
Truth Initiative calls on the FDA to immediately remove all unauthorized e-cigarettes including synthetic nicotine now on the market illegally to protect public health

Statement by Robin Koval, CEO and President, Truth Initiative

WASHINGTON, D.C. (July 14, 2022) – While we are glad to see the Food and Drug Administration begin to take action on synthetic nicotine – now is the time for bold versus incremental steps. Truth Initiative calls on the FDA’s leadership to immediately remove all synthetic nicotine products now on the market illegally like Puff Bar, a top youth brand, and to only allow e-cigarettes that have been reviewed and meet the rigorous public health standards to remain on the market. FDA should accelerate and prioritize the application review process for tobacco derived and synthetic nicotine e-cigarette products that make up the majority of sales and are most popular among youth. Until then it should use its full authority to remove any product that has not received authorization either because it has not submitted an application, has received a marketing denial order, or is still in the process of review.

The Food and Drug Administration’s decision in 2017 to extend the deadline for e-cigarettes to submit Premarket Tobacco Product Applications for years and allow manufacturers to continue to market products while the agency reviews applications, was flawed from the start and has clearly failed the American people. This action, under the guise of helping smokers by providing continued access to e-cigarettes during the review process, worked instead to enable the proliferation and appeal of these products to young people leaving our nation’s youth at risk for long-term nicotine addiction. As for benefits to smokers, it has been five years since FDA’s 2017 decision and there is still insufficient evidence to show that these products help people either quit nicotine entirely or even switch completely from cigarettes.

Now the FDA is faced with an impossible situation playing catch-up on the review of millions of individual applications for both tobacco-derived and synthetic nicotine e-cigarette products currently on the market issuing decisions on a one-by-one product basis. The bulk of completed reviews have been for products that have insignificant market share, while the products that make up the majority of the market remain on the shelves either unreviewed or as in the case of JUUL, in limbo due to confusing start/stop FDA action. At the same time, new products are entering the market every day enjoying a free-ride and profit-making opportunity while FDA struggles under the burden of its enforcement discretion policy. The FDA needs to rethink its strategy and do what the law was intended to do and



requires. Simply put, the process is supposed to be a “pre-market” authorization review not “post-market.”

We are hopeful that under Center for Tobacco Products Director Brian King’s leadership the FDA can make the changes needed and accelerate progress. Time is of the essence as every day of delay results in hundreds of new products flooding the market, more young people taking their first “hit”, and smokers uncertain whether these products will truly help or are even safe to use.

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.

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