

TESTIMONY

OF

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BEFORE THE

SUBCOMMITTEE ON ECONOMIC AND CONSUMER POLICY

COMMITTEE ON OVERSIGHT AND REFORM

U.S. HOUSE OF REPRESENTATIVES

**“THE FEDERAL RESPONSE TO THE EPIDEMIC OF E-CIGARETTE USE,
ESPECIALLY AMONG CHILDREN, AND THE FOOD AND DRUG
ADMINISTRATION’S COMPLIANCE POLICY”**

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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 the epidemic of youth use of electronic nicotine delivery systems, or ENDS, which include e-cigarettes.¹ I am Mitch Zeller, Director of the U.S. Food and Drug Administration's Center for Tobacco Products (CTP).

I also want to recognize the Subcommittee for its important work to carefully examine the potential causes and response to this epidemic and I appreciate the opportunity to be here today to provide background on FDA's regulation of e-cigarettes and where we find ourselves today, confronting the epidemic levels of youth use of e-cigarettes.

Background

Let me start with some background on our tobacco regulatory authorities and the regulatory history of 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 secondhand 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-

¹ The term "e-cigarette" will generally be used in this testimony as it is a more familiar term. There are some instances where it is more appropriate to use both "e-cigarette" and "ENDS."

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’s important to note FDA’s initial efforts to regulate e-cigarettes more than a decade ago, long before the rise in youth use and the multi-state lung injury outbreak. 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. *Sottera, Inc. v. Food and Drug Administration*, 627 F.3d 891 (D.C. Cir. 2010).

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 makers of e-cigarettes and other ENDS products. These include:

- Registering domestic establishments and submitting lists of products manufactured at those establishments, including all labeling and representative samples of advertisements;

- Submitting tobacco health documents;
- Submitting ingredient listings;
- Marketing new tobacco products only after FDA review; 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.

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

- Minimum age restriction (18 years or older) and identification requirements to prevent sales to youth;
- Requirements to bear certain health warnings on packages and advertisements (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.

To provide time for industry to come into compliance with some of the new regulatory requirements triggered by the final deeming rule, FDA announced an enforcement policy with staggered timeframes. Some of the requirements, such as the Federal minimum age of purchase (18 years or older), 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.

Premarket Review of ENDS

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 that was modified after February 15, 2007.

Through premarket review, FDA evaluates new tobacco products based on applicable public health standards that include, for example, a consideration of the risks and benefits of the tobacco product to the population as a whole, including users and non-users. Similarly, when developing certain regulations such as product standards or restrictions on tobacco sales and advertising, the law requires FDA to apply a public health approach that considers the effect of the regulatory action on the population as a whole, not just on individual users, taking into account the likelihood of initiation and cessation of tobacco product use.

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 comprehensive plan for tobacco and nicotine regulation that would serve as a multi-year roadmap in an effort to significantly reduce tobacco-related disease and death. The comprehensive plan was announced in part to afford the Agency time to explore other meaningful measures, beyond premarket review, to make combustible tobacco products less toxic, less appealing, and less addictive. One aspect of the plan involved striking a balance between conducting reasonable oversight through regulation and encouraging development of innovative tobacco products that may be less harmful than cigarettes. The Agency announced that it planned to issue an updated compliance policy to defer some enforcement timelines described in the preamble to the final deeming rule.

Since that announcement, FDA has been hard at work on rules, guidances, and other communications to ensure higher quality applications, including the issuance of the following:

- Substantial Equivalence pathway proposed rule
- Premarket Tobacco Application (PMTA) for ENDS final guidance

- Premarket Tobacco Application proposed rule
- Vape shops final guidance
- Regular meetings with manufacturers to provide guidance on premarket authorization processes
- Regular meetings with retailers on e-cigarette policies of particular importance for retailers such as efforts to prevent youth sales and the availability of free educational resources for retailers to assist them in preventing youth sales
- Draft guidance on Developing Nicotine Replacement Therapy Drug Products
- Draft guidance on Nonclinical Testing of Orally Inhaled Nicotine-Containing Drug Products Guidance for Industry

The July 2017 announcement led to publication of the August 2017 Compliance Policy, which was later the subject of litigation. In May 2019, a U.S. District Court in 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 filed 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 prior to May 12, 2020, or during the one-year review period.

As the Subcommittee considers the issues related to e-cigarette use today, it is important to remember that 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 (assuming that the product is being reviewed through the PMTA pathway) the Agency would have to find that 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 (e.g., smoking cessation) would need to be reviewed and approved under FDA's drug authorities to be legally marketed as a drug. Currently, there is no FDA-authorized or FDA-approved ENDS product on the market.

