Statement from FDA Commissioner Scott Gottlieb, M.D., on proposed new steps to protect youth by preventing access to flavored tobacco products and banning menthol in cigarettes

Statement

As a physician who cared for hospitalized cancer patients, I saw first-hand the devastation that smoking-related diseases had wrought on the lives of patients and their families, and dedicated myself to helping ease this suffering.

As a cancer survivor myself, I understand too well the uncertainty, grief and struggle that accompanies a cancer diagnosis.

And as a father of three young children, I hear daily from parents and teachers worried about the epidemic use of electronic cigarettes and nicotine addiction among kids.

When I pledged last year to reduce addiction to nicotine, I was driven by the fact that, in the U.S., tobacco use remains the leading cause of preventable death and disease. Combustible cigarettes cause the overwhelming majority of tobacco-related disease. When used as intended, they are responsible for the death of half of all long-term users.

Today, I'm pursuing actions aimed at addressing the disturbing trend of youth nicotine use and continuing to advance the historic declines we've achieved in recent years in the rates of combustible cigarette use among kids.

These actions are grounded in hard evidence. But they also are deeply personal.

When I first announced our comprehensive tobacco framework plan in July 2017, I recognized my opportunity – an almost unprecedented opportunity – to use the tools that the FDA had been given in the Family Smoking Prevention and Tobacco Control Act to bring about meaningful, lasting change to dramatically alter this cycle of disease and death.

I envisioned a world in which cigarettes lose their addictive potential through reduced nicotine levels. I envisioned a regulatory paradigm that focused on nicotine and evaluated the diverse nicotine delivery mechanisms along a continuum of risk. On one end, there are combustible tobacco products. At the other end, there are medicinal nicotine products sold as gums and patches. And there is an array of products in between.

I saw the opportunity to advance new technologies like electronic nicotine delivery systems (ENDS) as an alternative to cigarettes for adults who still seek access to satisfying levels of nicotine, without all the deadly effects of combustion.

I believed then – and I continue to believe – that we must recognize the potential for innovative, less harmful products that can efficiently deliver satisfying levels of nicotine to adults who want them.

But as I said at that time, as I said at my confirmation hearing, as I said in my first remarks to the professional staff of the FDA three days after being confirmed as the FDA's Commissioner in May of 2017, and as I've said dozens of times in the months that followed: any policy accommodation to advance the innovations that could present an alternative to smoking – particularly as it relates to e-cigarettes – cannot, and will not, come at the expense of addicting a generation of children to nicotine through these same delivery vehicles. This simply will not happen. I will take whatever steps I must to prevent this.

Today, I'm announcing proposals to help reverse these trends, with the unwavering support of HHS Secretary Alex Azar, who shares my deep commitment to protecting the health of our nation's children. Today, we advance our efforts to combat youth access and appeal with a policy framework that firmly and directly addresses the core of the epidemic – flavors.

The data show that kids using e-cigarettes are going to be more likely to try combustible cigarettes later. This is a large pool of future risk. The policies I'm outlining now strives to strike a careful public health balance between our imperative 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.The data make unmistakably clear that, if we're to break the cycle of addiction to nicotine, preventing youth initiation on nicotine is a paramount imperative.

Almost all adult smokers started smoking when they were kids. Nearly 90 percent started smoking before the age of 18, and 95 percent by age 21. Only about 1 percent of cigarette smokers begin at age 26 or older. When I announced the FDA's Comprehensive Plan for Tobacco and Nicotine Regulation in July 2017, I made clear my concerns about kids' use of e-cigarettes, especially those products marketed with obviously kid-appealing flavors. At the time, however, the trends in youth use appeared to be changing in the right direction – reported e-cigarette use among high school students, which peaked at 16.0 percent in 2015, had decreased to 11.3 percent in 2016 and held steady in 2017. What I did not predict was that, in 2018, youth use of e-cigarettes and other ENDS products would become an epidemic.

