

U.S. Sen. Baldwin: Senator Baldwin, Democratic colleagues to FDA Commissioner: Remove all unauthorized e-cigarettes from market immediately

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WASHINGTON – U.S. Senator Tammy Baldwin today joined a letter led by Majority Whip Dick Durbin (D-IL) to Food and Drug Administration (FDA) Commissioner Dr. Robert Califf urging the FDA to immediately remove all unreviewed e-cigarettes from store shelves until the agency completes its public health review of these vaping products. Currently, addictive, kid-friendly e-cigarettes like JUUL are on the market illegally but are being granted a free pass to be sold due to FDA’s decision to grant enforcement discretion. The court-ordered deadline for FDA to finish reviewing e-cigarette applications was September 9, 2021, more than eight months ago—leaving dangerous, kid-friendly e-cigarettes available on store shelves to hook children.

Last Friday, FDA submitted an update on the agency’s long-overdue review of e-cigarette applications. In it, FDA admitted it will not finish reviewing e-cigarettes until July 2023—nearly two years past the court’s deadline. JUUL and other e-cigarettes that get kids hooked on nicotine—and which have not received an authorization from FDA—may continue being sold for more than a year.

“Millions of children today are hooked on e-cigarettes promoted by some of the largest tobacco corporations in the country. After years of delay and inaction that allowed these products to proliferate and addict kids across America, the U.S. District Court of the District of Maryland ordered

the Food and Drug Administration (FDA) to finally begin enforcing its own deeming rule to regulate these addictive, kid-friendly vaping products,” the Senators wrote. Along with Baldwin and Durbin, the letter was also signed by Senators Tammy Duckworth (D-IL), Sherrod Brown (D-OH), Elizabeth Warren (D-MA), Ed Markey (D-MA), Tina Smith (D-MN), Richard Blumenthal (D-CT), Jack Reed (D-RI), Jeff Merkley (D-OR), and Sheldon Whitehouse (D-RI).

“We recognize that FDA has finished its review of the majority of e-cigarette applications, including rejecting millions of flagrantly kid-friendly flavored e-cigarettes. However, we are disappointed that FDA has blown past the court-ordered deadline of September 9, 2021, for many of the e-cigarettes with the greatest market share. Notably, FDA still has not reviewed JUUL, the company arguably most responsible for causing the youth vaping epidemic—allowing unreviewed, unauthorized nicotine products to remain on the market, free to prey upon children.” the Senators continued.

In March, Baldwin joined a bipartisan [letter](#) with 14 of her colleagues calling on FDA to finish its review of e-cigarettes immediately; reject applications for e-cigarettes, especially kid-friendly flavors, that do not prove they will benefit the public health; and clear the market of all unapproved e-cigarettes.

The FDA’s and Centers for Disease Control (CDC) and Prevention’s National Youth Tobacco Survey found that more than two million youth used e-cigarettes in 2021. The National Institute on Drug Abuse’s Monitoring the Future survey found that 19.6 percent of high school seniors used e-cigarettes last year. Approximately 85 percent of youth e-cigarette users report using flavored products.

“The agency cannot sit back and allow its lengthy review period to provide a free pass for Big Tobacco to target kids with addictive, dangerous products. Yet e-cigarettes that are on store shelves today while under review, such as JUUL, only are permitted to stay on the market due to FDA exercising enforcement discretion...To protect public health, we urge you to cease FDA’s enforcement discretion on unreviewed e-cigarettes by immediately removing these products from store shelves until their review is completed,” the Senators continued.

Full text of the letter is available [here](#) and below.

An online version of this release is available [here](#).

May 20, 2022

Dear Commissioner Califf:

Millions of children today are hooked on e-cigarettes promoted by some of the largest tobacco corporations in the country. After years of delay and inaction that allowed these products to proliferate and addict kids across America, the U.S. District Court of the District of Maryland ordered the Food and Drug Administration (FDA) to finally begin enforcing its own deeming rule to regulate these addictive, kid-friendly vaping products.

We recognize that FDA has finished its review of the majority of e-cigarette applications, including rejecting millions of flagrantly kid-friendly flavored e-cigarettes. However, we are disappointed that FDA has blown past the court-ordered deadline of September 9, 2021, for many of the e-cigarettes with the greatest market share. Notably, FDA still has not reviewed JUUL, the company arguably most responsible for causing the youth vaping epidemic—allowing unreviewed, unauthorized nicotine products to remain on the market, free to prey upon children.

In a court filing on May 13, 2022, the FDA made an alarming admission and disclosed that it will not finish its premarket tobacco product application reviews until June 30, 2023. FDA is already more than eight months past the court-ordered deadline to finish reviewing e-cigarettes—now, the agency has revealed it may be nearly two years delayed before its work is done. This delay threatens public health.

The agency cannot sit back and allow its lengthy review period to provide a free pass for Big Tobacco to target kids with addictive, dangerous products. Yet e-cigarettes that are on store shelves today while under review, such as JUUL, only are permitted to stay on the market due to FDA exercising enforcement discretion. It runs contrary to the Tobacco Control Act that products that have not been granted authorization are allowed to be sold to new, young users. FDA has the authority and duty to halt this grace period today and restore the statutory burden of proof on manufacturers to demonstrate their product is “appropriate for the protection of public health” prior to market entrance.

To protect public health, we urge you to cease FDA's enforcement discretion on unreviewed e-cigarettes by immediately removing these products from store shelves until their review is completed