RICHARD J. DURBIN
ILLINOIS
MAJORITY WHIP

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

United States Senate

WASHINGTON, DC 20510-1304

January 16, 2024

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

Dear Commissioner Califf:

Another Durbin vaping letter for you to ignore.

As we begin a new year, it appears very little has changed in the Food and Drug Administration's (FDA) shamefully inadequate enforcement of the *Tobacco Control Act* against e-cigarettes that are addicting America's children. Despite modest and long-overdue actions to forge interagency collaboration and conduct enforcement in the most flagrant of cases, the FDA's delays in completing its reviews of premarket tobacco product applications and failure to remove all unauthorized e-cigarettes pose a threat to public health.

On January 1, 2024, FDA missed yet another deadline before a federal district court to complete reviews of e-cigarettes with the largest market share and youth appeal. FDA is now 28 months past the court-ordered deadline.

This repeated failure to meet FDA's own stated projections tells us FDA is not meeting its obligations under the court order. Given these delays, and with no end in sight, there is absolutely no reason why FDA continues to permit unauthorized e-cigarettes to remain on store shelves. FDA has the tools and the authority to clear the market of unauthorized products today, yet the agency instead is granting a free pass to scores of vaping products that are harming the health of children in our country.

At the same time, FDA is now also 18 months past a statutory deadline related to all unauthorized synthetic nicotine products. After you testified to the Senate that, "we've got to close this loophole," Congress acted swiftly to do so, and all unauthorized synthetic nicotine products were prohibited from being marketed after July 13, 2022. While FDA rejected a number of applications that lacked basic required information, the agency's regulatory delays and timid enforcement has meant in practice that the statutory deadline has come and gone as if the new law never even took effect. It is outrageous that FDA sounded the alarm on this emerging public health threat, but has failed to issue a marketing denial order for a single product, at a time when the most popular e-cigarettes used by children contain synthetic nicotine.

I have sought to assist FDA in its mission through legislative, regulatory, funding, and public awareness efforts. But the simple truth is that FDA does not appear to want to meet court

711 HART SENATE OFFICE BUILDING
WASHINGTON, DC 20510-1304
(202) 224-2152

230 S. DEARBORN STREET
SUITE 3892
CHICAGO, IL 60604
(312) 353-4952

525 SOUTH EIGHTH STREET
SPRINGFIELD, IL 62703
(217) 492-4062

1504 THIRD AVENUE
SUITE 227
ROCK ISLAND, IL 61201
(309) 786-5173

250 W. CHERRY STREET
SUITE 115-D
CARBONDALE, IL 62901
(618) 351-1122

durbin.senate.gov

orders or statutory requirements. Your unwillingness to utilize FDA's arsenal of enforcement tools and the repeated apparent deference to industry is at the expense of our children.

What could be more important than the health of our children?

Sincerely,

Richard J. Durbin
United States Senator