TESTIMONY

An Epidemic Continues: Youth Vaping in America

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Testimony of

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Introduction

Good morning, Chairman Krishnamoorthi, Ranking Member Cloud, and Members of the Subcommittee. Thank you for the opportunity to be here today to discuss the Food and Drug Administration's (FDA or the Agency) efforts to address youth use of electronic nicotine delivery systems, or ENDS, which include e-cigarettes. I am Janet Woodcock, Acting FDA Commissioner.

I appreciate the opportunity to be here today to provide background on FDA's regulation of e-cigarettes and our efforts to prevent youth initiation and address this important public health issue.

Background

Let me start with some information on our tobacco regulatory authorities and our recent regulatory efforts regarding ENDS and e-cigarettes.

Tobacco use is the single largest preventable cause of disease and death in the United States. Each year, more than 480,000 people in the United States die prematurely from diseases caused by cigarette smoking and exposure to tobacco smoke. In 2009, Congress passed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to authorize FDA to oversee the manufacture, marketing, distribution, and sale of tobacco products and protect the public from the harmful effects of tobacco product use. This authority gave FDA comprehensive tools to protect the public from the harmful effects of tobacco use through science-based tobacco product regulation.

Under the statute, FDA had immediate authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. The Tobacco Control Act also authorized FDA to "deem" other "tobacco products" (which include "any product made or derived from tobacco that is intended for human consumption" that is not a drug, device, or combination product under the FD&C Act, "including any component, part, or accessory" of that product) to be subject to the Agency's regulatory authority in Chapter IX of the FD&C Act.

It is important to note FDA's initial efforts to regulate e-cigarettes began more than a decade ago. Between 2008 and 2010, FDA attempted to regulate e-cigarettes as unapproved drug/device combination products. FDA's action was challenged and ultimately, the U.S. Court of Appeals for the D.C. Circuit ruled that while FDA could choose to regulate e-cigarettes and other products "made or derived from tobacco" under its new tobacco authorities, it could not regulate these products under FDA's drug and device authority unless they were marketed for therapeutic purposes.[1]

Publication of the final deeming rule brought e-cigarettes under FDA's regulatory authority for tobacco products. That rule was issued on May 10, 2016, deeming additional products that meet the statutory definition of a "tobacco product," except for accessories of such products, to be subject to FDA's regulatory authority. Deemed products include ENDS, cigars, pipe tobacco, nicotine gels, waterpipe (or hookah) tobacco, and any future tobacco products. The deeming rule, and FDA's regulation of these products, took effect on August 8, 2016.

Regulatory Requirements for ENDS Products

When the Deeming rule took effect in August 2016, many of the regulatory and legal requirements that had been in place for manufacturers of cigarettes, smokeless tobacco, cigarette tobacco, and roll-your-own tobacco since 2009, as well as several new requirements specific to deemed products, became applicable to manufacturers of e-cigarettes and other ENDS products. These include:

- Marketing new tobacco products only after FDA review and authorization; and
- Marketing products with direct or implied claims of reduced risk only if FDA confirms that scientific evidence supports the claim and determines that providing a marketing authorization for the product will, among other things, benefit the health of the population as a whole.
- Submitting ingredient listings;
- Registering domestic establishments and submitting lists of products manufactured at those establishments, including all labeling and representative samples of advertisements;
- Submitting tobacco health documents;

In addition, under the deeming rule, the following regulatory provisions also apply to deemed tobacco products, including ENDS products:

- Minimum age restriction (now 21 years or older) and identification requirements to prevent sales to underage youth;
- Requirements to bear certain health warnings on packages and advertisements[2] (including certain ENDS components, such as e-liquids) such as, "WARNING: This product contains nicotine. Nicotine is an addictive chemical," and
- Prohibition of vending machine sales, unless in a facility that never admits youth.

Following publication of the final deeming rule, FDA announced an enforcement policy with staggered timeframes. Some of the requirements, such as the Federal minimum age of sale, were enforced immediately when the deeming rule took effect on August 8, 2016, while through an exercise of enforcement discretion, FDA temporarily deferred enforcement of other provisions such as premarket review of "new" tobacco products.

All deemed products, including ENDS, became subject to the premarket authorization requirements in the Tobacco Control Act on August 8, 2016. All "new tobacco products" are required to obtain authorization from FDA before they can be legally marketed. Pursuant to the Tobacco Control Act, a "new tobacco product" is one that was not commercially marketed as of February 15, 2007, or one that was modified after February 15, 2007. Since no ENDS product is known to have been commercially marketed in the U.S. as of February 15, 2007, all such products are understood to be new tobacco products.

