



MEMORANDUM

January 31, 2020

To: Subcommittee on Oversight and Investigations Members and Staff

Fr: Committee on Energy and Commerce Staff

Re: Hearing on “Vaping in America: E-Cigarette Companies’ Impact on Public Health”

On **Wednesday, February 5, 2020, at 10:30 a.m. in the John D. Dingell Room, 2123 of the Rayburn House Office Building**, the Subcommittee on Oversight and Investigations will hold a hearing entitled, “Vaping in America: E-Cigarette Companies’ Impact on Public Health.” The hearing will examine the role of manufacturers in the marketing and use of e-cigarettes in the United States as well as associated public health implications.

I. BACKGROUND

Electronic cigarettes, also known as “e-cigarettes,” are one type of electronic nicotine delivery system (ENDS) that have been available on the U.S. market since the mid-2000s, growing to an estimated \$19.3 billion global industry.¹ Available in many forms, these products consist of a battery-operated device that heats a liquid containing nicotine, flavoring, additives, or other chemical components into an aerosol that users inhale.² On May 10, 2016, under the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), the Food and Drug Administration (FDA) issued a final “deeming” rule, extending FDA regulatory authority over all tobacco products, including e-cigarettes and other ENDS products.³

In 2018, 20 percent of U.S. adults reported currently using a tobacco product, and conventional cigarette smoking reached an all-time low of 13.7 percent, while 3.2 percent—8.1 million adults reported currently using e-cigarettes.⁴ E-cigarettes became the most commonly

¹ U.S. Department of Health and Human Services, Office of the Surgeon General, *E-Cigarette Use Among Youth and Youth Adults: A Report of the Surgeon General* (2016); *Vaping: How popular are e-cigarettes*, BBC News (Sept. 15, 2019).

² *Id.*

³ U.S. Food and Drug Administration, *Deeming Tobacco Products to be Subject to the Federal Food, Drug and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act*, 81 Fed. Reg. 28974 (May 10, 2016) (final rule).

⁴ U.S. Centers for Disease Control and Prevention, “Tobacco Product Use and Cessation Indicators Among Adults – United States, 2018,” *MMWR*, 68(45); 1013-1019 (Nov. 15, 2019).

used tobacco product among youth in 2014, surpassing conventional cigarettes.⁵ From 2018 to 2019 alone, the number of U.S. middle and high school students reporting current use of e-cigarettes increased from 3.6 million to over five million young people—10.5 percent of middle school students and 27.5 percent of high school students.⁶

II. FEDERAL REGULATORY FRAMEWORK

Some provisions of the final deeming rule have since come into effect, including the prohibition of e-cigarette sales to young people under the age of 18 and FDA authority to conduct inspections of ENDS manufacturers and retailers.⁷ In December 2019, Congress increased the minimum purchasing age for all tobacco products including e-cigarettes from 18 to 21 years old, effective as of December 20, 2019.⁸

Under the final deeming rule, manufacturers of ENDS products already on the market as of August 8, 2016, could continue to market those products under FDA’s enforcement discretion, subject to FDA review, conducted pursuant to the submission of a premarket tobacco application (PMTA), by August 8, 2018.⁹ Although these products had not yet undergone FDA review at the time, FDA permitted the products to remain on the market. In August 2017, FDA extended the compliance deadline for submitting PMTAs for e-cigarettes to August 8, 2022.¹⁰ Following a district court order in July 2019, however, the compliance deadline was moved-up: manufacturers of e-cigarettes and other ENDS products on the market under FDA’s enforcement discretion were required to submit their PMTAs by May 12, 2020.¹¹

⁵ U.S. Department of Health and Human Services, Office of the Surgeon General, *E-Cigarette Use Among Youth and Youth Adults: A Report of the Surgeon General* (2016).

⁶ Cullen, K.A., et al, *e-Cigarette Use Among Youth in the United States, 2019*. JAMA (Nov. 5, 2019). Note reported use of an e-cigarette within the past 30 days.

⁷ U.S. Food and Drug Administration, *Deeming Tobacco Products to be Subject to the Federal Food, Drug and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act*, 81 Fed. Reg. 28974 (May 10, 2016) (final rule).

⁸ U.S. Food and Drug Administration, *Selling Tobacco Products in Retail Stores* (Dec 20, 2020) (www.fda.gov/tobacco-products/retail-sales-tobacco-products/selling-tobacco-products-retail-stores).

⁹ U.S. Food and Drug Administration, *Deeming Tobacco Products to be Subject to the Federal Food, Drug and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act*, 81 Fed. Reg. 28974 (May 10, 2016) (final rule).

¹⁰ U.S. Food and Drug Administration, *Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule; Guidance for Industry; Availability*, 82 Fed. Reg. 37459 (Aug. 10, 2017).

¹¹ Memorandum Opinion and Order, *American Academy of Pediatrics v. FDA*, Doc. 127, No. 18-cv-00883 (July 12, 2019) (notice of appeal filed by proposed intervenors representing vaping industry on July 30, 2019).

