Testimony of Senator Richard J. Durbin

House Oversight & Government Reform Subcommittee on Economic and Consumer Policy

Hearing: "An Epidemic Continues: Youth Vaping in America"
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Chairman Krishnamoorthi, Ranking Member Cloud, thank you for inviting me to testify again about the youth vaping epidemic and the role of the Food and Drug Administration in overseeing the tobacco industry. The campaign to reduce tobacco use and prevent our kids from a lifetime of addiction is a personal one to me. My father died from lung cancer. He smoked two packs of Camels a day. As a young high school student, I will never forget how he struggled to breathe during my visits to the hospital in his last days. Cigarettes are responsible for more than 480,000 deaths every year in the U.S.—they were responsible for my dad's death.

So ever since I came to Congress, I have dedicated my career in public service to this fight: holding the tobacco industry accountable for its lies and deceptive promotion; empowering families, schools, and health care providers to prevent kids from the terrible addiction to nicotine; and working to build and strengthen a regulatory framework that emphasizes public health.

When I last testified before this Subcommittee in July 2019, most of our focus was on the skyrocketing rates of youth e-cigarette use—fueled primarily by the kid-friendly flavors, aggressive promotion, and high-nicotine concentration of products made by JUUL. Since that time, my office, this Subcommittee, and the public health community have shone a bright light on the abusive tactics by JUUL that contributed to its foothold with our children. We now have uncovered the disgusting tactics used by this company to hook our kids on its addictive e-cigarette products. And I'm pleased our public health and anti-trust regulators have begun to step in.

But what I want to focus on today are the shortcomings of the FDA over the last several years, and the opportunity that sits before the agency today to rectify its missteps and finally put public health, and children, at the forefront of its mission. Flavored e-cigarette products have exploded in popularity among our kids—with nearly 4 million kids now vaping, a 361 percent increase in just 8 years when fewer than 800,000 kids were vaping. One in five high-school students are use e-cigarettes. These alarming trends are erasing the historic progress we've made in reducing youth tobacco use over the past several decades.

Who is the cop on the beat? It's the FDA. And this agency has been asleep at the wheel for too long. For years, the FDA delayed implementation of its requirement that companies submit "PMTA" applications for review. At the same time, the FDA allowed e-cigarettes to proliferate essentially unregulated, failing to enforce its own "deeming rule"—which required that all new products entering the market after August 8, 2016, undergo a public health review.

Since my last testimony, we had a glimmer of hope when President Trump promised in September 2019 to ban all e-cigarette flavors. And as part of that, the FDA in January 2020 had a golden opportunity to finally clear the market of these addictive kid-friendly products—the vast majority of which were on the market illegally. But instead, FDA took a half-measure, only partially clearing the market, and leaving major loopholes for industry to exploit.

The result? Kids migrated to products that remained unregulated on the market: menthol flavored e-cigarettes and disposable vaping products. The use of disposable e-cigarettes—which were exempted from FDA's January 2020 action—increased 1,000 percent in 2020. And because FDA allowed menthol-flavored cartridges from JUUL and others to stay on the market, their use increased from 11 percent of the cartridge market to 62 percent. This was yet another failure by the FDA to take adequate action to protect kids.

Now we approach one of the biggest milestones in FDA's tobacco regulation history, and I worry the agency will again fail to meaningfully side with our kids to prevent addiction.

After years of delay by Administrations of both parties, the FDA—under court order—finally required e-cigarette and tobacco manufacturers to submit applications for their vaping products on September 9, 2020. This is the long-awaited opportunity for the FDA to apply the public health standard that Congress passed in 2009 under the Tobacco Control Act to evaluate whether a product can stay on the market if it is, "appropriate for the protection of public health." That is an intentionally high bar—it requires the FDA to balance the risk of youth initiation with potential benefit of adult cessation from tobacco products. And the burden is on the manufacturers to show their products will not lead to youth use, to show their products do not harm the user, and to show they actually help adults quit.

But I am deeply troubled by what I have heard and responses I've received to my letters from FDA. I fear that FDA will over-value the unproven potential benefit of cessation for adult smokers, while under-valuing the clear evidence and experience we've had over the past several years on how these flavored products hook our kids. Only 4 percent of adults are using e-cigarettes compared to 20 percent of high-school students. Kids who never would have picked up a tobacco product are vaping.

It's quite simple: any product with a history of increasing youth use must be rejected by FDA—especially flavored products that we know are meant to hook kids, and, sadly, do an effective job of it. This is the Super Bowl for the FDA's tobacco effort. I worry they are not up for this primetime challenge.

The FDA recently announced plans to ban menthol cigarettes, an important public health action which I commended Acting Commissioner Woodcock on when she called me with the news.

But just like that step, the time is now for FDA to take meaningful action on how it applies its public health standard to e-cigarettes. We know that FDA's after-the-fact enforcement, warning letters, and this perpetual game of whack-a-mole is not an effective way to prevent youth use. To put it more bluntly: FDA's slow-walking and refusal to forcefully act has enabled e-cigarette

companies to addict a new generation of children on nicotine. It is time for FDA to be our partner in public health, not Big Vape, and take these dangerous products off the market.

As this Subcommittee continues to examine the youth e-cigarette epidemic and the role of the FDA in policing the tobacco industry, I hope we prioritize our kids by ensuring flavored, addictive e-cigarette products are not given the green light by FDA.

Thank you for the opportunity to testify.