Through premarket review, FDA evaluates new tobacco products based on the applicable public health standard, considering, for example, the risks and benefits to the population as a whole, including users and non-users of the tobacco product, and taking into account the increased or decreased likelihood that existing users of tobacco products will stop using such products; and the increased or decreased likelihood that those who do not use tobacco products, including youth, will start using such products.

FDA's initial compliance policy for premarket review stated that the Agency did not intend to enforce the requirements of premarket review against manufacturers of newly-regulated new tobacco products that were on the market as of August 8, 2016, as long as they submitted marketing applications and received authorization within specific timeframes. As a result, FDA anticipated that many ENDS products would remain on the market without premarket authorization for up to three years.

In July 2017, FDA announced a new plan for tobacco and nicotine regulation, and in August 2017, FDA published a compliance policy, which extended the compliance period for premarket review of deemed new tobacco products (that were on the market on August 8, 2016) to August 2022. This policy became the subject of litigation and in May 2019, the U.S. District Court for the District of Maryland vacated FDA's August 2017 Compliance Policy. In July 2019, the court issued a further order directing FDA to require that applications for deemed "new tobacco products" such as e-cigarettes, cigars, pipe tobacco, and hookah tobacco, that were on the market as of August 8, 2016, be filed with FDA no later than May 12, 2020. The court order also provided for a one-year period during which products with timely submitted applications might remain on the market pending FDA review, but subsequently clarified that its order does not restrict the Agency's authority to enforce the premarket review provisions against deemed products during the pendency of the submission or one-year review period. Due to the SARS-CoV-2 pandemic, the Agency requested, and the court granted, a 120-day extension of the deadline to September 9, 2020. Nine months have now passed since that September 2020 deadline and we have received thousands of submissions for millions of new tobacco products. I will describe FDA's progress on the processing and review of these applications later in my testimony.

As the Subcommittee considers the issues related to e-cigarette use today, it is important to remember that as of yet, no ENDS product in the United States is on the market legally. To be legally marketed as a tobacco product, the product would need to obtain premarket authorization from the Agency. The product would undergo FDA scientific review and need to meet the applicable statutory standard for marketing. For ENDS products going through the premarket tobacco product application (PMTA) pathway, the Agency would have to find that the marketing of the product is appropriate for the protection of the public health in order for the product to receive marketing authorization. Alternatively, an ENDS product that is intended for therapeutic purposes, such as smoking cessation, would need to be reviewed and approved under FDA's drug authorities to be legally marketed as a drug. Currently, there are no ENDS products that have been authorized for marketing under our tobacco authorities or approved under our drug authorities.

Data on Youth Use of E-Cigarettes

FDA collaborates with the Centers for Disease Control and Prevention (CDC) to administer the National Youth Tobacco Survey (NYTS) to middle and high school students each year. The survey provides important data that allow us to understand current youth tobacco product use in a larger historical context.

NYTS data from 2018 and 2019 showed disturbing increases in the use of e-cigarette products among middle and high school students.[3] [4] In 2020, however, NYTS data showed that 1.8 million fewer U.S. youth were currently using e-cigarettes compared to 2019.[5] While that finding was promising, the data also showed disposable e-cigarette use among high school students increased from 2.4 percent in 2019 to 26.5 percent in 2020 – a 1,000 percent increase; similarly, disposable e-cigarette use among middle school students increased from 3.0 percent to 15.2 percent – a 400 percent increase, and more than 8 out of 10 youth who used e-cigarettes reported use of flavored products. While the use of fruit- and mint- flavored e-cigarettes was common among users in 2020, the use of menthol flavored e-cigarettes was also prominent. In addition, almost 40 percent of high school students using e-cigarettes were using them on 20 or more days out of the month and almost a quarter of them used e-cigarettes every single day, indicating a strong dependence on nicotine among youth.

While we are seeing some progress in youth prevalence rates, the fact that there are still 3.6 million youth e-cigarettes users in 2020 is deeply concerning and underscores the critical need for FDA to address youth use of e-cigarettes and other ENDS.