Among other requirements, PMTAs must include full reports of health risk investigations; a complete statement of product ingredients; a complete description of the manufacturing and processing methods; and proposed product labeling.¹² In order for FDA to issue a PMTA marketing order, the manufacturer must demonstrate, and FDA must find, that the marketing of the product is “appropriate for the protection of public health.”¹³ FDA is also required to consider the risks and benefits of the product to the population as a whole, including tobacco product users as well as non-users.¹⁴ On September 20, 2019, FDA issued a proposed rule on the content and formatting requirements for PMTAs, as well as the agency’s review and communications procedures for PMTA submissions.¹⁵

In September 2018, FDA wrote to JUUL, Reynolds, Fontem, and Logic regarding their respective plans to address youth access and use of their products.¹⁶ In September 2019, FDA also issued a warning letter to e-cigarette manufacturer JUUL Labs, Inc. for making unauthorized claims that its products are less harmful than other traditional tobacco products.¹⁷

On September 11, 2019, the Trump Administration announced that FDA would finalize a compliance policy to prioritize the agency’s enforcement of premarket authorization requirements to clear the market of non-tobacco-flavored e-cigarettes, including mint and menthol e-cigarettes.¹⁸ The final policy, announced by FDA on January 2, 2020, retreated from this initial statement.¹⁹ Instead, until these products undergo FDA review, FDA will prioritize enforcement against the manufacturing, distribution, or sale of non-tobacco-flavored cartridge-based e-cigarettes with the exception of menthol-flavored products; any product for which the manufacturer fails to take adequate measures to prevent minors’ access; and instances in which

¹² FFDCFA Section 910(b)(1). *See also* FDA, *Draft Guidance: Applications for Premarket Review of New Tobacco Products* (Sept. 2011).

¹³ FFDCFA Section 910(c)(4).

¹⁴ *Id.*

¹⁵ U.S. Food and Drug Administration, *Premarket Tobacco Product Applications and Recordkeeping Requirements*, 84 Fed. Reg. 50566 (Sept. 20, 2019) (proposed rule).

¹⁶ U.S. Food and Drug Administration, *FDA takes new steps to address epidemic of youth e-cigarette use, including a historic action against more than 1,300 retailers and 5 major manufacturers for their roles perpetuating youth access* (Sept. 11, 2018) (press release).

¹⁷ Letter from Ann Simoneau, Director, Office of Compliance and Enforcement, Center for Tobacco Products, U.S. Food and Drug Administration, to Kevin Burns, JUUL Labs, Inc. (Sept. 9, 2019).

¹⁸ U.S. Food and Drug Administration, *Trump Administration Combating Epidemic of Youth E-Cigarette Use with Plan to Clear Market of Unauthorized, Non-Tobacco-Flavored E-Cigarette Products* (Sept. 11, 2019) (press release).

¹⁹ U.S. Food and Drug Administration, *FDA Finalized Enforcement Policy on Unauthorized Flavored Cartridge-Based E-Cigarettes that Appeal to Children, Including Fruit and Mint* (Jan. 2, 2020).

the product is targeted or promoted to minors.²⁰ Disposable e-cigarettes, open tank systems, and e-liquids of any flavor, including those mixed in vape shops, will remain available, subject to enforcement action on a case-by-case basis if there are inadequate measures to prevent youth access or if the product is targeted or promoted to minors.²¹ The new FDA policy will take effect on February 6, 2020.²²

III. PUBLIC HEALTH IMPLICATIONS

A. Youth Use and Growing Epidemic

In 2016, following a 900 percent rate increase of e-cigarette use among U.S. high school students from 2011 to 2015, the Surgeon General characterized e-cigarette use among young people as a “major public health concern.”²³ In September 2018, FDA declared youth vaping an epidemic, due to an “accelerating trajectory of use” and “resulting path to addiction” among young people.²⁴ Survey data published in September 2019 showed that rates of e-cigarette use among eighth, 10th, and 12th graders doubled in just two years.²⁵ In addition to substantial evidence that e-cigarette use among youth increases their likelihood of using combustible cigarettes, the nicotine contained in most e-cigarettes can cause addiction and pose unique harms to a young person’s developing brain.²⁶

The taste of e-cigarette flavors, curiosity, and a perception of lower harm to human health compared to other tobacco products are the most commonly reported reasons young people use e-cigarettes.²⁷ According to the 2019 National Youth Tobacco Survey, an estimated 72 percent of high school students currently using e-cigarettes as their only tobacco product used flavored e-

²⁰ U.S. Food and Drug Administration, *Enforcement Priorities for Electronic Nicotine Delivery System (ENDS) and Other Deemed Products on Market Without Premarket Authorization; Guidance for Industry; Availability*, 85 Fed. Reg. 720 (Jan. 7, 2020).

²¹ *Id.*

²² *Id.*

²³ U.S. Department of Health and Human Services, Office of the Surgeon General, *E-Cigarette Use Among Youth and Youth Adults: A Report of the Surgeon General* (2016).

