
FDA’s Delay on Largest E-Cigarette Companies’ Applications Allows Top Brands with 75% of the Market Share to Remain Widely Available, Extending the Youth Vaping Epidemic and Delaying Necessary Regulations to Help Smokers

Statement of Robin Koval, CEO and President, Truth Initiative

WASHINGTON, D.C. (September 9, 2021) – Today marked the long-awaited deadline for the FDA to finish reviewing applications from e-cigarette makers and decide whether their products are “appropriate for the protection of public health,” and can stay on the market. We are encouraged that the FDA appears to be recognizing that flavors must be removed in the interest of protecting youth and public health, and menthol should absolutely be included. But we are very concerned that the FDA did not prioritize and complete the reviews of the companies with over 75% of the e-cigarette market as they promised to do, especially category leader JUUL, which started the youth e-cigarette epidemic in the first place, followed by Vuse, blu, Logic, and NJOY, which round out the top brands. Postponing decisions on those with the lion’s share of the market further empowers the big, rich, tobacco companies to continue to grow their business and profits on the backs of young people putting millions at risk for a lifetime of nicotine addiction. As the FDA grapples with its responsibilities and timelines, unbridled access to youth-appealing e-cigarettes containing highly addictive nicotine, and found in most neighborhood corner stores, cannot be allowed to stand.

Truth Initiative has long called on the FDA to fully regulate e-cigarettes and remove all non-tobacco flavors, including menthol, from the market. Their removal is critical as flavors remain a key factor in hooking youth on tobacco products. In 2020, 82.9% of youth who vape used flavored e-cigarettes, including 84.7% of high school users and 73.9% of middle school users. Menthol must not be exempted – the flavor has long played a role in drawing youth and young adults to tobacco products and perpetuating tobacco use disparities, with disproportionately higher use among Black Americans and youth.

Moreover, as detailed in [our statement on harm reduction](#), we believe adult smokers who might possibly benefit from a carefully regulated market with products that have proved they are safe and do what they promise are not well served by the continuation of a free-for-all commercial market.

Indeed, the usage rate of e-cigarettes among adults continues to hover around 4%, essentially unchanged from when national surveys began monitoring it in



2014 and with no concurrent significant change in the annual decline of adult smoking rates. A regulatory regime aimed at focusing the market on adult smokers and restricting it from youth would include carefully weighing access restrictions to products with high appeal and/or addiction liability. The ideal path for these products would be as cessation therapies through the Center for Drug Evaluation and Research.

To protect both young people and potentially help adult smokers, no nicotine product should be marketed to youth or non-nicotine users. Rather, marketing efforts should focus exclusively on adult smokers seeking to quit smoking completely and ideally who will stop using all nicotine eventually. As the FDA considers the pending applications, it is imperative the agency carefully reviews manufacturer marketing plans, advertising, and perception studies to confirm the products do not appeal to youth or new users. This should include research confirming lack of appeal among young people. FDA authorization of e-cigarettes should be accompanied by strict requirements that restrict access to adult smokers, including selling e-cigarettes in adult-only retail spaces, no internet sales, no self-service sales, and no in-store/window promotional signage near schools. Any marketing authorization should be followed up with post-marketing surveillance to confirm the product has not attracted youth users.

The FDA should also limit nicotine levels of e-cigarettes – which if left unchecked will continue to grow, making products increasingly addictive – by capping nicotine strength as is done in the EU and Canada. The average nicotine concentration in e-cigarettes sold in U.S. retailers more than doubled from 2013 to 2018, according to [a study by Truth Initiative and Centers for Disease Control and Prevention](#) researchers.

According to the latest [National Youth Tobacco Survey \(NYTS\) 2020](#), 19.6% of high school students and 4.7% of middle school students are current e-cigarette users, significantly increasing the likelihood that they will continue to use tobacco products, including the most dangerous combustible products such as cigarettes, in the future. New research amasses daily about the potential health risks of e-cigarettes and vaping, especially for youth, and we know little about their long-term effects. In addition to the health risks, vaping saddles young people with the problems of a potentially lifelong addiction, such as physical and mental health issues, financial costs, and more.

Truth Initiative will continue to combat the youth e-cigarette epidemic with public education and prevention, scientific research and policy studies, community and



youth engagement programs, and innovations to help young people quit. These efforts include our proven effective [truth[®]](#) youth and young adult public education and prevention campaigns; [Vaping: Know the truth](#), a national youth vaping prevention curriculum available for free to schools and communities; and [This is Quitting](#), a free and anonymous text message-based quit program that has enrolled more than 367,000 young people.

We will continue to urge the agency to remove all non-tobacco flavors from the commercial market and limit the addiction liability of these products as part of a comprehensive set of federal regulatory measures to help protect youth from a lifetime of nicotine addiction. In the absence of necessary federal protections, states and local communities – often the incubators of strong tobacco control policies – should continue leading the way by enacting flavor restrictions and other local policies on the sale of tobacco products.

About Truth Initiative[®]

Truth Initiative is a national public health organization that is inspiring lives free from smoking, vaping and nicotine and building a culture where all young people reject tobacco. In 2020, we celebrated 20 years of saving lives and preventing millions of youth from smoking. Our impact has helped drive the teen smoking rate down from 23% in 2000 to 4.2% in 2020. The truth about tobacco and the tobacco industry are at the heart of our proven-effective and nationally recognized **truth[®]** public education campaign. **truth** has also recently taken on the youth epidemics of vaping and opioids. Our rigorous scientific research and policy studies, community and youth engagement programs supporting populations at high risk of using tobacco and innovation in tobacco dependence treatment, are also helping to end one of the most critical public health battles of our time. Based in Washington D.C., our organization, formerly known as the American Legacy Foundation, was established and funded through the 1998 Master Settlement Agreement between attorneys general from 46 states, five U.S. territories and the tobacco industry. To learn more, visit truthinitiative.org.

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