Today, the FDA and the Centers for Disease Control and Prevention are publishing data from the 2018 National Youth Tobacco Survey (NYTS). The data from this nationally representative survey, conducted of middle and high school students, show astonishing increases in kids' use of e-cigarettes and other ENDS, reversing years of favorable trends in our nation's fight to prevent youth addiction to tobacco products. These data shock my conscience: from 2017 to 2018, there was a 78 percent increase in current e-cigarette use among high school students and a 48 percent increase among middle school students. The total number of middle and high school students currently using e-cigarettes rose to 3.6 million — that's 1.5 million more students using these products than the previous year. Additionally, more than a quarter (27.7

percent) of high school current e-cigarette users are using the product regularly (on 20 or more days in the past month). More than two-thirds (67.8 percent) are using flavored e-cigarettes. Both these numbers have risen significantly since 2017.

These increases must stop. And the bottom line is this: I will not allow a generation of children to become addicted to nicotine through e-cigarettes. We won't let this pool of kids, a pool of future potential smokers, of future disease and death, to continue to build. We'll take whatever action is necessary to stop these trends from continuing.

Over the past months, the FDA has worked aggressively to address youth use of e-cigarettes.

We deployed a range of our regulatory tools.

We launched a multi-pronged Youth Tobacco Prevention Plan. We escalated enforcement against retailers who illegally sell ENDS products to minors. We partnered with the Federal Trade Commission to target e-liquid manufacturers whose products used misleading, kid-appealing imagery that mimicked juice boxes, lollipops and other foods. We worked with eBay to remove listings for these products on their websites. We launched innovative campaigns, including "The Real Cost" Youth E-Cigarette Prevention Campaign, to educate teens about the consequences of addiction to e-cigarettes.

And I made clear – in speeches, in statements and in interviews – that we were closely watching what appeared to be disturbing trends. I repeatedly said that, although we continue to believe that non-combustible tobacco products may provide an important opportunity to migrate adult smokers away from more harmful forms of nicotine delivery, these opportunities couldn't come at the expense of addicting a generation of kids to nicotine. I told the manufacturers of e-cigarettes that the youth use of their products was an existential threat to this innovation. In short, over the past year we weren't sitting still. And we weren't quiet about our concerns. And yet these deeply disturbing trends continued to build.

In September, after receiving the raw data from the NYTS survey, I took additional action. I called on manufacturers to step up, to take voluntary actions to prevent youth access to these products and to take meaningful steps to curb their youth appeal. Some manufacturers have already responded to these requests and pledged to take some meaningful voluntary steps to curb youth access and appeal to their products. I also said that the FDA would be re-evaluating our own policy approach and that all options would be considered. Given the startling and disturbing youth use rates in the 2018 NYTS data being released today, it's clear that we must do more – specifically, several policy changes to target what appear to be the central problems – youth appeal and youth access to flavored tobacco products.

Some of these changes would involve revisiting the FDA's compliance policy, issued in 2017, which extended the dates by which manufacturers of deemed tobacco products that were on the market as of Aug. 8, 2016, were expected to submit premarket applications to the FDA for review (after receipt of an application, the FDA reviews the application and determines if the product meets the applicable statutory standard to be marketed). Under that policy of enforcement discretion, the premarket application compliance date for newly regulated

combustible tobacco products, including certain cigars and pipe tobacco, was extended to August 2021. The premarket application compliance date for newly regulated non-combustible tobacco products was extended to August 2022. This applied to most ENDS or e-cigarettes.

Today, I'm directing the FDA's Center for Tobacco Products (CTP) to revisit this compliance policy as it applies to deemed ENDS products that are flavored, including all flavors other than tobacco, mint and menthol. The changes I seek would protect kids by having all flavored ENDS products (other than tobacco, mint and menthol flavors or non-flavored products) sold in age-restricted, in-person locations and, if sold online, under heightened practices for age verification.

