or civil monetary penalties to companies with unauthorized e-cigarette products?
    a. If yes, please provide an example of the considerations or feedback DOJ would provide to FDA prior to such enforcement action.
    b. If not, please provide an explanation for why FDA has issued only four civil monetary penalties, and issued warning letters to only approximately 450 manufacturers, representing a mere fraction of the tens of thousands of unauthorized e-cigarette products on the market today?

4. Other than the instances referenced above in which DOJ sought injunctions against six unauthorized e-cigarette manufacturers, has FDA referred any manufacturers of unauthorized e-cigarettes for enforcement?
    a. If yes, please provide a numerical tally of the number of such referrals, disaggregated by month over the past three years, as well as a de-identified description of the outcome of those referrals.
    b. If not, please explain the lack of referrals. In particular, is FDA unaware of other unauthorized e-cigarettes that are out of compliance with FDA's regulations or enforcement actions?

5. Has DOJ indicated, advised, or set any informal or formal policy with respect to FDA referring cases to DOJ for enforcement against manufacturers of unauthorized e-cigarettes?
    a. If yes, please describe that indication, advice, or policy.
    b. Would the mere fact that an unauthorized e-cigarette has a pending pre-market tobacco product application before FDA prevent or preclude FDA from referring such a product to DOJ for enforcement?

6. Has DOJ identified any barriers to additional enforcement actions against unauthorized e-cigarettes that are being peddled to children? If so, please describe them.

7. Has FDA identified any barriers to additional enforcement actions against unauthorized e-cigarettes that are being peddled to children? If so, please describe them.

8. Will FDA and DOJ commit to increasing their commitment and resource allocation to enforcement against unauthorized e-cigarettes that are being peddled to children?

9. What additional resources or tools, if any, can Congress provide to facilitate this interagency coordination on enforcement?

Thank you for your attention to this important matter. I look forward to receiving your responses and working with you to address the public health harm that e-cigarettes pose to our children.

Sincerely,

Richard J. Durbin
United States Senator