

TESTIMONY

OF

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“FDA REGULATION OF ELECTRONIC NICOTINE DELIVERY SYSTEMS
AND INVESTIGATION OF VAPING ILLNESSES”

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Introduction

Good morning, Chairwoman DeGette, Ranking Member Guthrie, 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) regulation of electronic nicotine delivery systems, or ENDS, which include e-cigarettes, and the Agency's role in the ongoing investigation into severe respiratory lung injury associated with e-cigarette use or vaping. I am Ned Sharpless, Acting Commissioner of the U.S. Food and Drug Administration, which is part of the Department of Health and Human Services (HHS).

FDA is deeply concerned by the severe respiratory lung injuries and reported deaths associated with e-cigarette use or vaping, and the Agency is working very closely with the Centers for Disease Control and Prevention (CDC) and state officials to investigate these incidents. FDA is committed to taking appropriate actions to protect the public as the facts emerge. To date, most patients have reported a history of using vaping products containing tetrahydrocannabinol (THC). Many patients have reported using products containing THC and products containing nicotine. Some have reported the use of e-cigarette products containing only nicotine.

I appreciate the opportunity to be here today to provide an update on FDA's regulation of ENDS, including the Administration's recent announcement to finalize a compliance policy that would prioritize enforcement against flavored ENDS to clear the market of those products, unless and until their marketing has been shown to be appropriate for the protection of the public health, as Congress required, and to provide an update on FDA's efforts to investigate the illnesses associated with the use of vaping products.

Background

Let me start with some basic background on our tobacco regulatory authorities.

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, the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) 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.

With limited exceptions, FDA evaluates new tobacco products based on a public health standard that considers the risks and benefits of the tobacco product to the population as a whole, including users and non-users. Similarly, when developing regulations, the law generally 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 initiation and cessation of tobacco use.

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.

On May 10, 2016, FDA issued a final rule (the “deeming rule”) to deem additional products that meet the statutory definition of a “tobacco product,” except for accessories, 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 benefit the health of the population as a whole.

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

- Minimum age restriction and identification requirement to prevent sales to underage 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.

FDA recognized that industry would need time to comply with some of the new regulatory requirements triggered by the final deeming rule and announced a compliance policy with staggered timeframes for compliance. Some of the requirements, such as the Federal minimum

age of purchase, took effect immediately when the deeming rule took effect on August 8, 2016, while, as an exercise of enforcement discretion, FDA provided industry with additional time to comply with other requirements, such as premarket review of “new” tobacco products.

Premarket Review of ENDS

All deemed products, including ENDS products, 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.

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 applications seeking marketing 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, in part, announced to afford the Agency time to explore clear and meaningful measures outside of premarket review to make combustible tobacco products less toxic, less appealing, and less addictive. One aspect of the plan involved striking a balance between 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 further deferring some enforcement timelines described in the final deeming rule.

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 2017 Compliance Policy. In July 2019, the court ordered 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, must 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.

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 undergo FDA scientific review and the Agency would have to find that the marketing of the product is appropriate for the protection of the public health. Alternatively, an ENDS product that is marketed for therapeutic purposes as a drug would need to be reviewed under FDA's drug authorities, and approved for such marketing. There is no FDA-authorized or FDA-approved ENDS product currently on the market.

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

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.¹ While no level of youth use is acceptable, FDA took this directional data into consideration, along with the potential for some such products to offer a public health benefit to some individual addicted adult smokers. In the context of these uncertainties and this evidence, and with the potential for FDA to pursue other bold measures, in part by reducing the addictiveness of combustible cigarettes while temporarily delaying the immediate market exit of innovative, potentially less harmful tobacco products, FDA determined that the balancing of public health considerations argued in favor of a different comprehensive approach. However, the NYTS 2018 data showed a significant increase in youth use of e-cigarettes. Data from the NYTS showed that, between 2017 and 2018, current e-cigarette use among high school students increased 78 percent, from 11.7 percent to 20.8 percent.² Current e-

¹ 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.”