FDA's Actions to Address Youth Use of ENDS Products

Protecting our nation's youth from the dangers of tobacco products is among the Agency's most important responsibilities, and we are taking aggressive steps to make sure tobacco products are not being marketed or sold to kids. Our work to protect youth from tobacco products is comprehensive and includes compliance and enforcement, premarket review, public education, and regulatory science research. I will provide a brief update on FDA's work in each of these areas, with a focus on our efforts related to youth use of e-cigarettes.

Compliance and Enforcement

FDA has a comprehensive tobacco compliance and enforcement program, which includes, among other things: inspecting brick-and-mortar tobacco retail establishments; inspecting tobacco manufacturing establishments, including vape shops that perform manufacturing activities; and monitoring and surveillance of websites, publications, and social media that sell, distribute, promote, or advertise regulated tobacco products.

On January 2, 2020, amid alarming levels of youth use of e-cigarettes and rising popularity of certain products among children, FDA finalized its policy prioritizing enforcement against unauthorized flavored e-cigarette products that appeal most to kids, including certain candy-, fruit- and mint-flavored products. FDA's final guidance (revised in April 2020) entitled, "Enforcement Priorities for Electronic Nicotine Delivery System (ENDS) and Other Deemed Products on the Market Without Premarket Authorization," describes how FDA is prioritizing its enforcement resources with regard to the marketing of certain deemed tobacco products that do not have premarket authorization.

On February 6, 2020, FDA began prioritizing enforcement against illegally marketed ENDS products by focusing on the following groups of products that do not have premarket authorization:

- Any flavored, cartridge-based ENDS products (other than tobacco- or menthol-flavored);
- All other ENDS products for which the manufacturer has failed to take (or is failing to take) adequate measures to prevent underage access; and
- Any ENDS product that is targeted to those underage or whose marketing is likely to promote use of ENDS by underage persons.

Since September 9, 2020, FDA is also prioritizing enforcement against ENDS products that are not the subject of a pending premarket application.

FDA generally issues a warning letter to a retailer the first time a tobacco retailer compliance check inspection reveals a violation of Federal tobacco law and regulation that FDA enforces. If FDA finds subsequent violations at a retail establishment after the issuance of a warning letter, it has the authority to seek a Civil Money Penalty (CMP) in accordance with the schedule published in the Tobacco Control Act. FDA may also seek a No-Tobacco-Sale Order (NTSO) against a retailer that has committed five or more repeated violations of certain restrictions in a 36-month period. Since the beginning of FDA's tobacco compliance check program in 2010, FDA has completed more than 1.2 million tobacco retailer inspections, issued over 98,000 warning letters, and filed over 25,000 CMP complaints and 220 NTSO complaints.

FDA has been holding retailers and manufacturers accountable for marketing and sales practices that have led to increased youth accessibility and appeal of e-cigarettes. Since the effective date of the Deeming rule in August 2016, FDA has issued more than 11,000 warning letters to, and filed more than 2,000 CMP complaints against, retailers, both online and in brick-and-mortar retail stores, for sales of ENDS and their components to youth.

FDA also conducts inspections of manufacturing establishments, which includes inspections of vape shop establishments, many of which mix and/or sell flavored ENDS products. During these inspections, FDA seeks to determine the type of activities that are performed at the establishment and whether they are in compliance with applicable requirements under the FD&C Act and its implementing regulations.

- Since 2010, FDA has conducted more than 900 inspections of manufacturing establishments, some of which manufacture ENDS products (including e-liquids).
- Since the Deeming rule took effect on August 8, 2016, FDA has conducted more than 2,500 vape shop inspections.

Another key component of FDA's tobacco compliance and enforcement program is our monitoring and investigations of tobacco product promotion, advertising, and labeling activities. FDA's monitoring of the tobacco product marketplace has resulted in a number of compliance and enforcement actions. Since 2009, we have enforced applicable laws and regulations and have issued over 1,000 warning letters to sites selling violative products and for online sales of products to kids.

In addition, in January 2021, FDA issued the first set of warning letters to firms that had not submitted premarket applications to FDA by September 9, 2020 and are continuing to market unauthorized ENDS after that deadline. As of May 31, 2021, FDA had issued more than 120 warning letters to firms selling or distributing unauthorized ENDS and that did not submit premarket applications by the September 9 deadline. Collectively these companies have listed a combined total of over 1,280,000 products with FDA.

