FDA Responds to New Data Showing More Youth Use Tobacco Products

The epidemic-level rises in youth e-cigarette use is threatening the progress we've made toward reducing youth tobacco use.

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Statement from FDA Commissioner Scott Gottlieb, MD, on new data demonstrating rising youth use of tobacco products and the agency's ongoing actions to confront the epidemic of youth e-cigarette use

Today, the U.S. Centers for Disease Control and Prevention (CDC) released additional data from our joint FDA/CDC 2018 National Youth Tobacco Survey. These data are a sobering reminder of the initial results we shared last fall indicating a rampant rise of youth e-cigarette use, which has prompted the FDA to take a series of escalating regulatory actions as part of our Youth Tobacco Prevention Plan. We are advancing those actions, and committing to some new steps. The epidemic use of e-cigarettes among children is one of the biggest public health challenges currently facing the FDA.

According to the data released today, approximately 4.9 million middle and high school students were current users (used in the past 30 days) of some type of tobacco product in 2018, up from 3.6 million in 2017. This increase is driven by an alarming surge in e-cigarette use. More than 3.6 million middle and high school students were current (past 30 day) e-cigarette users in 2018, a dramatic increase of more than 1.5 million students in one year. The study authors suggest -- as the FDA also noted at the time of the initial release of this data in the fall — that the rise in e-cigarette use in the last year is likely due to the recent popularity of certain types of e-cigarettes, such as JUUL. Further, youth who use e-cigarettes also are using them more frequently and using flavored products more often than last year. Many youth tobacco product users are also using multiple products. Among current tobacco users, about 2 in 5 (1.68 million) high school students and 1 in 3 (270,000) middle school students used two or more tobacco products in 2018. The most commonly used tobacco product combination was e-cigarettes and conventional cigarettes among both middle and high school students.

Similarly, data from the recent National Institutes of Health's Monitoring the Future study found comparable trends: From 2017 to 2018, current (past 30-day) e-cigarette use reportedly increased from 6.6 percent to 10.4 percent among 8th grade students; 13.1 percent to 21.7 percent among 10th grade students; and 16.6 percent to 26.7 percent among 12th grade students. In other

words, more than a quarter of 12th graders in the U.S. are using e-cigarettes—exposing them to harmful effects of nicotine and other chemicals and putting them at risk of transitioning to other tobacco products.

These risks were further reinforced in research recently published in JAMA Network Open, which showed that, compared with non-users, youth who use e-cigarettes are more likely to transition to conventional cigarettes – risking a lifetime of addiction to smoking and resulting smoking-attributable disease and erasing the reductions in youth smoking rates that we've achieved in America. The bottom line is that kids using e-cigarettes aren't kids who "would have smoked cigarettes." Quite the opposite. As a society, we've made great strides in stigmatizing cigarette use among kids. The kids using e-cigarettes are children who rejected conventional cigarettes, but don't see the same stigma associated with the use of e-cigarettes. But now, having become exposed to nicotine through e-cigs, they will be more likely to smoke. I will not allow a generation of children to become addicted to nicotine through e-cigarettes. We must stop the trends of youth e-cigarette use from continuing to build and will take whatever action is necessary to ensure these kids don't become future smokers.

Based on a growing body of evidence, I fear the youth trends will continue in 2019, forcing us to make some tough decisions about the regulatory status of e-cigarettes. The signs that we're seeing are not encouraging. They point to continued growth in youth use of these products. No child should be using any tobacco or nicotine-containing product. We'll continue to take steps to try to investigate the root causes of this spike in youth e-cigarette use and arrest the momentum of these trends, in particular, by ensuring these products are sold in ways that make them less accessible and appealing to youth. But, if these youth use trends continue, we'll be forced to consider regulatory steps that could constrain or even foreclose the opportunities for currently addicted adult smokers to have the same level of access to these products that they now enjoy. I recognize that such a move could come with significant impacts to adult smokers. The FDA has repeatedly affirmed our collective view that e-cigarettes may have promise as a tool for helping currently addicted adult smokers quit smoking. But, with the staggering data on youth trends, we're struggling to preserve these opportunities for adults while addressing the youth epidemic. I simply won't allow their sale to come at the expense of addicting a generation of kids to nicotine.

To help address this growing use among kids, over the past year, the FDA has taken a rigorous enforcement stance, including a number of actions to combat the illegal sales of e-cigarettes to youth through our enforcement efforts at brick-and-mortar and internet storefronts, as well as taken steps to target companies engaged in kid-friendly marketing that increases the appeal of these products to youth. I've also appealed to the companies responsible for many of these products, and met with senior executives from five of the largest manufacturers of e-cigarette products. In addition, last week, I sent letters to the chief executive officers of Altria Group Inc. and JUUL Labs Inc. asking to meet with them to discuss my concerns that they don't seem fully committed to their written promises about the steps they'd take to stop youth use of their products.

Just last week, the FDA escalated enforcement action against certain local Walgreens and Circle K

retail locations for repeatedly selling tobacco products to minors by filing a complaint seeking to bar the two specific retail locations from selling tobacco products for 30 days. As part of that effort we're also writing the corporate management of a number of large, national retail chains to discuss whether there is a corporate-wide issue related to their stores' non-compliance and put them on notice that the FDA is considering additional corporate-wide enforcement avenues to address violative tobacco sales to youth, which have also included illegal sales of e-cigarettes to kids. This past fall, we marked a historic milestone of conducting a total of one million tobacco retailer inspections since we began doing so in 2010. To commemorate this, we're sending letters to governors and agencies across the country thanking them for their work to support our efforts to protect youth — and reminding them of the need for continued vigilance to make sure retailers aren't selling tobacco products to minors.