These changes will not include mint- and menthol-flavored ENDS. This reflects a careful balancing of public health considerations. Among all ENDS users, data suggests that mint- and menthol-flavored ENDS are more popular with adults than with kids. One nationally representative survey showed that, among ENDS users aged 12-17 years old, 20 percent used mint- and menthol-flavored ENDS while, among adult ENDS users, 41 percent used mint- and menthol-flavored ENDS. Any approach to mint- and menthol-flavored ENDS must acknowledge the possibility that the availability of these flavors in ENDS may be important to adult smokers seeking to transition away from cigarettes. Moreover, I recognize that combustible cigarettes are still sold in menthol flavor, including in convenience stores. I don't want to create a situation where the combustible products have features that make them more attractive than the non-combustible products. Or a situation where those who currently use menthol-flavored cigarettes might find it less attractive to switch completely to an e-cigarette. This is a difficult compromise that I'm trying to strike, recognizing the public health risk posed by cigarettes still being available in menthol flavor.

But at the same time, I'm deeply concerned about the availability of menthol-flavored cigarettes. I believe these menthol-flavored products represent one of the most common and pernicious routes by which kids initiate on combustible cigarettes. The menthol serves to mask some of the unattractive features of smoking that might otherwise discourage a child from smoking. Moreover, I believe that menthol products disproportionately and adversely affect underserved communities. And as a matter of public health, they exacerbate troubling disparities in health related to race and socioeconomic status that are a major concern of mine. Although I'm not proposing revisions to the compliance policy for the mint- and menthol flavors in e-cigarettes at this time, we need to address the impact that menthol in cigarettes has on the public health.

I'm also aware that there are potentially important distinctions even between mint- and menthol-flavored e-cigarette products. I'm particularly concerned about mint-flavored products, based on evidence showing its relative popularity, compared to menthol, among kids. So, I want to be clear that, in light of these concerns, if evidence shows that kids' use of mint or menthol e-cigarettes isn't declining, I'll revisit this aspect of the current compliance policy.

In addition, I'm directing CTP to revisit the compliance policy for all flavored ENDS products

(other than tobacco, mint and menthol flavors or non-flavored products) that are sold online without additional, heightened age-verification and other restrictions in place. As part of that effort, I'm directing CTP to publish additional information regarding best practices for online sales. My aim is to have these best practices available soon, so sites can quickly adopt them to help prevent youth access to these flavored products. Of course, no tobacco products, including non-flavored ENDS products or those with tobacco, mint and menthol flavors, should be sold to kids. For this reason we'll continue to enforce the law whenever we see online sales of these products to minors and will closely monitor online sales of mint and menthol ENDS products.

If youth trends don't move in the right direction, we will revisit all of these issues.

I hope I'll soon see manufacturers of ENDS products preparing, with the FDA input as appropriate, premarket tobacco product applications (PMTAs) to demonstrate that their products meet the public health standard in the Tobacco Control Act. In the coming months, CTP plans to issue additional policies and procedures to further make sure that the process for reviewing these applications is efficient, science-based and transparent. We'll also explore how to create a process to accelerate the development and review of products with features that can make it far less likely that kids can access an e-cigarette.

Other considerations of our policy framework would apply to traditional forms of combustible tobacco products.

I noted that the popularity of menthol cigarettes with youth is especially troubling. In fact, youth smokers are more likely to use menthol cigarettes than any other age group. More than half (54 percent) of youth smokers ages 12-17 use menthol cigarettes, compared to less than one-third of smokers ages 35 and older. Prevalence of menthol use is even higher among African-American youth, with data showing that seven out of 10 African-American youth smokers select menthol cigarettes.

And, unlike menthol-flavored ENDS, there's no evidence to suggest that menthol-flavored cigarettes may play a role in harm reduction for adult smokers.