FDA's compliance and enforcement program for tobacco products is robust, however, we did need to make some adjustments for health and safety reasons throughout the SARS-CoV2 pandemic. As a result of the SARS-CoV2 pandemic, a number of FDA's compliance and enforcement activities were disrupted. In March 2020, FDA announced it would suspend all physical inspections and compliance checks due to health and safety concerns related to the SARS-CoV2 pandemic. Suspending inspections was necessary to protect the health and safety of FDA's staff and contractors (both adults and youth) who participate in the inspections. However, FDA's monitoring and surveillance of websites, publications, and social media continued without interruption during that time. Surveillance includes monitoring and following-up, when possible, on complaints to FDA's potential tobacco product violation reporting system. Before inspections were suspended, however, FDA completed thousands of inspections focusing on the priorities identified in the final guidance issued in January 2020. And in FY 2021, some tobacco manufacturer and retailer inspections have resumed in certain areas where the spread of SARS-CoV2 is less prevalent. FDA continues taking appropriate actions that are guided by health and safety considerations and as outlined by the Agency's priorities.

Prior to temporarily halting inspection activities due to the SARS-CoV2 pandemic, and then including the time period from October 2020 – May 2021 when inspections resumed, FDA conducted inspections of over 170 tobacco manufacturing establishments and over 550 vape shops and conducted investigations involving thousands of websites.

We will continue to take vigorous compliance and enforcement actions aimed at ensuring e-cigarettes, and all tobacco products, are not being marketed or sold to youth.

Premarket Review

Ensuring new tobacco products undergo a robust premarket evaluation by FDA is a critical part of our mission to protect the public health, particularly youth, and to reduce tobacco-related disease and death. The September 9, 2020, premarket submission deadline for certain deemed new tobacco products marked a major milestone for tobacco product regulation and for public health. By requiring premarket applications for new ENDS and other "deemed" new tobacco products, such as hookah and pipe tobacco, FDA is taking steps to transform the marketplace toward one where new tobacco products available for sale will have undergone careful, science-based review and oversight. We have worked for several years to prepare for premarket review of a large number of deemed products. These efforts included, but were not limited to, improving information technology systems, engaging with stakeholders, significantly increasing hiring, streamlining review procedures, and providing and promoting guidance and resources to inform industry.

As anticipated, FDA received thousands of tobacco product submissions covering millions of tobacco products, the vast majority of which are for ENDS products. FDA has completed initial processing of all timely submitted PMTAs—more than 6.5 million products submitted by over 550 companies—and the acceptance, filing, and substantive scientific review of the applications is underway.

On May 20, 2021, FDA posted a list of deemed new tobacco products for which a PMTA was submitted by September 9, 2020.[6] The list includes over 6 million products. The Agency made the list available to the public to be transparent and increase stakeholder knowledge of these products; however, the list is only one source of information. FDA continues to remind retailers that they should discuss with their suppliers the current status of any particular tobacco product's application and marketing authorization.

Due to the large number of applications moving into review at the same time, the novelty of this review, the finite nature of our review resources, and the necessarily rate-limiting effects of ensuring consistency across reviews, FDA developed a process to determine the review order for the applications. For PMTAs, the review order for most of the products is determined using a computer-generated randomization process. However, due to the large number of ENDS products currently marketed and for which we received

applications, FDA decided to dedicate a portion of its resources to reviewing the products that account for the vast majority of the current market.

The continued marketing of these widely-used products has the potential to have the greatest public health impact—either positively or negatively—as they hold the largest overall market share and therefore are likely used by the largest number of people. For this reason, FDA pulled several applications into a separate review queue and dedicated resources to their review. By identifying and ensuring review of these applications, we believe we can achieve the greatest public health impact most quickly. If FDA finds that a currently marketed product is not appropriate for the protection of public health—the standard in the law for marketing a new tobacco product that is the subject of a PMTA—the Agency will issue a No Marketing Order (NMO) and the product must be removed from the market. Conversely, if FDA finds that a currently marketed product does meet the standard in the law for marketing, the Agency will grant a marketing order and the product may remain on the market subject to the conditions in the order. In either case, earlier review of a currently marketed product ensures a faster transition to a marketplace of products that have been scientifically reviewed for their impact on public health.

We are working to review applications as quickly as possible. However, given the unprecedented number of applications and other factors discussed above, reviewing all the applications by September 9, 2021, will be challenging. We will continue to allocate our resources with the goal of working as quickly as possible to transition the current marketplace for deemed products to one in which all new tobacco products available for sale have undergone a careful, science-based review by FDA. We will focus resources on products where scientific review will have the greatest public health impact, including with respect to youth use of ENDS products, based on their market share, while also reviewing as many applications as possible from all companies regardless of size, prior to September 9, 2021, at which time they risk FDA enforcement.