At the time FDA issued the August 2017 Compliance Policy to modify the enforcement discretion policies regarding premarket authorization, nationally representative data suggested that youth use of e-cigarettes had declined during 2015-2016.² While no level of youth use is acceptable, FDA took this directional data into consideration, along with the potential benefits some of these products might provide to some addicted individual adult smokers seeking to make a complete transition away from combustible cigarettes.

The Agency was engaged in a public health balancing act. Given the then-existing evidence suggesting a decline in youth use, FDA planned to pursue bold measures, in part by reducing the addictiveness of combustible cigarettes while temporarily delaying the likely immediate market exit of newly deemed tobacco products that could be potentially less harmful to individual adult smokers. FDA determined that the balancing of public health considerations argued in favor of a different comprehensive approach to nicotine and tobacco regulation.

However, only a year after we announced the 2017 comprehensive plan, the National Youth Tobacco Survey (NYTS) in 2018 showed a new and significant increase in youth use of e-cigarettes.

Data on Youth Use of E-Cigarettes

FDA collaborates with CDC to administer the NYTS survey 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.

² Jamal A, Gentzke A, Hu SS, et al. Tobacco Use Among Middle and High School Students — United States, 2011–2016. *MMWR Morb Mortal Wkly Rep* 2017;66:597–603. https://www.cdc.gov/mmwr/volumes/66/wr/mm6623a1.htm?s_cid=mm6623a1_w. The NYTS defines e-cigarettes as “battery-powered devices that provide nicotine and other additives to the user in the form of an aerosol.”

Between 2017 and 2018, current (past 30-day) e-cigarette use among high school students increased 78 percent, from 11.7 percent to 20.8 percent.³ Current e-cigarette use among middle school students increased by 48 percent over the same time period, from 3.3 percent to 4.9 percent.⁴ Moreover, evidence demonstrated that youth are especially attracted to flavored ENDS products. Data from the 2018 NYTS showed that, in just one year, current use of flavored e-cigarettes increased substantially among high school students who were current e-cigarette users, from 60.9 percent in 2017 to 67.8 percent in 2018.⁵ In addition, the proportion of current e-cigarette users in high school who reported frequent use (use on 20 or more days of the past 30 days) increased from 20.0 percent in 2017 to 27.7 percent in 2018.

FDA and CDC recently published 2019 NYTS data in the *Journal of the American Medical Association* (JAMA) on November 5, 2019.⁶ Unfortunately, the data show that current e-cigarette use among youth remains alarmingly high, with 27.5 percent of high school students and 10.5 percent of middle school students reporting current use of e-cigarettes. The data also showed that more than five million U.S. middle and high school students are current e-cigarette users. Further, most of those middle and high school students who exclusively use e-cigarettes are using flavored products. And the survey shows that 34.2 percent of current high school e-cigarette users in 2019 are using the product frequently (use on 20 or more days in the last 30 days). In total, 1.6 million middle school and high school current e-cigarette users were frequent users, with nearly one million using e-cigarettes daily.

As in previous years, the 2019 NYTS shows a disturbing rate of youth use of non-tobacco flavored e-cigarettes. In particular, the data show that among current exclusive e-cigarette users, nearly three quarters of those in high school and more than half of those in middle school used

³ Gentzke A.S., Creamer M., Cullen K.A., et al., “Vital Signs: Tobacco Product Use Among Middle and High School Students — United States, 2011–2018,” *MMWR Morb Mortal Wkly Rep*, 68:157–164 (2019), DOI: <http://dx.doi.org/10.15585/mmwr.mm6806e1>.

⁴ *Id.*

⁵ 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).

⁶ Cullen KA, Gentzke AS, Sawdey MD, et al. E-cigarette Use Among Youth in the United States, 2019. *JAMA*. Published online November 05, 2019. doi:<https://doi.org/10.1001/jama.2019.18387>

flavored e-cigarettes. The most commonly reported flavors were fruit, menthol or mint (evaluated as a single category), and candy, desserts, or other sweets.⁷ Importantly, findings from another study, the 2019 Monitoring the Future (MTF) survey—also published in *JAMA* on November 5, 2019—give us a more granular picture of flavor preferences as they relate to this public health balancing act. These findings indicate that self-reported youth use of menthol- and tobacco-flavored products is much *lower* than that for mint- and fruit-flavored products. This recent analysis was limited to youth who indicated they had specifically used the JUUL brand, which, according to the NYTS, is the most popular brand among kids. It is important to note that JUUL also has the greatest market share of any ENDS product on the U.S. market.