Beyond enforcement and social responsibility, we've committed to meaningful policy changes. Notably, in November, I announced proposed new steps to protect youth by preventing access to flavored tobacco products, including e-cigarettes. This policy framework will both address the disturbing trend of youth e-cigarette use and advance the historic declines we've achieved in recent years in the rates of combustible cigarette use among kids. This framework reflects a re-doubling of the FDA's efforts to protect kids from all nicotine-containing products. It also reflects a very careful public health balance between steps to enable the opportunities to transition to non-combustible products to be available for adults; and our solemn mandate to make nicotine products less accessible and less appealing to children. In other words — a balance between closing the on-ramp for kids to become addicted to nicotine through combustible and non-combustible products, while maintaining the off ramp for adults through access to potentially less harmful forms of nicotine delivery for adult smokers seeking to transition away from combustible tobacco products.

Evidence shows that minors are especially attracted to flavored e-cigarette products, and that youth access these products from both brick and mortar retailers as well as online. With that in mind, we're revisiting our compliance policy that has resulted in certain e-cigarettes, including flavored e-cigarettes, remaining on the market until 2022 while their manufacturers submit applications for premarket authorization. In particular, as I announced on Nov. 15, 2018, the FDA is revisiting the compliance policy on premarket tobacco product application authorization for all flavored e-cigarette products other than tobacco, mint, and menthol, sold in physical locations where people under the age of 18 are permitted. For example, this would include e-cigarettes or electronic nicotine delivery system (ENDS) products, such as e-liquids, cartridge-based systems, and cigalikes, in fruit and candy flavors like cherry, vanilla, crème, tropical, melon and others. In addition, we will seek to curtail the sale of applicable flavored ENDS products that are sold online without heightened age verification processes.

We'll be providing further information on these policies soon. If data continue to show upwards trends in youth use of tobacco products, we'll continue to refine our policies as necessary, taking additional steps to strengthen our response.

More recently, we've undertaken efforts to further the discussion and understanding around how

we can help aid those kids who are already addicted to the nicotine in e-cigarettes quit. This includes holding a public hearing to discuss efforts to eliminate youth e-cigarette use as well as other tobacco product use, with a focus on the potential role of drug therapies to support cessation and the issues impacting the development of such therapies for youth. Already, I've heard too many troubling stories from parents of teenagers, pediatricians, and young people themselves about the effects of this epidemic. The stories make clear that, for many young e-cigarette users, addiction has already taken hold.

We've also launched "The Real Cost" Youth E-Cigarette Prevention Campaign — a new, comprehensive effort targets nearly 10.7 million youth, aged 12-17, who have used e-cigarettes or are open to trying them. The new campaign features hard-hitting advertising on digital and social media sites popular among teens, as well as posters with e-cigarette prevention messages in high schools across the nation. The new e-cigarette prevention effort builds off the FDA's first youth tobacco prevention campaign, "The Real Cost," which launched in 2014 to reduce teen cigarette smoking. In its first two years, the youth smoking prevention campaign prevented nearly 350,000 teens from initiating cigarette smoking and resulted in savings of more than $31 billion for youth, their families and society at large by reducing smoking-related costs like early loss of life, costly medical care, lost wages, lower productivity and increased disability. The success of "The Real Cost" campaign suggests that our other tobacco prevention campaigns, including our campaign on youth use of e-cigarettes, can build on this success as we strive to reduce the number of kids who use tobacco products.

As part of the youth e-cigarette prevention campaign, we also joined forces with Scholastic to expand distribution of youth e-cigarette prevention posters to every public and private high school in the U.S. and released new resources for doctors, youth groups, churches, state and local public health agencies, and others on the dangers of youth e-cigarette use. Additionally, our work with Scholastic to provide educators with resources to help them engage with students about e-cigarette use has helped reach more than 2.7 million students so far. We've also received very positive teacher feedback on the helpfulness of these resources. Vaping remains a top issue at some schools, but teachers are reporting that vaping on campus has declined after using these resources on the dangers of youth e-cigarette use.

While these efforts are a good start, we recognize they're not enough. This is an exploding epidemic. We'll continue to put the full scope of our regulatory tools against this mounting public health crisis. We're considering some new steps for 2019.

Moving forward, the FDA has a number of actions planned and we'll have more to say on these and other actions very soon. We're continuing our stepped-up enforcement actions with a sustained campaign to monitor, penalize and prevent e-cigarette sales to minors in retail locations, including manufacturers' internet storefronts. The agency is also exploring action under both its civil and criminal enforcement tools to target potentially violative sales and marketing practices by manufacturers as well as retailers. We're also investigating counterfeit e-cigarette products. In addition to our meeting with Altria and JUUL, we also plan to meet with state attorneys general to discuss how they can help combat youth e-cigarette use in their states. We're also exploring how

we can partner with others to look at opportunities to work together around these shared goals. These are just some of the additional steps that we're taking.

The numbers are clear — we're experiencing epidemic-level rises in youth e-cigarette use, which is threatening the progress we've made toward reducing youth tobacco use. These trends require forceful and sometimes unprecedented action among regulators, public health officials, manufacturers, retailers and others to address this troubling problem. Our commitment to stemming the epidemic of youth e-cigarette use has not waivered, but we know there's more to be done by all parties.

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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http://beta.docker.cancerhealth.com/blog/fda-responds-new-data-showing-youth-use-tobacco-products