FDA has commenced substantive scientific review on over a thousand products submitted through the PMTA pathway. The Agency continues to review tobacco product applications through all applicable premarket pathways and provide updates on its progress through FDA's *Tobacco Product Applications: Metrics and Reporting* webpage.[7]

Public Education

Mass market public education campaigns are a proven strategy to prevent use of tobacco products, especially among youth, and are another important tool in FDA's efforts to prevent youth use of tobacco products. From its launch in February 2014 to November 2016, "The Real Cost" campaign, FDA's first public education cigarette prevention effort, prevented up to 587,000 youth ages 11 to 19 from initiating smoking, and over time those prevention efforts will save more than $53 billion in smoking-related costs for youth, their families, and society at large—a cost savings of $180 for every dollar of the nearly $250 million invested.

Leveraging the success of "The Real Cost," FDA began prioritizing prevention efforts to address youth use of e-cigarette products in 2017. Targeting over 10 million teens who have used e-cigarettes or are susceptible to its use, FDA launched "The Real Cost" Youth E-Cigarette Prevention Campaign[8]—a full-scale mass media effort in 2018, urging teens to "know the real cost of vaping" by highlighting the potential addiction and health risks. As FDA's highest tobacco public education priority, the Agency will have invested nearly $248 million to prevent teen ENDS use by the end of this year.

The campaign has successfully reached and engaged teens, generating over 5 billion views, more than 3.5 million likes, 350,000 shares, and 88,000 comments. To provide resources for youth who are seeking to quit using e-cigarettes, FDA collaborated with the National Cancer Institute to add youth-focused e-cigarette cessation content on SmokeFree.gov. Since July 2019, there have been over six million-page views regarding how to quit e-cigarette use, manage withdrawal and acquire tips for managing stress and anxiety.

More importantly, the latest wave of outcome evaluation results assessing the impact of "The Real Cost" are promising, indicating that 75 percent of youth are aware and receptive to our ads. Over time, increased exposure to the campaign is expected to increase population-level shifts in youth beliefs about e-cigarettes.

FDA has also created important partnerships with prominent educational and medical organizations to advance the Agency's youth e-cigarette prevention efforts. Since 2018, FDA has worked with Scholastic to develop e-cigarette prevention resources for schools, including lesson plans, activity sheets and other materials to foster learning and conversations with students. This suite of free materials has been distributed to over 1.3 million educators to reach roughly 2.7 million students. In addition, FDA and the American Academy of Pediatrics (AAP) recently developed video interviews with pediatricians talking about the dangers of youth ENDS use.

Due to collective public health efforts, these results not only reinforce the importance of our public education efforts in reducing the public health and financial burden of tobacco use, but also highlight the importance of investing in education which can garner huge returns.

Regulatory Science Research

FDA is investing in regulatory science research to learn more about how ENDS products are being used and their health impacts. Research findings help inform the Agency's regulatory decision-making.

From 2010 to the present, FDA's Center for Tobacco Products (CTP) has funded more than 240 projects addressing ENDS' use. Currently, the CTP research portfolio includes more than 145 active research e-cigarette projects using a variety of research models (e.g., in vitro, animal models, human use studies). These projects address research priority areas including use behavior (e.g., impact of flavors on use, youth use, dual use, switching behaviors and cessation), toxicity, addiction, communications, health effects, chemistry, and engineering. CTP-funded e-cigarette research is administered through federal contracts, interagency agreements, and grants funded through a partnership with the National Institutes of Health (NIH) Tobacco Regulatory Science Program (TRSP). A key component of the TRSP grant program is the establishment of the Tobacco Centers of Regulatory Science (TCORS). Since fiscal year 2013, scientists with a broad range of expertise (e.g., epidemiology, economics, toxicology, addiction and marketing) at TCORS-funded research institutions across the country have generated critical research on: the role of flavors on initiation, continued use, and addiction; product characteristics and marketing approaches that are appealing to youth; health effects of e-cigarette use; and modeling behavior and public health impacts of tobacco regulations.

