Following The Two-Year Anniversary Of FDA Failing To Regulate Unlawfully Marketed Vaping Products, Durbin Again Urges FDA, DOJ To Act

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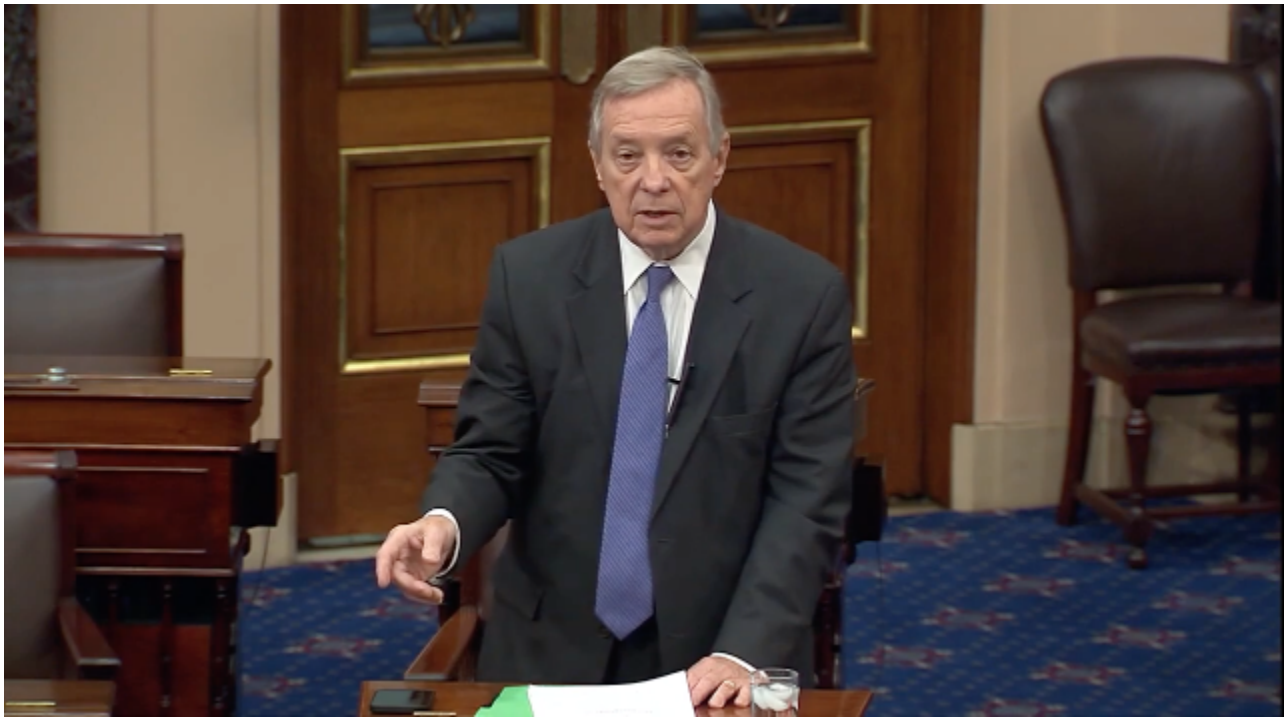

WASHINGTON – Following the two-year anniversary of a federal court-ordered deadline for the Food and Drug Administration (FDA) to complete its long-overdue review of pre-market tobacco product applications (PMTAs) from e-cigarette manufacturers, U.S. Senate Majority Whip Dick Durbin (D-IL), Chair of the Senate Judiciary Committee, sent a letter to FDA's Commissioner Dr. Robert Califf and a letter

to Attorney General Merrick Garland urging them to immediately address the youth vaping epidemic. Since FDA missed the September 9, 2021 deadline, an estimate of approximately two million children may have picked up vaping.

Durbin has slammed FDA for its continued lack of urgency as millions of children have begun using addictive e-cigarettes. For years, FDA has failed to regulate e-cigarettes—currently falling more than two years past a court-ordered deadline to review applications from vaping companies, and refusing to enforce the law and take action against companies marketing illegal vaping products to children. Under the *Tobacco Control Act* (TCA), e-cigarette companies are required to obtain authorization from FDA prior to entering the market, which the agency has neglected to properly enforce.

