Three Months From E-Cigarette Review Deadline, Senators Urge FDA to Protect Kids

February 13 2020 1:27 PM

WASHINGTON – U.S. Senate Democratic Whip Dick Durbin (D-IL), along with 16 other bipartisan Senators, today urged Commissioner of the Food and Drug Administration (FDA) Dr. Stephen Hahn 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. The Senators, in a letter to Commissioner Hahn, 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.

"As head of the FDA, your responsibility is to the American public, including, and most important, our nation's children," the Senators wrote. "As you know, five million children are now vaping, including one in four high school students—an increase of 135 percent over the past two years alone … we do not believe that a product that has increased or is likely to increase youth use of nicotine or tobacco can meet the public health standard required under the ."

The Senators also urged FDA to act quickly and decisively to remove from the market all tobacco products that are out of compliance with its January 2 guidance or the May 12 deadline, including products that do not submit premarket tobacco product applications (PMTAs), flavored cartridge-based products, and products that appeal to or are targeted to minors.

“When looking at the changing e-cigarette marketplace, including the proliferation of products that use nicotine salts, JUUL-like products, and disposable flavored products, it is virtually certain that many products have entered illegally. FDA will have failed to uphold its responsibility to protect public health if the May 12 deadline is enforced in the same manner as the deeming rule,” the Senators continued.

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.

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.”

Joining Durbin in sending today’s letter include: U.S. Senators Lisa Murkowski (R-AK), Patty Murray (D-WA), Susan Collins (R-ME), Sherrod Brown (D-OH), Mitt Romney (R-UT), Sheldon Whitehouse (D-RI), Elizabeth Warren (D-MA), Tammy Baldwin (D-WI), Jack Reed (D-RI), Richard Blumenthal (D-CT), Jeanne Shaheen (D-NH), Ed Markey (D-MA), Jeff Merkley (D-OR), Maggie Hassan (D-NH), Ron Wyden (D-OR), and Tom Udall (D-NM).