² *Id.*

cigarette use among middle school students also increased by 48 percent over the same time period, from 3.3 percent to 4.9 percent.³

Moreover, evidence demonstrates that youth are especially attracted to flavored ENDS products. Data from the 2018 NYTS showed that current (past 30-day) use of any flavored e-cigarette increased substantially among high school students who reported current e-cigarette use (60.9 percent to 67.8 percent) in just one year.⁴

Preliminary data from the 2019 NYTS show a continued rise and disturbing rate of youth e-cigarette use, especially through the use of non-tobacco flavors that appeal to kids. In particular, the preliminary data show that more than a quarter of high school students were current e-cigarette users in 2019, and the majority of youth e-cigarette users cited the use of popular fruit and menthol/mint flavors.

FDA must act to try to reverse these trends. We are committed to keeping tobacco products out of the hands of youth and will not stand idly by as a new generation becomes addicted to nicotine and tobacco products. I am committed to tackling the epidemic of youth e-cigarette use using the regulatory tools at the Agency's disposal. We are taking a number of actions to help address the epidemic:

- Earlier this month, the President announced that as part of the Administration's ongoing work to tackle the epidemic of youth e-cigarette use, FDA intends to finalize a compliance policy in the coming weeks that would prioritize the Agency's enforcement of the premarket authorization requirements for non-tobacco-flavored e-cigarettes, including mint- and menthol-flavored products. It is important to note that this does not mean flavored e-cigarettes can never be marketed—if companies think they can show that specific products meet the standards established by Congress, then they can submit that evidence to FDA through a product application, which FDA will then evaluate. It

³ *Id.*

⁴ 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).

does mean that FDA intends to prioritize enforcement action such that, unless and until the manufacturers of these products meet their burden under the Tobacco Control Act to show that scientific evidence demonstrates that their marketing is appropriate for the protection of the public health, these products will be expected to exit the market.

- 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. For example, FDA has issued more than 10,000 warning letters and more than 1,400 civil money penalties to retailers, both online and in brick-and-mortar retail stores, for sales of ENDS and their components to youth.
- FDA has sent letters to about 90 companies seeking information on over 110 brands, including 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 five ENDS companies notifying them of the need to remove a combined total of more than 40 products from the market.
- 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.
- FDA and FTC sent warning letters to firms that make and sell flavored e-liquids for violations related to online posts by social media influencers on their behalf that lacked the required nicotine addiction warnings.
- On September 9, 2019, FDA issued a warning letter⁵ 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, by marketing it for reduced risk or harm from using the product compared to cigarette smoking. Concurrently, the Agency issued a second letter expressing its concern and requesting additional information about several issues raised by Congress regarding JUUL's outreach and marketing practices, including those targeted at students, tribes, health insurers and employers.

⁵ 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>.

- The Administration has also continued to invest in campaigns to educate youth about the dangers of e-cigarette use. Last year, FDA launched “The Real Cost” Youth E-Cigarette Prevention Campaign⁶– 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, 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 high school teachers and administrators. These materials have been distributed to over 700,000 high school educators. Our work with Scholastic continues, and we are currently developing additional resources, including lesson plans, for both middle and high school educators throughout this school year.
- The Agency also developed posters and resources for doctors, youth groups, churches, 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 quit.

We will continue to take vigorous actions aimed at ensuring e-cigarettes and other tobacco products are not being marketed or sold to kids. In addition, we will continue and expand our public education efforts to get the word out to youth about the harms of e-cigarettes.

Investing in Research to Learn More About the Health Impacts of ENDS Products

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

⁶ More information is available at: <https://www.fda.gov/tobacco-products/real-cost-campaign>.

behavioral and health impacts, including collecting biospecimens to analyze for biomarkers of exposure and harm.⁷

In 2016, FDA awarded a contract to National Academy of Sciences, Engineering and Medicine (NASEM) to “conduct an in-depth evaluation of the available evidence of health effects from electronic nicotine delivery systems (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 in order to obtain input from a wide range of stakeholders. The committee’s methodology included a comprehensive literature search, literature review and quality assessment, evidence synthesis to assess causality for health effects, and application of a framework for 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 2018.⁸ 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, e-liquid substrates, nicotine concentration, flavors and flavoring ingredients, and use of other ingredients or contaminants with unknown inhalation effects. A specific ENDS product’s health impact is also likely to be significantly affected by user behaviors (and we know that many ENDS users also use other tobacco products in addition to e-cigarettes). 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 funding studies assessing the short- and long-term health effects of e-cigarettes including nicotine

⁷ 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>.

