Durbin Probes DOJ, FDA Coordination, Urges Enhanced Enforcement Of Unlawfully Marketed Vaping Products

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WASHINGTON – U.S. Senate Majority Whip Dick Durbin (D-IL), Chair of the Senate Judiciary Committee, today sent a letter to Attorney General Merrick Garland and Food and Drug Administration (FDA) Commissioner Dr. Robert Califf urging them to enhance interagency coordination to address unlawfully marketed vaping products, and requesting more information about their enforcement efforts. 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, which Durbin's letter commended.

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 18 months 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 enforce. DOJ also plays an important role in enforcement of the TCA, given FDA's lack of independent litigation authority.

Durbin wrote, "I write to express my concern that the Biden Administration has not taken more aggressive enforcement action to stop thousands of illegal e-cigarettes from flooding the market and addicting children. I urge you to enhance interagency coordination to address unlawfully marketed vaping products, and request more information about your enforcement efforts."

In the letter, Durbin commended DOJ for acting last fall, for the first time, to seek injunctions against six manufacturers of e-cigarettes that were selling products without authorization. The letter pointed out, however, that more still needs to be done.

"But make no mistake: there are more than six e-cigarette manufacturers selling without authorization on the market today. In fact, there are thousands of vaping products on the market in violation of the law. Under the TCA, no new e-cigarette is permitted onto the market unless its manufacturer first proves to FDA that the product is 'appropriate for the protection of public health.' Yet this statutory pre-market review requirement is not properly enforced by our federal agencies. While I applaud FDA's efforts to adjudicate 99 percent of the 26 million applications it has received, those regulatory efforts are undermined if FDA fails to police the market and permits even those rejected vaping products to continue to be sold. Every single day in America, children pick up vaping with unauthorized products that are on store shelves only because FDA has seemingly granted these illegal e-cigarettes a free pass," Durbin continued.

Durbin's letter follows 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."

In the letter, Durbin requested that FDA and DOJ respond to a number of questions by April 7, 2023, to provide an update on interagency effort progression. The full list of questions can be found in the letter text below.

Full text of the letter is available here.