FDA’s Aggressive Actions to Address the Youth Epidemic of ENDS Product Use

Protecting our nation’s youth from the dangers of tobacco products is among FDA’s most important responsibilities, and we will continue to take aggressive steps to make sure tobacco products are not being marketed or sold to kids. These efforts are a cornerstone of our comprehensive approach for the regulation of tobacco and are also the focus of our Youth Tobacco Prevention Plan.⁸ FDA’s Youth Tobacco Prevention Plan demonstrates the Agency’s commitment to protecting our children. FDA’s work to protect youth from tobacco products includes compliance and enforcement, public education, regulatory science research, premarket review, and regulatory policy. 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,

⁷ Cullen KA, Gentzke AS, Sawdey MD, et al., “E-Cigarette Use Among Youth in the United States, 2019,” *JAMA*.

⁸ <https://www.fda.gov/TobaccoProducts/PublicHealthEducation/ProtectingKidsfromTobacco/ucm608433.htm>.

distribute, promote, or advertise regulated tobacco products.

Since the enactment of the Tobacco Control Act, FDA has commissioned more than 700 local government officers and employees, working under contracts with the Agency, who have assisted FDA in inspections of tobacco retailers to help enforce the youth access restrictions in the statute and FDA regulations.

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 and adjusted for inflation. FDA may also seek a No-Tobacco-Sale Order (NTSO) against a retailer that has committed five or more repeat violations in a 36-month period. Since the beginning of FDA's tobacco compliance check program, FDA has completed more than 1 million tobacco retailer inspections, issued well over 90,000 Warning Letters, and filed well over 20,000 CMP complaints and 170 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 issued more than 10,000 warning letters to, and filed more than 1,600 civil money penalty complaints against, retailers, both online and in brick-and-mortar retail stores, for sales of e-cigarettes and their components to youth. These actions included a number of coordinated efforts. For example:

- In the spring 2018, FDA conducted a nationwide undercover enforcement effort to determine if retailers were selling e-cigarettes, specifically JUUL products, to kids in brick-and-mortar stores and online. As a result of this effort, a total of 56 warning letters and six CMP complaints were issued to retailers for selling JUUL and other e-cigarette products to minors.
- In the summer of 2018, FDA issued more than 1,300 warning letters and CMP complaints to retailers who illegally sold e-cigarettes products, including JUUL, to

minors during nationwide, undercover investigations of brick-and mortar and online stores. It was the largest coordinated enforcement effort in FDA's history.

FDA conducts inspections of manufacturing establishments, which includes inspections of vape shop establishments, many of which mix and/or sell flavored e-cigarette and other 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.

- To date, FDA has conducted more than 650 inspections of manufacturing establishments, some of which manufacture e-cigarettes and other ENDS products (including e-liquids).
- Since the Deeming rule took effect on August 8, 2016, FDA has conducted more than 2,000 vape shop inspections.
- FDA has sent letters to over 100 companies seeking information on over 130 brands, including e-cigarette and ENDS products, to determine whether those products were not marketed as of August 8, 2016, and therefore not subject to any previous FDA compliance policy. To date, FDA has issued warning letters to six ENDS companies notifying them of the need to remove a combined total of nearly 140 unauthorized products from the market.

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. For example:

- FDA has issued more than 790 warning letters as a result of its internet surveillance activities. More than 280 of these warning letters cited online sales of ENDS, including e-liquids, to kids.

- The Agency has issued warning letters, many in collaboration with the Federal Trade Commission (FTC), that resulted in the removal of dozens of e-liquid products resembling kid-friendly foods, such as juice boxes, cereal, and candy.

Recent JUUL-specific actions by FDA

On September 9, 2019, FDA issued a warning letter⁹ to JUUL Labs Inc. for marketing unauthorized modified risk tobacco products by engaging in labeling, advertising, and/or other activities directed to consumers, including a presentation given to youth at a school, marketing JUUL products as posing reduced risk or harm compared to cigarette smoking. As stated in the warning letter, JUUL’s labeling, advertising, and/or other activities directed to consumers represent, or would be reasonably expected to result in consumers believing, that the products 1) present a lower risk of tobacco-related disease or are less harmful than one or more other commercially marketed tobacco products; 2) contain a reduced level of a substance or present a reduced exposure to a substance; and/or 3) do not contain or are free of a substance or substances. The warning letter identified several statements, including statements discussed in testimony to this Subcommittee on July 24, 2019. According to that testimony, a JUUL representative speaking with students at his presentation in a school stated that JUUL “was much safer than cigarettes” and that “FDA would approve it any day”; JUUL was “totally safe”; a student “...should mention JUUL to his [nicotine-addicted] friend...because that’s a safer alternative than smoking cigarettes, and it would be better for the kid to use.”; and “FDA was about to come out and say it [JUUL] was 99% safer than cigarettes...and that...would happen very soon....”