⁸ More information can be found at <http://nationalacademies.org/hmd/Reports/2018/public-health-consequences-of-e-cigarettes.aspx>.

dependence, cardiovascular and pulmonary toxicity, potential carcinogenesis, effects of maternal use during pregnancy, and effects in the oral cavity.⁹

Investigation of Severe Respiratory Illnesses Associated with Vaping Products

In recent weeks, an outbreak of severe respiratory lung injury associated with the use of vaping products has possibly sickened over 530 people from 38 states and one U.S. Territory. Sadly, seven deaths have been confirmed in California, Illinois, Indiana, Kansas, Minnesota, and Oregon. These illnesses do not appear to be due to infectious diseases but rather appear to be associated with a chemical exposure from vaping products. Patients report a gradual start of symptoms including breathing difficulty, shortness of breath, and/or chest pain before hospitalization. Many patients have reported recent use of vaping products containing THC. Although these cases seem similar, it is not clear if they have a common cause, or if they involve different diseases with similar presentations. The investigation has not identified any specific product or substance or vaping product that is linked to all cases.

FDA is working closely with CDC and the affected states to investigate these cases. FDA's Office of Emergency Operations has activated an Incident Management Group (IMG) and is working alongside CDC's Incident Management System. The IMG serves as FDA's focal point for emergency management and is staffed by experts from across FDA.

FDA's work to investigate the illnesses includes field sample collections in coordination with states, sample analysis, criminal and civil investigations, and coordination with state and Federal partners.

FDA is also assisting states by collecting and analyzing samples. FDA's Forensic Chemistry Center (FCC) is an accredited laboratory in the field of forensic science testing and has experience in rapid response and specialized analytical services. FDA is analyzing samples for the presence of a broad range of chemicals, including nicotine, THC and other cannabinoids

⁹ More information can be found on the FDA website at <https://www.fda.gov/tobacco-products/research/ctp-supported-tobacco-regulatory-research-projects>.

along with cutting agents/diluents and other additives, pesticides, opioids, poisons, and toxins. Many samples received have contained little to no liquid, which limits the amount of testing our laboratory is able to conduct. In most cases, patients have acknowledged recent use of THC-containing vaping products. Many patients have reported using products containing THC and products containing nicotine. Some have reported the use of e-cigarette products containing only nicotine. Similarly, the samples we are continuing to evaluate show a mix of results and no single substance, including Vitamin E acetate, has been identified in all of the samples tested. Importantly, identifying any compounds that are present in the samples will be one piece of the puzzle but will not necessarily answer questions about causality, which makes our ongoing work critical.

Investigating this crisis is FDA's Office of Criminal Investigations' top priority. Our agents are following every possible lead, which includes traveling throughout the country and attempting to gather any available evidence, including devices, pods/cartridges, diluting agents, etc.

FDA is working with our other Federal partners to investigate the illnesses. For example, we are working with Customs and Border Protection to identify potential illicit FDA-regulated products at the border.

It is critical that FDA communicate with the public when we have information to share, and we work to do that as frequently and openly as possible. For example, earlier this month, FDA issued a warning to consumers to avoid THC-containing vaping products. While the investigation is ongoing, we strongly encourage consumers to help protect themselves and avoid buying vaping products of any kind on the street, and to refrain from using THC oil or modifying/adding any substances to products purchased in stores. FDA also encourages the public to submit detailed reports of any unexpected tobacco- or vaping-related product issues to FDA via the online Safety Reporting Portal, which can be found on our website (or at www.safetyreporting.hhs.gov).

Conclusion

Thank you for the opportunity to testify today about FDA's work to investigate the severe respiratory illnesses associated with vaping and our efforts to regulate ENDS products. It is an ever-changing landscape that FDA is committed to navigating with the goal of vigorously protecting and improving the public health.

I am happy to answer any questions you may have.