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

October 16, 2020

The Honorable Stephen M. Hahn, M.D.
Commissioner
United States Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

Dear Commissioner Hahn:

After years of delay, I am pleased that e-cigarette manufacturers were required to submit premarket tobacco product applications (PMTAs) to the Food and Drug Administration (FDA) on September 9, 2020. This public health milestone holds promise to address gaps in tobacco product oversight and enforcement, and finally bring sensible regulation to addictive and kid-friendly e-cigarettes as required by the Family Smoking Prevention and Tobacco Control Act.

Thousands of products now under FDA review have been on the market for years, including those responsible for fueling the youth e-cigarette epidemic—which has resulted in nearly four million children vaping, including one in five high school students. Many of these products were illegally introduced to the market after August 8, 2016, without an FDA marketing order. For years, FDA has inadequately enforced this deeming rule requirement, stemming from the fact that the agency never maintained a list of products on the market by August 8, 2016.

As part of FDA's plan under the order from the U.S. District Court of Maryland, the agency committed to quickly removing from the market all new tobacco products that did not submit PMTAs by September 9. To do so, FDA has stated it will, "make publicly available a list of the deemed new tobacco products that are subject to the Sept. 9 deadline, were on the market as of Aug. 8, 2016, and for which a premarket application is submitted by Sept. 9, 2020."

It has been more than one month since PMTA applications were submitted to FDA.

In order to protect public health and uphold the duty to enforce against products on the market that are out of compliance, I urge FDA to immediately publish a comprehensive product listing of all relevant e-cigarette applications received by FDA. While I appreciate the sheer volume of applications submitted to FDA, and the agency's intention to prioritize review of those with the greatest market share and public health impact, we know from recent years that youth shift patterns of e-cigarette use based upon what products are available to them. Therefore, it is imperative that FDA publicize its list and incorporate the totality of products that have submitted PMTAs, so thorough enforcement can quickly follow.

Thank you for your attention and efforts to protect youth from e-cigarette addiction.

Sincerely,

Dick Durbin

Richard J. Durbin
United States Senator

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