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New Truth Initiative data show 2.5 million youth and young adults started using e-cigarettes since FDA missed the September 9, 2021, court-ordered deadline to remove unreviewed products from the market

Statement of Robin Koval, CEO and President, Truth Initiative

WASHINGTON, D.C. (September 9, 2022) – Today marks one year since the Food and Drug Administration (FDA) was required by court-order to remove all ecigarettes from the market that had not received marketing authorization. Yet, today, thousands of products remain on the shelves illegally, and millions of young Americans continue to be at risk of nicotine addiction as the FDA postpones its decisions on the major brands most popular with youth. A new analysis from Truth Initiative shows the high cost of the FDA's inaction, estimating that nearly 2.5 million youth and young adults (15-24 years old) have started using e-cigarettes for the first time following the missed deadline. This includes up to 1.2 million teenagers (15-17 years old), over 500,000 underage young people (18-20 years old), and over 700,000 young adults (21-24 years old).

While it is true that the FDA has authorized 23 e-cigarette products and denied more than 1.2 million others, the fact remains that those products represent a very small percent of the market and in fact in a number of cases were for products no longer on the market. At the same time, products representing a 75% share of the market remain on the shelves illegally including market leaders Vuse and JUUL. Even more troubling, after initially denying the application for JUUL, the company that started the youth e-cigarette epidemic and the subject of an imminent \$440 million settlement with 34 states and territories for doing so, the FDA quickly put a stay on their own decision, making an already complex process even more confusing and opaque. Delays and backtracks such as these have allowed the tobacco industry to continue to flood the market with new products with apparently little fear of federal reprisal and have essentially morphed the intention of Congress for pre-market review of any tobacco product before being offered for sale to a post-market "catch us if you can" endless conveyor belt of new offerings. In fact, according to Nielsen data, since late 2021 more than 1,000 new products have entered the retail distribution chain, allowing both big tobacco companies and foreign supplied backyard start-ups to continue to expand their business while America's young people pay the price in terms of their physical and mental health.

It is long past time for FDA to grapple with the failures of its discretionary enforcement policy and the now clear intentions of the industry to game the





system flooding and overloading FDA's review process. It is evident now that the agency erred in allowing these products to stay on shelves while their applications were pending. Rather than significantly accelerating the demise of deadly combustible cigarettes and rapidly raising quit rates among smokers as once hoped, this policy has instead provided a "free pass" for manufacturers and retailers to capture a next generation of potential addicted users for life. We implore FDA's new leadership to rethink their current strategy and review all tobacco products *before* they are available for purchase and only allow them on the market once they have been reviewed and meet the rigorous public health standards required to be considered appropriate for the protection of public health. That is what Congress intended, what adult smokers should demand to make sure any product they might choose to help them switch completely from deadly cigarettes is significantly safer and likely to help them stay off cigarettes, and most importantly what our young people deserve.

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 addict a new generation to nicotine, 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.