Sen. Durbin Slams FDA's Missed Deadlines To Protection Our Children From Nicotine Addiction

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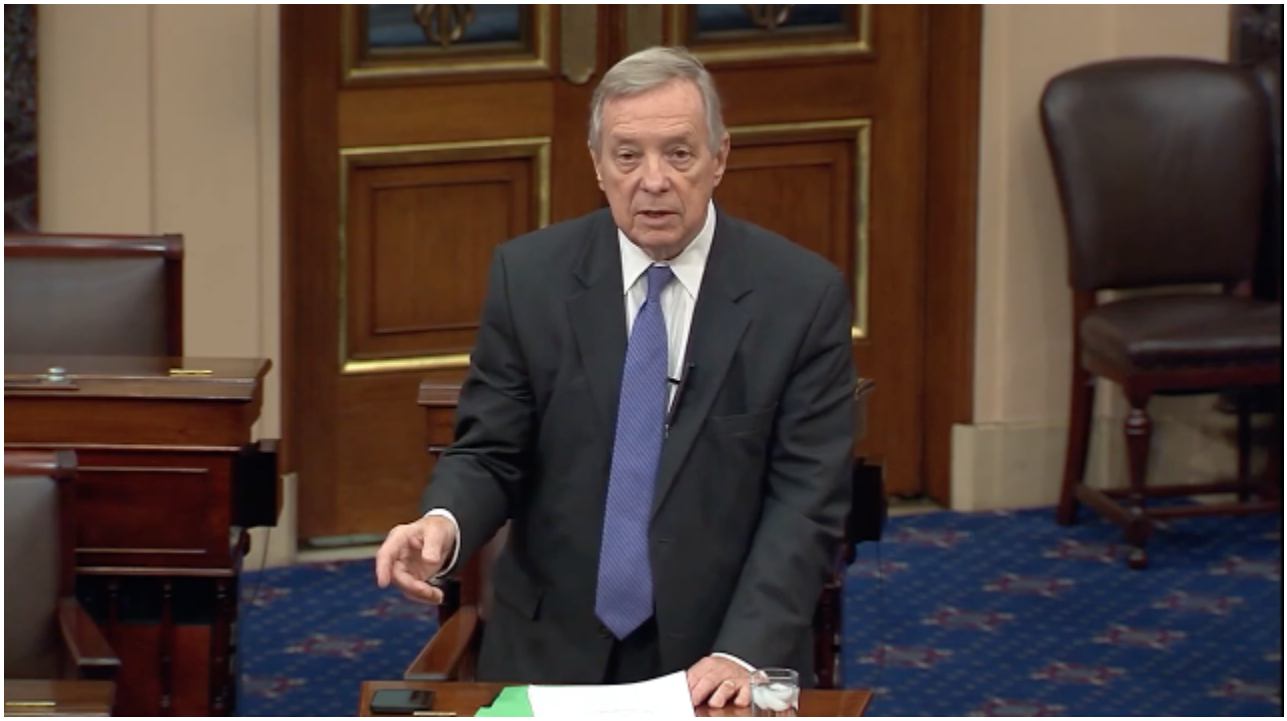

WASHINGTON – In a speech on the Senate floor today, U.S. Senate Majority Whip Dick Durbin (D-IL) condemned the Food and Drug Administration's (FDA) failure to meet e-cigarette and synthetic nicotine deadlines, unwillingness to take action against companies that defy the agency's orders, and general lack of urgency when it comes to protecting children from the harms of tobacco and nicotine use. The court-ordered deadline for FDA to finish reviewing e-cigarette applications was more than one year ago, September 9, 2021, and yet the agency has only completed reviews of about half of

those e-cigarettes with submitted applications that represent a large share of the market—leaving dangerous, kid-friendly e-cigarettes available on store shelves to hook children.

Durbin said, “As a result of FDA’s inaction, dangerous, kid-friendly e-cigarettes remain available on store shelves without FDA review or authorization. The Truth Initiative estimates that in the year since the FDA missed the federal court deadline to approve or reject e-cigarette applications, nearly two and a half million children and young adults started using vaping products. Many of those young people may go on to develop nicotine addictions, with serious harm to their health. That is the human cost of the FDA’s unwillingness to do its job.”

Durbin also condemned FDA for failing to meet synthetic nicotine application deadlines. Durbin and Senator Susan Collins (ME-R) successfully secured a bipartisan provision in the Fiscal Year 2022 Omnibus Appropriations bill that clarified FDA’s ability to regulate products containing synthetic nicotine as tobacco products. This legislative fix was necessary to close legal loopholes that manufacturers of kid-friendly, flavored e-cigarettes sought to sidestep FDA regulation, which had the potential to erase recent progress made toward curbing the nationwide youth vaping epidemic. Unfortunately, FDA also failed to complete its review of synthetic nicotine products by a July 13th deadline, leaving these addictive products on the market without authorization and in violation of the law. One of the most popular e-cigarettes among children today, Puff Bar, uses synthetic nicotine.

“To make matters worse, even when the FDA does review a product and issues a denial, many e-cigarette companies just ignore them. It's reached a point that they're not viewed seriously. The number one regulator of food and drugs in America when it comes to protecting our kids from these deadly addictive products isn't viewed seriously. The FDA has the legal right and the legal authority to do something. They can pull these products off the shelves tomorrow. And yet with respect to illegal e-cigarettes, they do nothing,” Durbin continued.

Given these ongoing failures of FDA to meet deadlines or enforce orders, last week, Durbin sent a letter to Health and Human Services (HHS) Secretary Xavier Becerra to step in.

During his speech, Durbin also urged his colleagues to attach his bipartisan dietary supplement legislation to an upcoming reauthorization of FDA’s “user fee” programs. These programs authorize FDA to collect various user fees from the companies they oversee, including prescription drug and medical device companies.

“Many people were surprised to learn that today dietary supplement companies are not even required to register their products with the FDA. They aren't required to tell the FDA the ingredients of their products,” Durbin said.

Durbin and Senator Mike Braun’s *Dietary Supplement Listing Act of 2022* would require dietary supplement manufacturers to list their products with the FDA, as well as provide basic, common-sense information about ingredients and labels. Durbin is currently pushing for the legislation to be included in any final “user fee” package that reaches the Senate floor.

Durbin concluded, “The FDA is one of the most important agencies in the federal government. It's fallen on hard times. It is there to protect the health of families across the country, especially our children. Whether it's dietary supplements, tobacco, or e-cigarettes, we need to make sure the FDA not only has the tools for the job, but uses them.”