Concurrently, the Agency issued a second letter¹⁰ expressing its concern and requesting additional information about several issues raised by this Subcommittee regarding JUUL’s outreach and marketing practices, including those targeted at students, tribes, health insurers and employers. This letter to JUUL notes that despite commitments JUUL has made to address the

⁹ The warning letter is available at: <https://www.fda.gov/news-events/press-announcements/fda-warns-juul-labs-marketing-unauthorized-modified-risk-tobacco-products-including-outreach-youth>.

¹⁰ The request letter is available at: <https://www.fda.gov/media/130859/download>

youth epidemic, JUUL products continue to represent a significant proportion of the overall use of ENDS products by children. Some of this youth use appears to have been a direct result of JUUL's product design and promotional activities and outreach efforts.

The letter outlines several additional issues, including specific statements and representations made as part of JUUL's "Make the Switch" campaign and JUUL's "Switching Program" presentation to the Cheyenne River Sioux Tribe, such as:

- "[JUUL is] a smart, really well thought-out alternative to smoking.' Make the switch."
- "I think [JUUL is] an amazing invention...I don't know how we lived without that. The alternative for adult smokers."
- "Elimination of combustible cigarettes is crucial to reduce risk of harm"
- "Improve the lives of the world's one billion adult smokers"

FDA is concerned these statements and representations may convey that switching to JUUL is a safer alternative to cigarettes, in that using JUUL products poses less risk or is less harmful than cigarettes. By law, a manufacturer must submit a modified risk tobacco product (MRTP) application and gain FDA authorization if it wishes to market a tobacco product as posing less risk. FDA requested documents and information about these practices, including any and all scientific evidence or data, such as consumer perception studies, related to whether these statements and representations explicitly or implicitly convey that JUUL products pose less risk, are less harmful, present reduced exposure, are safer than other tobacco products or that the products are smoking cessation products.

FDA also asked JUUL to explain why it uses nicotine salts, which was described at the Congressional hearing as masking the harshness of nicotine. The Agency further asked JUUL why it uses a nicotine concentration of five percent in its products, which the Agency is concerned could potentially increase their addictiveness.

I want to acknowledge and commend the work the Subcommittee has done to shine the spotlight on issues related to JUUL. FDA shares your concerns about the popularity of this product, and

others like it, with young people. And we have our own ongoing investigation into issues related to the manufacturing and marketing of this product.

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 kids.

Public Education

FDA has made a significant investment in campaigns to educate youth about the dangers of e-cigarette use. Last year, FDA launched “The Real Cost” Youth E-Cigarette Prevention Campaign¹¹—a comprehensive effort targeting nearly 10.7 million youth, aged 12-17, who have used e-cigarettes or are open to trying them. The campaign features hard-hitting advertising on TV, digital and social media sites popular among teens, such as YouTube, as well as posters with e-cigarette prevention messages in high schools across the nation.

FDA joined forces with Scholastic to develop educational resources for middle and high school teachers and administrators. These materials have been distributed to more than 1 million middle and high school educators. Our work with Scholastic continues and more resources will be made available in Spring 2020.

The Agency also developed posters and resources for doctors, youth groups, religious institutions, state and local public health agencies, and others on the dangers of youth e-cigarette use and has worked to advance discussion and understanding around how to help those kids who are already addicted to e-cigarettes to quit.

Since its launch, “The Real Cost” Youth E-Cigarette Prevention Campaign is showing positive results for reach and engagement. The campaign has generated over 2 billion teen views, reaching between 80-85 percent of all teenagers nationwide with prevention messages. Across social media platforms, FDA has engaged teen audiences with more than 768,000 likes, 100,000 shares, and 43,000 comments. Additionally, since the Agency’s work began driving teens who

¹¹ More information is available at: <https://www.fda.gov/tobacco-products/real-cost-campaign>.

want to quit vaping to the National Cancer Institute’s (NCI) website, Teen.SmokeFree.gov, visits to the site have increased substantially. Likewise, total interactions from all users seeking information about e-cigarettes and vaping from the NCI’s Cancer Information Service telephone and online chat services have increased by more than 250 percent.

