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## FDA's decision to deny JUUL marketing authorization is a major public health victory; but swift action on other leading brands must be taken as new data shows youth e-cigarette initiation continues

Statement by Robin Koval, CEO and President, Truth Initiative

WASHINGTON, D.C. (June 23, 2022) – Today's announcement by the Food and Drug Administration to deny marketing authorizations for all JUUL e-cigarettes, thereby making them an illegally marketed product, is a huge public health victory that will save lives and protect millions of teens and young adults from the harms of nicotine use and risks of addiction. We applaud the Biden Administration and FDA for taking this urgently necessary and long-awaited action that clearly acknowledges the significant role JUUL played in igniting the ongoing youth e-cigarette epidemic, one that the U.S. Surgeon General says has had a negative impact on the physical and mental health of America's youth. By holding JUUL accountable and prioritizing public health over corporate profiteering, the FDA is making the right decision – one that we, with our public health partners, have been urgently calling for along with the removal of all flavored e-cigarettes, including menthol.

FDA noted in its denial of JUUL's application that there was insufficient toxicological evidence to determine that keeping them on the market would be "appropriate for the protection of public health" – the standard by which FDA must evaluate tobacco products. The history of JUUL makes it clear that these products – owned in part by Altria, the maker of Marlboro – have no place in our society. Congressional hearings in 2019 about JUUL's role in the youth ecigarette crisis provided, with the company's own testimony and documents, startling evidence that since virtually day one of its existence, the company employed numerous strategies and tactics targeting young people, including the use of social media influencers, attempts to infiltrate school programs, and even funding summer camp programs for children as young as eight. The result, by 2018 JUUL had captured an astonishing 75% share of the e-cigarette market and even more shocking had been the driver behind a youth vaping rate that at its peak included 27.5% of high school students as regular e-cigarette users and was so ubiquitous in youth culture that school bathrooms were dubbed "JUUL rooms."

Now that the FDA has taken action on the brand that ignited the youth vaping epidemic, the agency must accelerate progress and act without further delay on the other e-cigarette products that are sustaining it by continuing to target youth.





The agency must immediately prioritize completing its review of the top brands that make up the majority of the total e-cigarette market and are most popular among youth, including Vuse Alto, Logic, NJOY, Blu, and newcomer Elf Bar. The FDA must also use its authority to address synthetic nicotine as part of this process so that leading disposable brands like Puff Bar can no longer slip through this loophole. The only way to end the "whack-a-mole" approach to regulation and enforcement is for FDA to comprehensively remove all flavored tobacco products, including menthol, from the market. Furthermore, the FDA should immediately remove all unreviewed e-cigarettes, which should have been removed from the market on September 9<sup>th</sup>, 2021.

This decision comes at a critical time as new data shows that every day we await the FDA to complete its review, more young people are put at risk of a lifetime of nicotine addiction. New Truth Initiative research shows that nearly 1.5 million young people, including nearly 800,000 teens between 15-18 years old, vaped nicotine for the first time between July 2021 and June 2022, the months surrounding and following the FDA's missed September 2021 deadline to complete its review of e-cigarettes. This initiation of children to the risks of nicotine addiction and the unknown physical health risks of e-cigarettes is made even more troubling amidst the toll of today's mental health crisis on young people and the known connection between nicotine and mental health symptoms of depression and anxiety.

Just as young people deserve to live free of the harms of nicotine addiction, adult smokers deserve products that meet public health standards. A completed FDA review can help determine if any tobacco-flavored e-cigarettes can help support adult smokers to improve their health outcomes. Truth Initiative supports regulation that encourages the development of consistently less harmful nicotine delivery alternatives that allow smokers to quit altogether or switch completely to a much less harmful, well-regulated product. For the many young people who want to quit vaping nicotine, support exists through This is Quitting, a free and anonymous text message program from **truth**® that has enrolled nearly 500,000 young people, providing them with tailored advice, cognitive and behavioral coping strategies, and social support to help them quit. Truth Initiative also offers free digital and community-based quit smoking programs for adults through BecomeAnEx.org and its enterprise EX Program for employers and health care providers.

Combined with the recent proposals to eliminate menthol cigarettes and flavored cigars, reduce nicotine in cigarettes to non-addictive levels and today's JUUL



news, the Biden Administration is taking historic, refocused actions to end our nation's tobacco epidemic. The FDA must move swiftly to finalize, implement, and enforce its proposed actions to protect youth, help adult smokers, and advance public health equity by ending the leading cause of preventable death and creating a future free from tobacco and nicotine addiction.

## About Truth Initiative®

Truth Initiative is a national public health organization dedicated to achieving a culture where all young people reject smoking, vaping and nicotine and a future where tobacco and nicotine addiction are a thing of the past. 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 under 3% in 2021. The truth about tobacco and the tobacco industry are at the heart of our proven-effective and nationally recognized truth® public education campaign. As youth e-cigarette use threatens to put a new generation at risk for nicotine addiction, we are leading the fight against tobacco and nicotine addiction in all forms. 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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