United States Senate
COMMITTEE ON THE JUDICIARY
WASHINGTON, DC 20510–6275

September 9, 2023

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

Dear Attorney General Garland:

I write regarding my ongoing concern about the lack of adequate federal enforcement action against e-cigarettes that are currently flooding the market and addicting children in violation of the *Tobacco Control Act* (TCA). This letter follows my March 15 letter and the Department of Justice's (DOJ) response on April 19.

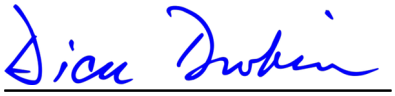
In the nearly six months since my correspondence, it is unclear what interagency coordination has taken place between the Food and Drug Administration (FDA) and DOJ to address the public health harm from thousands of unauthorized e-cigarettes that are marketed to youth online and in stores. Because FDA lacks independent litigation authority, DOJ plays an important role in taking enforcement action in response to these violations of the TCA.

My office has investigated FDA's public data files to identify e-cigarette manufacturers who have received both marketing denial orders and warning letters from FDA yet continue to sell unauthorized products (capturing only the most obviously defiant examples—*e.g.,* excluding products with pending pre-market tobacco product applications (PMTAs), that have a PMTA that FDA refused to file or accept, that never submitted PMTAs, or those sold exclusively in brick and mortar stores). 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 to be among the top-five highest selling e-cigarettes in America.

These appear to be flagrant examples of e-cigarette companies flouting FDA rules that are ripe for additional penalties. In its April 19 response to my March 15 letter, 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 (CMPs)." It is not clear why, in these instances, FDA has not used its authority to issue CMPs. Due to FDA's inaction, with this correspondence, I am transmitting these flagrant cases to you for review and potential enforcement action. Please find the enclosed document capturing the relevant findings from my review.

I appreciate DOJ's prompt attention to this matter.

Sincerely,



Richard J. Durbin
Chair