

Durbin, Senators To Trump Administration: Don't Let Tobacco Companies Evade E-cigarette Product Review

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WASHINGTON – Today, U.S. Senator Dick Durbin (D-IL), along with 10 of his Democratic Senate colleagues, sent a letter to Department of Health and Human Services (HHS) Secretary Alex Azar requesting clarification on his recent comments made on a radio program regarding Food and Drug Administration (FDA) review of vaping products. Secretary Azar hinted the Trump Administration could create a big loophole for tobacco companies by saying that "not all vaping products" are required to apply for premarket approval from FDA by May of this year—despite a July 2019 federal court order requiring such applications for all new tobacco products.

"It is incredibly alarming that while youth e-cigarette use is skyrocketing, the Trump Administration continues to focus on ideas that would delay and diminish long-overdue steps to hold tobacco companies accountable. In July 2019, a federal judge issued an order requiring that manufacturers submit premarket applications to FDA for deemed new tobacco products by May 12, 2020. In a January 21 interview on an Ohio radio program, you stated that 'by May of this year, all e-cigarettes – not all vaping products, just e-cigarettes, which are nicotine delivery devices – are required by law to come in and seek FDA approval.' You also stated the Administration was working 'to create pathways that would streamline approval for the open-tank, small vape shop-based products.'... It is essential FDA abide by the court's order, as well as all appropriate statutory and regulatory premarket review requirements for all new tobacco products, including open-tank systems and e-liquids made in small vape shops," wrote the Senators.

Last week, Durbin, along with 16 other bipartisan Senators, <u>wrote</u> to FDA Commissioner Dr. Stephen Hahn urging him to comply with the agency's requirements

to reject e-cigarette applications that do not protect the public health, upon the FDA's May 12 deadline for e-cigarette product review. Durbin highlighted concerns with FDA's ongoing lax oversight of e-cigarettes and tobacco products, and pressed the agency for a science-based review that holds the industry accountable for products that are responsible for fueling the youth e-cigarette epidemic.

On May 12, due only to a court order, all e-cigarette manufacturers will be required to submit product applications to the FDA in order to be allowed on the market. If an e-cigarette company wants to keep or put any new device or flavor product onto the market, they 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.

Today's letter was also signed by Senators Patty Murray (D-WA), Sherrod Brown (D-OH), Richard Blumenthal (D-CT), Jeanne Shaheen (D-NH), Jack Reed (D-RI), Amy Klobuchar (D-MN), Tina Smith (D-MN), Jeff Merkley (D-OR), Ed Markey (D-MA), and Elizabeth Warren (D-MA).

Full text of today's letter is available <u>here</u>: