FDA Launches New Campaign to Warn Kids About E-Cigs

"The Real Cost" campaign to target nearly 10.7 million at-risk youth through digital platforms, social media and in-school ads nationwide.

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FDA launches new, comprehensive campaign to warn kids about the dangers of e-cigarette use as part of agency's Youth Tobacco Prevention Plan, amid evidence of sharply rising use among kids.

In the latest of a series of actions to address the epidemic of youth e-cigarette use, the U.S. Food and Drug Administration today launched "The Real Cost" Youth E-Cigarette Prevention Campaign, a new, comprehensive effort aimed at educating kids about the dangers of e-cigarettes. The campaign targets nearly 10.7 million youth, aged 12–17, who have used e-cigarettes or are open to trying them, and features hard-hitting advertising on digital and social media sites popular among teens, as well as placing posters with e-cigarette prevention messages in high schools across the nation.

"HHS is committed to comprehensive efforts to protect America's youth from the dangers of using any tobacco or nicotine-containing products. We congratulate the FDA on the launch of this new, hard-hitting campaign about the risk of addiction and other health consequences that can result from youth using e-cigarettes. This public education campaign will reach teens directly and complement the aggressive steps the FDA is taking to crack down on the sale and marketing of e-cigarettes to minors," said HHS Secretary Alex Azar.

"E-cigarettes have become an almost ubiquitous — and dangerous — trend among youth that we believe has reached epidemic proportions. This troubling reality is prompting us to take even more forceful actions to stem this dangerous trend, including revisiting our compliance policy that extended the compliance dates for manufacturers of certain e-cigarettes, including flavored e-cigarettes, to submit applications for premarket authorization. Based on our evidence, we believe the presence of flavors is one component making these products especially attractive to kids. The mandate to reverse this trend in youth addiction to nicotine is one of my highest priorities. I'm employing every tool at my disposal in these efforts. As a parent, a survivor of cancer, and someone entrusted with responsibilities to protect our nation's kids from certain dangers — I won't allow this rising youth use to continue on my watch. The new campaign we're announcing today seeks to snap teens out of their 'cost-free' mentality regarding e-cigarette use with powerful and creative messages that reach kids where they spend a lot of their time: online and in school. In

particular, these compelling prevention messages will be displayed in high school bathrooms, a place we know many teens are using e-cigarettes or faced with the peer pressure to do so," said FDA Commissioner Scott Gottlieb, MD. "Even as we consider the potential benefits of innovative tobacco products and the role that some such products may play in reducing harm to current adult smokers, the FDA won't tolerate a whole generation of young people becoming addicted to nicotine as a tradeoff for enabling adults to have unfettered access to these same products. No youth should be using any nicotine-containing product, and the trends underway are more than a small amount of casual experimentation among kids. They are evidence of a significant swath of a generation of kids becoming regular users of nicotine. Kids who use e-cigarettes are more likely to try combustible cigarettes. And that jeopardizes the extraordinary public health gains we've made in reducing smoking rates in this nation. Making sure e-cigs aren't being marketed to, sold to, or used by kids is a core priority and the guiding principle behind our efforts. We want to assure parents, educators, health professionals and the public that we're using all of our tools and authorities to quickly tackle this public health threat. We're committed to taking more aggressive steps to address this challenge and will continue to hold retailers and manufacturers of e-cigarettes accountable for their role in perpetuating youth access and use of these products, including new actions in the coming weeks and months."

Over the past several years, e-cigarettes were the most commonly used tobacco product by youth. In fact, more than 2 million middle and high school students were current users of e-cigarettes in 2017, and the FDA now believes that youth use of e-cigarettes is reaching epidemic proportions. This belief is based on a number of factors, including the agency's mounting enforcement actions, recent sales trends, news coverage, increased concerns among kids, parents and educators, as well as preliminary data that will be finalized and released in the coming months. Additional research from another survey, Monitoring the Future, shows that about 80 percent of youth do not see great risk of harm from regular use of e-cigarettes. This is particularly alarming considering that harm perceptions can influence tobacco use behaviors.

With its tagline, "Know the Real Cost of Vaping," the campaign aims to educate youth that using e-cigarettes, just like cigarettes, puts them at risk for addiction and other health consequences. The messages highlight that nicotine can rewire the brain to crave more nicotine, particularly because adolescent brains are still developing. Other messages highlight that e-cigarettes, among other things, can contain dangerous chemicals such as: acrolein, a chemical that can cause irreversible lung damage; formaldehyde, a cancer-causing chemical; and toxic metal particles, like chromium, lead and nickel, which can be inhaled into the lungs.

