

Senators Urge FDA to Protect Kids as it Reviews E-Cigarette Applications

January 13 2021 4:03 PM

WASHINGTON – U.S. Senate Democratic Whip Dick Durbin (D-IL), along with 11 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, as part of the FDA's long-overdue product review for e-cigarettes that began on September. The Senators, in a letter to Commissioner Hahn, highlighted the high standard the Family Smoking Prevention and Tobacco Control Act (TCA) sets for authorizing premarket tobacco product applications (PMTAs), and urged the agency to conduct a science-based review that holds industry accountable for products that are fueling the youth e-cigarette epidemic. The Senators also provided a list of principles for the FDA to use as it reviews PMTAs, including to implement the statutory requirement by rejecting applications unless the manufacturer can prove the product does not lead to youth tobacco initiation and will reduce the risk of harm.

"For years, delays by FDA to enforce the premarket review requirements of the TCA for all new tobacco products enabled thousands of products to be marketed without undergoing a scientific review by FDA, including a wide array of flavored, highnicotine e-cigarettes targeted to youth. If implemented properly, the long-overdue PMTA review can protect public health and halt our nation's epidemic of youth ecigarette use," the Senators wrote.

The 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), Sherrod Brown (D-OH), Richard Blumenthal (D-CT), Jeanne Shaheen (D-NH), Sheldon Whitehouse (D-RI), Jack Reed (D-RI), Tammy

Duckworth (D-IL), Tammy Baldwin (D-WI), Tina Smith (D-MN), and Jeff Merkley (D-OR).

Full text of the letter is available here