Durbin wrote to FDA, "Since FDA missed the court's deadline two years ago, I have sent eight letters raising key questions about FDA's regulatory review process and enforcement actions. You and I have met and spoken by phone several times. And a July 26, 2023, letter from public health leaders representing 24 of the nation's largest cities pleaded with FDA to shut down domestic distribution of unauthorized e-cigarettes that are filling store shelves across the country. Despite these efforts, FDA has failed to meaningfully act. It is unclear what—if anything—will finally prompt FDA to get its act together and take more seriously the risk of the tobacco industry addicting a new generation of kids."

The letters also follow a March 16th letter Durbin sent to FDA and the Department of Justice (DOJ) urging them to enhance interagency coordination. DOJ plays an important role in enforcement of the TCA, given FDA's lack of independent litigation authority. Following a scathing independent review of FDA's tobacco regulatory program that highlighted how inadequate enforcement efforts are jeopardizing public health, the agency recently announced its intention to convene a summit with DOJ related to tobacco enforcement. It remains unclear whether such summit has taken place or been scheduled, and what participants or outcomes there may have been.

Durbin wrote to DOJ, "In the nearly six months since my correspondence, it is unclear what interagency coordination has taken place between the Food and Drug Administration (FDA) and DOJ to address the public health harm from thousands of unauthorized e-cigarettes that are marketed to youth online and in stores. Because FDA lacks independent litigation authority, DOJ plays an important role in taking enforcement action in response to these violations of the TCA."

Durbin's office examined FDA's public data files to identify e-cigarette manufacturers who have received both marketing denial orders and warning letters yet continue to sell unauthorized products, in order to assess FDA's effectiveness in taking enforcement action against some of the most obviously defiant examples. Durbin's office found at

least 22 vaping products that currently appear to be sold online by the manufacturer in violation of the law and in defiance of repeated enforcement actions by FDA. In addition to those products sold online by the manufacturer, several other such products remain available for purchase from third-party retailers, including one of the most popular e-cigarettes, Breeze Smoke. These products are on the market illegally and pose a significant public health threat, yet FDA has repeatedly and inexplicably shied away from using its full arsenal of enforcement tools granted to the agency by Congress. Durbin's investigation also found that FDA has only issued "closeout letters" to 10 percent of the 685 tobacco warning letters it has issued since January 1, 2021. A closeout letter indicates that FDA has verified that corrective action has taken place to address the violations contained in the warning letter.

Durbin's letter to FDA continued, "In response to my March 16, 2023, inquiry, DOJ stated that, 'FDA is not required to give notice to or receive approval from the Department before issuing such warning letters or civil monetary penalties.' It is not clear why in these instances FDA has not used its authority to issue CMPs . In the continued absence of FDA action, my office has referred these cases to DOJ for review and potential enforcement action."

Durbin's letter to FDA concluded, "For years, you and FDA leadership have sought to distract from or justify your failures to protect children from being preyed upon by Big Tobacco by touting something around the corner: needing to close the synthetic loophole; a Reagan-Udall review; a summit with DOJ; time for a new Center for Tobacco Products Director to get acclimated. Meanwhile, FDA has missed a federal court deadline by two years, and the problem has only grown worse: the CDC found a 46 percent increase in the number of e-cigarette brands on the market between 2020 and 2022. If you are unwilling to meet this moment, perhaps FDA requires new leadership."

Durbin's letters follow a December 2022 report from the independent Reagan-Udall Foundation, which highlighted poor collaboration between the FDA and DOJ on enforcement against unauthorized e-cigarettes. The report found that FDA's "failure to take timely enforcement action jeopardizes public health and undermines credibility and effectiveness in tobacco product regulation." It further stated that "the Agency has not been transparent regarding the reasons it has failed to clear the market of illegal products." The report describes how "the current process of bringing enforcement actions is cumbersome, and ultimate decisions on whether to take enforcement action rest with DOJ rather than FDA." Additionally, the report concluded that "FDA's tobacco cases must compete for DOJ resources with other issues that require DOJ attention" and that DOJ's procedures have created "a high bar for the Agency in bringing cases."

Full text of the letter to FDA is available here.

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