To ensure these messages are reaching the intended youth audience, the ads will run on age-verified digital platforms such as YouTube, Spotify, Pandora, Facebook and Instagram, as well as "The Real Cost" campaign website and are targeted to reach these teens with digital media and printed prevention messages in a school environment. This includes using location-targeted advertising around high schools nationwide and placing e-cigarette prevention content on educational platforms that are typically accessed by students during the school day. Posters also will be placed in at least 10,000 high school bathrooms, and additional materials for students and educators will be distributed to schools, in collaboration with Scholastic and Students Against

Destructive Decisions (SADD).

“The FDA has a successful track record of using compelling, science-based public education campaigns to encourage kids to rethink their relationship with tobacco and is bringing the same approach to these new efforts to prevent youth use of e-cigarettes,” said Mitch Zeller, J.D., director of the FDA’s Center for Tobacco Products. “E-cigarette use among youth is a tremendous concern and this new campaign will allow us to effectively communicate the dangers of these products to teens. Public education is a critical component of our ongoing work to prevent youth use of tobacco products and complements our enforcement and regulatory efforts to protect kids.”

As part of the agency’s Youth Tobacco Prevention Plan and ongoing work to protect youth from the dangers of tobacco products, the FDA has taken a series of actions over the past several months to more immediately target the illegal sales of e-cigarettes to youth, as well as the kid-friendly marketing and appeal of these products.

In particular, the FDA last week announced a series of critical and historic enforcement actions and signaled its intention to take new and significant steps to address the sale and marketing of e-cigarettes to kids. Those steps included issuing more than 1,300 warning letters and civil money penalty complaints (fines) to retailers who illegally sold JUUL and other e-cigarette products to minors during a nationwide, undercover blitz of brick-and-mortar and online stores this summer — the largest coordinated enforcement effort in the FDA’s history. Moving forward, the FDA is stepping up enforcement actions indefinitely with a sustained campaign to monitor, penalize and prevent e-cigarette sales to minors in retail locations including manufacturers’ own internet storefronts

The agency last week also issued letters to five major e-cigarette manufacturers whose products — JUUL, Vuse, MarkTen, blu e-cigs, and Logic — were sold to kids during the enforcement blitz asking them to submit to FDA within 60 days plans describing how they will address the widespread youth access and use of their products. If they fail to do so, or if the plans do not appropriately address this issue, the FDA will consider whether it would be appropriate to revisit the current policy that results in these products remaining on the market without a marketing order from the agency. This could mean requiring these brands to remove some or all of their flavored products that may be contributing to the rise in youth use from the market until they receive premarket authorization and otherwise meet all of their obligations under the law.

The FDA also committed to taking even stronger measures to stem the troubling trends of youth use, including, among others, investigating whether manufacturers of certain e-cigarette products may be marketing new products that were not on the market as of Aug. 8, 2016, thus falling outside of the FDA’s compliance policy, and have not gone through premarket review. The agency has other active investigations underway related to the marketing of these products.

The FDA is also exploring clear and meaningful measures to make tobacco products less toxic, appealing and addictive. These measures, which will intensely focus on protecting youth, could include an examination of flavors/designs that appeal to youth, child-resistant packaging and

product labeling to prevent accidental child exposure to liquid nicotine.

The agency also issued an advance notice of proposed rulemaking in March to seek public comment on the role that flavors in tobacco products play in attracting youth. The FDA intends to expedite the review and analysis of the comments so it can leverage the information into policy as quickly as possible, should the science support further action.

Additionally, the agency plans to explore additional restrictions on the sale and promotion of ENDS to further reduce youth exposure and access to these products.

“The Real Cost” Youth E-Cigarette Prevention Campaign is a nearly $60 million effort funded by user fees collected from the tobacco industry, not by taxpayer dollars. Initial e-cigarette prevention content first debuted in October 2017.

This new campaign is part of the FDA’s ongoing efforts to prevent disease and death caused by tobacco use and will complement the agency’s other youth tobacco prevention campaigns. The FDA launched “The Real Cost” Smoking Prevention Campaign in February 2014, “Fresh Empire” a multicultural tobacco prevention campaign in October 2015, and “The Real Cost” Smokeless Tobacco Prevention Campaign in April 2016. The FDA’s campaigns are based on the best available science and are evaluated to measure effectiveness in changing tobacco-related knowledge, attitudes, beliefs, intentions and/or behaviors over time.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation’s food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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