FDA'S PLAN TO TACKLE YOUTH E-CIGARETTE "EPIDEMIC" IS A SIGNIFICANT AND MUCH NEEDED STEP BUT ACTION MUST BE TAKEN QUICKLY

Statement by Robin Koval, CEO & President, Truth Initiative®

We are in complete agreement with Food and Drug Administration (FDA) Commissioner Scott Gottlieb's acknowledgment that <u>e-cigarette use among youth has hit "epidemic proportions"</u> and are very pleased that the FDA has listened to and taken to heart what public health advocates, parents, educators and youth have been saying for months — e-cigarettes and particularly high nicotine "pod mod" products like <u>JUUL</u> are addicting a new generation of young people and putting them at risk for even more dangerous combustible tobacco use that risks reversing decades of progress.

By definition, an epidemic requires immediate and serious action, and we are encouraged by Commissioner Gottlieb's strong announcement of enforcement and other actions. At the same time, we urge the FDA not to cede its authority to the industry. The FDA's request that five e-cigarette manufacturers come up with plans to tackle the youth e-cigarette problem within the next 60 days is the equivalent of asking the fox to recommend plans for guarding the hen house. After decades of experience, we know that the tobacco industry is unable to regulate itself. We have learned the hard way that tobacco companies are motivated by self-interest and profit — not public health — and that vague promises from the tobacco industry, such as a "smoke-free world," are nothing more than well-crafted public relations schemes.

The FDA should act immediately to use its pre-market review and approval authorities to ensure that products like JUUL are not allowed free access to addict youth. Indeed, the JUUL phenomenon is a cautionary example of the consequences of unfettered commercial exploitation of regulatory delays, such as moving the deadline for submission of new product pre-market authorizations from August 2018 to 2022. The time for action is before a product such as JUUL is in every high school in the United States, not after. The FDA must use all its authorities and enforce the law. Further, the FDA should remove all <u>flavored tobacco products</u> from the market, putting the burden on manufacturers to show that they are designed and marketed to help adults switch completely from cigarettes and not to attract new youth customers.

New, youth-appealing and highly addictive e-cigarette products are appearing in market at a record pace. We applaud the FDA's announcement and urge rapid action to direct the potential for these products to responsibly help adult smokers move away from deadly combustible tobacco and not to use flashy product design, candy and fruit flavors, and social marketing strategies to recruit a new generation of addicted customers.