We will advance a Notice of Proposed Rulemaking that would seek to ban menthol in combustible tobacco products, including cigarettes and cigars, informed by the comments on our Advanced Notice of Proposed Rulemaking (ANPRM) .

Finally, to ensure that we're taking a comprehensive approach, we must evaluate our regulatory approach to flavored cigars. Flavors are added to cigars and other tobacco products for various reasons, such as reducing the harshness, bitterness and astringency of tobacco products during inhalation and to soothe irritation during use. Research shows that, compared to adults (25 or older) who smoke cigars, a higher proportion of youth who smoke cigars use flavored cigars.

These data also indicate that eliminating flavors from cigars would likely help prevent cigar initiation by young people. Accordingly, I am also outlining policy goals to address the

presence of flavors in cigars – including those that were subject to the compliance policy for newly deemed products, and those that were "grandfathered."

Specifically, I propose a policy through appropriate means to ban flavors in cigars.

The bottom line is that these efforts to address flavors and protect youth would dramatically impact the ability of American kids to access tobacco products that we know are both appealing and addicting. This policy framework reflects a re-doubling of the FDA's efforts to protect kids from all nicotine-containing products. They also reflect a very careful public health balance that we're trying to achieve. A balance between closing the on-ramp for kids to become addicted to nicotine through combustible and non-combustible products, while maintaining access to potentially less harmful forms of nicotine delivery through ENDS for adult smokers seeking to transition away from combustible tobacco products.

This policy framework is an important step toward reversing the epidemic that is underway and that is confirmed by the data from the NYTS. I could take more aggressive steps. I could propose eliminating any application enforcement discretion to any currently marketed ENDS product, which would result in the removal of ALL such products from the marketplace. At this time, I am not proposing this route, as I don't want to foreclose opportunities for currently addicted adult smokers.

But make no mistake. If the policy changes that we have outlined don't reverse this epidemic, and if the manufacturers don't do their part to help advance this cause, I'll explore additional actions.

We've already seen some positive steps announced voluntarily by manufacturers. Responsible manufacturers certainly don't need to wait for the FDA to finalize these policies to act. They can stop certain marketing and sales practices — the ones we believe are part of the youth access and youth appeal problem — right now. We hope that within the next 90 days, manufacturers will choose to remove flavored ENDS products from stores where kids can access them and from online sites that do not have sufficiently robust age-verification procedures.

The FDA continues to take aggressive action to protect the public health, especially among kids at risk of nicotine addiction and tobacco use. As part of our Comprehensive Plan, in addition to issuing the ANPRMs to hear the public's input on the role of flavors in tobacco products, and on cigars, we also issued an ANPRM on lowering nicotine in cigarettes. We have expedited the review of many of the comments, and spent hours, days and months taking close consideration of the questions raised and evidence presented by the public and various stakeholders.

This policy framework reflects the FDA's consideration of available data and information to get the most complete picture possible of the causes of the epidemic rise in youth use of ENDS.

We'll continue to base our actions on the best available science. And when it comes to protecting our youth, we'll continue to actively pursue a wide range of prevention and enforcement actions. We'll leave no stone unturned.

This is one of our highest priorities.

The tobacco marketplace has changed dramatically in the past year when it comes to youth use of ENDS. And the vision for public health achievements from reduced use of combustible products and reduced nicotine addiction is at risk.

But with implementation of the forceful and far-reaching actions that are outlined today, and with the commitment of tobacco manufacturers to take additional, voluntary actions to reduce youth access to their products, we can reverse these trends.

As I said after becoming Commissioner, I can think of no more impactful action the FDA could possibly take on my watch to help American families.