We will continue to expand our public education efforts to get the word out to youth about the harms of e-cigarettes.

Regulatory Science Research

FDA is investing in regulatory science research to learn more about how ENDS products are being used and their health impacts. FDA is funding several research projects assessing the health impact of e-cigarettes, including the FDA and NIH Population Assessment of Tobacco and Health (PATH) Study. 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 is following study participants over time to learn how and why people start using 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 is tracking potential behavioral and health impacts, including collecting biospecimens to analyze for biomarkers of exposure and harm.¹²

In 2016, FDA awarded a contract to the National Academy of Sciences, Engineering and Medicine (NASEM) to “conduct an in-depth evaluation of the available evidence of health effects from ENDS and make recommendations for future federally funded research.” This work included convening a multi-disciplinary committee of 13 members that met several times and holding an open meeting to obtain input from a wide range of stakeholders. The committee’s methodology included: a comprehensive literature search and review; a quality assessment and evidence synthesis to assess causality for health effects; and an application of a framework for

¹² 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>.

levels of evidence. Over 800 peer-reviewed scientific studies were evaluated and the consensus report, “Public Health Consequences of E-Cigarettes,” was released by NASEM in January 2018.¹³ Among the conclusions in the NASEM report is that teens who experiment with an e-cigarette are more likely to try conventional cigarettes compared to teens who never used an e-cigarette.

As noted in the NASEM report, assessing the long-term health effects of e-cigarettes is challenging given the range of devices and constituents. For example, products can vary widely in terms of device type, mechanism, ingredients and the characteristics of aerosol generation. Variables of ENDS that could affect health impact include factors such as: exposure to metals (including heavy metals), heating capacity, voltage, e-liquid solvent chemicals, nicotine formulations and concentration, flavors and flavoring ingredients, and use of other ingredients or contaminants with unknown inhalation effects. Many of the chemicals used in the products pose unknown inhalation effects. A specific ENDS product’s health impact is also likely to be significantly affected by user behavior (and we know that many ENDS users also use other tobacco products in addition to e-cigarettes, known as dual use or poly-use; frequency and intensity of use also varies widely). Assessing the short-term health effects is also challenging for these same reasons. To help understand the individual and population impact of ENDS, FDA is currently funding more than 115 studies assessing the short- and long-term health effects of e-cigarettes including nicotine dependence, cardiovascular and pulmonary toxicity, potential carcinogenesis, effects of maternal use during pregnancy, and effects in the oral cavity.¹⁴ Most of this research is supported through the Tobacco Regulatory Science Program, an interagency partnership between FDA and the National Institutes of Health.

FDA will continue to support and fund research to evaluate the public health impact of ENDS, both at the individual and population level.

¹³ More information can be found at <http://nationalacademies.org/hmd/Reports/2018/public-health-consequences-of-e-cigarettes.aspx>.

¹⁴ More information can be found on the FDA website at <https://www.fda.gov/tobacco-products/research/ctp-supported-tobacco-regulatory-research-projects>.

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. While the authorization of new tobacco products doesn't mean they are safe, the review process under the PMTA pathway makes certain that the marketing of the product is appropriate for the protection of the public health, taking into account the risks and benefits to the population as a whole. This includes how the products may impact youth use of nicotine and tobacco, and the potential for the products to completely move adult smokers away from use of combustible cigarettes. As part of the premarket review process under the PMTA pathway, FDA also has the ability to put in place post-marketing requirements aimed at, among other things, monitoring market dynamics such as potential youth uptake. FDA also has the ability to withdraw a PMTA marketing order if it, among other reasons, determines that the continued marketing of a product is no longer appropriate for the protection of the public health, such as if there is an uptake of the product by youth.

For example, issues related to the manufacturing and marketing of e-cigarettes and ENDS products, from the use of nicotine salts, to the levels of nicotine in the finished product, and the manner in which the product is marketed and sold, are all issues FDA will consider as part of our review of their marketing applications.

Regulatory Policy

We are committed to doing everything we can to prevent kids from using tobacco products and will continue to develop a policy approach that aligns with that concern. Most recently, the Administration held a listening session on the youth e-cigarette epidemic to help inform our policy actions going forward. I will be happy to return to brief members of the Subcommittee and staff when updates are available.

Conclusion

Thank you again for the opportunity to testify about FDA's efforts to regulate e-cigarettes, including our actions to prevent youth from using these products. The efforts I described today are just some examples of the important work FDA is doing to protect children from tobacco products. We still have much to accomplish. We will continue to take strong action to protect youth and monitor the effectiveness of our actions.