In addition, the FDA and NIH Population Assessment of Tobacco and Health (PATH) Study is providing population-level longitudinal data on the use, attitudes, biomarkers, and health conditions related to tobacco use, including e-cigarettes. The PATH Study is a national, longitudinal cohort study of almost 46,000 youth and adults in the United States that collected its first wave of data in 2013 and follows study participants over time to learn how and why people start using tobacco products, switch tobacco products, use multiple tobacco products, quit using them, and start using them again after they have quit, as well as how different tobacco products affect health (such as cardiovascular and respiratory health) over time. The PATH Study may help identify and explain differences in use patterns (e.g., switching, dual use, polyuse), risk perceptions, and attitudes related to e-cigarettes. The PATH Study is tracking potential behavioral and health impacts, including collecting biospecimens to analyze for biomarkers of exposure and harm.[9]

CTP also supports two other national surveys in collaboration with CDC. The aforementioned NYTS and the National Health Interview Survey (NHIS) evaluate the prevalence of e-cigarette use and user characteristics, among adolescents, young adults, and adults, that can help inform policy decisions. The NYTS provides important data on current youth tobacco product use. The NHIS is a cross-sectional, multistage area probability design with a representative sample of households with tobacco use questions asked of one randomly selected adult (aged 18 or older) in each family.

FDA will continue to support and fund research to evaluate the health impacts of ENDS, both at the individual and population levels.

Other Efforts to Address Youth use of Tobacco Products

In addition to our efforts to prevent youth use of ENDS, FDA is taking important action to address youth use of combusted tobacco products as well. On April 29, 2021, FDA announced the Agency's commitment to advance two tobacco product standards to significantly reduce disease and death from cigarettes and cigars. Specifically, FDA will work toward issuing tobacco product standards that will ban menthol in cigarettes and ban all flavors, including menthol, in cigars. Given the inherent toxicity of combusted tobacco products, decreasing their appeal will maximize the potential public health benefits of these regulatory actions. Nearly 41 million adults in the U.S. use combusted tobacco products, including cigarettes and cigars. The Agency's actions here reiterate our commitment to reducing tobacco-related death and disease by targeting the deadliest tobacco products. The actions combined will truly benefit the public health and save hundreds of thousands of lives.

The Agency will continue to work with the Administration to advance these efforts and implement regulatory policy on tobacco that improves the public health.

Conclusion

Thank you again for the opportunity to testify about FDA's comprehensive efforts to regulate ENDS, including our actions to prevent youth access to, and use of, these products. The efforts described here are just a part of the important work FDA and the Administration are undertaking to protect children and youth from the harms of tobacco products. We still have much to accomplish and will continue to take strong action to protect youth and monitor the effectiveness of our actions.

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1. *Sottera, Inc. v. Food and Drug Administration*, 627 F.3d 891 (D.C. Cir. 2010).
2. The U.S. District Court for the District of Columbia recently issued an order vacating the health warning requirements for cigars and pipe tobacco set forth in 21 CFR §§ 1143.3 and 1143.5 and remanding the Final Deeming Rule's warning requirements for cigars and pipe tobacco back to the Agency. See Order, *Cigar Ass'n of Am. v. U.S. Food & Drug Admin.*, No. 1:16-cv-01460 (D.D.C. September 11, 2020). Although the requirement has been vacated, cigar and pipe tobacco firms may choose to voluntarily comply with these health warning provisions.
3. Cullen, K.A., B.K. Ambrose, A.S. Gentzke, et al., "Notes from the Field: Increase in e-cigarette use and any tobacco product use among middle and high school students – United States, 2011-2018," *Morbidity and Mortality Weekly*, 67(45);1276-1277 (2018).
4. Cullen KA, Gentzke AS, Sawdey MD, et al., "E-Cigarette Use Among Youth in the United States, 2019," JAMA.
5. Wang, TW; Neff, LJ; Park-Lee, E; et al., "E-cigarette Use Among Middle and High School Students — United States, 2020," *Morbidity and Mortality Weekly*, 69(37);1310–1312 (2020).
6. https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/deemed-new-tobacco-product-applications-lists (/tobacco-products/market-and-distribute-tobacco-product/deemed-new-tobacco-product-applications-lists)
7. https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/tobacco-product-applications-metrics-reporting (https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/tobacco-product-applications-metrics-reporting)
8. More information is available at: https://www.fda.gov/tobacco-products/real-cost-campaign. (/tobacco-products/public-health-education/real-cost-campaign)
9. More information on the PATH Study can be found at https://www.fda.gov/tobacco-products/research/fda-and-nih-study-population-assessment-tobacco-and-health (/tobacco-products/research/fda-and-nih-study-population-assessment-tobacco-and-health).

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