Sen. Durbin Urges FDA To Enhance E-Cigarette Transparency and Enforcement

October 19 2020 10:30 AM

CHICAGO – U.S. Senator Dick Durbin (D-IL) today urged the Food and Drug Administration (FDA) to strongly enforce its own regulations to protect kids from addictive e-cigarettes by publishing a list of products that submitted premarket tobacco product applications (PMTAs), and remove products that did not submit PMTAs. After years of delayed regulatory oversight, which fueled the explosion in youth e-cigarette use, FDA finally required e-cigarette PMTAs to be submitted for review on September 9. It has now been more than one month, and the agency has yet to publish a comprehensive list of products that submitted applications. Durbin cited concerns that the delay to publish the list of products that have submitted applications will allow products that remain out of compliance and illegally on the market to proliferate.

“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,” Durbin wrote in a letter to FDA Commissioner Dr. Stephen Hahn.

If an e-cigarette company wants to keep or put any new device or flavor product onto the market, it must submit an application to the FDA, including for products recently banned (such as certain flavored JUUL pods). E-cigarette products can remain on the market while FDA determines whether to approve or reject their applications. FDA has one year to make these determinations.

According to the 2020 National Youth Tobacco Survey, 3.6 million children are using e-cigarette products, including one in five high school students. More than 80 percent of such youth e-cigarette users reported using flavored products. In August, the Centers for Disease Control and Prevention (CDC) reported that half of Illinois high school students reported vaping or using an e-cigarette last year.

The Family Smoking Prevention and Tobacco Control Act (TCA) prohibits any new tobacco products, including e-cigarettes, from entering the U.S. market unless the FDA determines that there is "a showing that permitting such tobacco product to be marketed would be appropriate for the protection of the public health."

Full text of today's letter is available here and below:

October 16, 2020

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.

Thousands of the products that FDA will begin regulating have been on the market for years, including those responsible for fueling the current epidemic of youth e-cigarette use—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, I have been troubled by FDA's inadequate enforcement of this deeming rule requirement, stemming from the fact that the agency never maintained a list of which products were on the market by August 8, 2016.

As part of FDA's January 2, 2020 guidance, and its PMTA 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 to this important matter. I look forward to the continued partnership to protect youth from e-cigarette addiction through effective FDA regulation.