Here are additional details regarding the policy framework that I seek to advance:

1. Flavored ENDS products that are not sold in an age-restricted, in-person location.
    - Have all flavored ENDS products (other than tobacco, mint and menthol flavors or non-flavored products) sold in age-restricted, in-person locations. All ENDS products, including e-liquids, cartridge-based systems and cigalikes, in flavors except tobacco, mint and menthol, would be included. For instance, the proposed policy would apply to flavors such as cherry, vanilla, crème, tropical, melon and others.
    - To advance this goal, the FDA is revisiting the compliance policy on PMTA authorization for such flavored products sold in physical locations where people under the age of 18 are permitted.
    - The FDA is not revisiting the compliance policy with respect to ENDS products sold exclusively in age-restricted locations – for instance, a stand-alone tobacco retailer (such as a vape shop) that adequately prevents persons under the age of 18 from entering the store at any time; or, a section of an establishment that adequately prevents entry of persons under the age of 18 and the flavored ENDS products are not visible or accessible to persons under the age of 18 at any time.
    - At this time, ENDS products with tobacco, mint or menthol flavors, as well as any non-flavored ENDS products, sold in any location, would not be included in any policy revisions. This distinction among flavors seeks to maintain access for adult users of these products, including adults who live in rural areas and may not have access to an age-restricted location, while evidence of their impacts continues to develop. It also recognizes that combustible cigarettes are currently available in menthol in retail locations that are not age-restricted. This approach is informed by the potential public health benefit for adult cigarette smokers who may use these ENDS products as part of a transition away from smoking.
    - The FDA, however, will not ignore data regarding the popularity of mint- and

menthol-flavored ENDS among kids. We will continue to use all available surveillance resources to monitor the rates and use patterns among youth and adults for these products, and we will reconsider our policies with respect to these products, if appropriate.

2. Flavored ENDS products (other than tobacco, mint and menthol flavors or non-flavored products) that are sold online.
    - In addition, we will seek to curtail the sale of applicable flavored ENDS products that are sold online without heightened age verification processes.
    - The FDA will be working to identify these heightened measures for age verification and other restrictions to prevent youth access via online sales. These best practices would be available soon, so sites can quickly adopt them.
    - Because no tobacco products should be sold to kids (including non-flavored ENDS products or those with tobacco, mint and menthol flavors), the FDA will continue to enforce the law whenever we see online sales of these products to minors and will closely monitor online sales of mint and menthol ENDS products.
3. Flavored cigars.
    - Research shows that, compared to adults (25 or older) who smoke cigars, a higher proportion of youth who smoke cigars use flavored cigars. This data also indicates that eliminating flavors from cigars would likely help prevent cigar initiation by young people.
    - Given these public health concerns, I believe flavored cigars should no longer be subject to the extended compliance date for premarket authorization — regardless of the location in which the products are sold.
    - The FDA's proposal to revisit the compliance policy for flavored cigars that are new tobacco products does not apply to the entire product category, as some products were considered "grandfathered." Accordingly, the FDA intends to propose a product standard that would ban flavors in all cigars.
    - In July, the comment period for our ANPRM on flavors in tobacco products closed. The FDA has expedited review and analysis of these comments, and we intend to proceed with developing a proposed regulation. As included in the most recent Unified Agenda, the FDA intends to prioritize the issuance of this proposed rule.
4. ENDS products that are marketed to kids.

    The FDA will pursue the removal from the market of those ENDS products that are marketed to children and/or appealing to youth. This could include using popular children's cartoon or animated characters, or names of products favored by kids like brands of candy or soda.
5. Menthol in combustible tobacco products.
    - Informed by the comments from our ANPRM, the FDA will advance a Notice of Proposed Rulemaking that would seek to ban menthol in combustible tobacco products, including cigarettes and cigars.
    - The FDA started this process several years ago with an ANPRM. That ANPRM issued alongside the FDA's preliminary scientific evaluation, which suggested menthol use is likely associated with increased smoking initiation by youth and

young adults.
    - Now, armed with the additional years of data, comments from the public – and with the perspective of our Comprehensive Plan and its implementation – the FDA will accelerate the proposed rulemaking process to ensure that our policies on flavored tobacco products protect public health across the continuum of risk.

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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