²⁴ U.S. Food and Drug Administration, *Statement from FDA Commissioner Scott Gottlieb, M.S., on New Steps to Address Epidemic of Youth E-Cigarette Use* (Sept. 11, 2018).

²⁵ U.S. National Institutes of Health, *Teen E-Cigarette Use Doubles Since 2017*, National Institute on Drug Abuse (Sept. 18, 2019) (www.drugabuse.gov/news-events/news-releases/2019/09/teen-e-cigarette-use-doubles-2017).

²⁶ National Academies of Sciences, Engineering, and Medicine, *Public Health Consequences of E-Cigarettes* (Jan. 23, 2018); U.S. Department of Health and Human Services, Office of the Surgeon General, *E-Cigarette Use Among Youth and Youth Adults: A Report of the Surgeon General* (2016).

²⁷ U.S. Department of Health and Human Services, Office of the Surgeon General, *E-Cigarette Use Among Youth and Youth Adults: A Report of the Surgeon General* (2016).

cigarettes, including fruit, menthol or mint, candy or other sweet flavors.²⁸ The Centers for Disease Control and Prevention (CDC) also attributes the extremely high nicotine content and the addition of nicotine salts—which reduces the bitterness of nicotine—in e-cigarettes, as well as youth-targeting advertisements, as a means of attracting and sustaining youth use.²⁹ Among e-cigarette products, the majority of middle and high school e-cigarette users reported JUUL as their usual brand.³⁰ In addition to its flavors and marketing, researchers also point to the stealthfulness of JUUL’s products, easily hidden from parents and teachers, as well the viral peer-to-peer spread via social media and in-person to explain the growth of JUUL use among young people.³¹

B. Cessation vs. Dual Use

E-cigarettes are not approved by the FDA as a smoking cessation aid, and research on their efficacy for smoking cessation remains limited.³² The January 2020 Surgeon General’s report on smoking cessation found inadequate evidence to conclude or infer that e-cigarettes increase smoking cessation, similar to the conclusion of the U.S. Preventive Services Task Force review in 2015.³³ Many adults report using e-cigarettes to try to quit smoking combustible cigarettes.³⁴ Most adult e-cigarette users, however, “do not stop smoking cigarettes and are instead continuing to use both products.”³⁵ In fact, more than half of current adult e-cigarette

²⁸ Cullen, Karen A., et al, *e-Cigarette Use Among Youth in the United States, 2019*, JAMA (Nov. 5, 2019).

²⁹ Anne Schuchat, Principal Deputy Director, Centers for Disease Control and Prevention, *Testimony before the Energy and Commerce Subcommittee on Oversight and Investigations* (Sept. 25, 2019).

³⁰ U.S. Food and Drug Administration, *Youth Tobacco Use: Results from the National Youth Tobacco Survey* (Nov. 18, 2019) (www.fda.gov/tobacco-products/youth-and-tobacco/youth-tobacco-use-results-national-youth-tobacco-survey#1).

³¹ Jackler, Robert K., et al, *JUUL Advertising Over its First Three Years on the Market*, Stanford University School of Medicine (Jan. 31, 2019).

³² U.S. Department of Health and Human Services, *Researchers Explore Health Effects of E-Cigarettes* (Nov. 6, 2018); National Academies of Sciences, Engineering, and Medicine, *Public Health Consequences of E-Cigarettes* (Jan. 23, 2018).

³³ U.S. Department of Health and Human Services, Office of the Surgeon General, *Smoking Cessation: A Report of the Surgeon General Executive Summary* (2020); Agency for Healthcare Research and Quality, *Behavioral Counseling and Pharmacotherapy Interventions for Tobacco Cessation in Adults, Including Pregnant Women: A Review of Reviews for the U.S. Preventive Services Task Force* (2015).

³⁴ U.S. Centers for Disease Control and Prevention, *About Electronic Cigarettes (E-Cigarettes)* (Nov. 15, 2018) (www.cdc.gov/tobacco/basic_information/e-cigarettes/about-e-cigarettes.html).

³⁵ *Id.*

users are “dual users,” who currently smoke combustible cigarettes and use e-cigarettes.³⁶ In 2018, the National Academies of Sciences, Engineering, and Medicine (NASEM) found conclusive evidence of reduced exposure to toxicants and carcinogens for users who completely substitute e-cigarettes for combustible cigarettes.³⁷ Given more recent findings that e-cigarette use is associated with increased risk of heart attack and an independent risk factor for respiratory disease, however, researchers have determined that, “dual use, the most common use pattern, is riskier than using either product alone.”³⁸

C. Long-Term Health Effects

While CDC states that “e-cigarettes have the potential to benefit adult smokers who are not pregnant if used as a complete substitute for regular cigarettes and other smoked tobacco products,” the agency has also determined that “e-cigarettes are not safe for youth, young adults, pregnant women, or adults who do not currently use tobacco products.”³⁹ In 2018, NASEM concluded that the long-term health effects of e-cigarettes are not yet clear, but stated there is “conclusive evidence that in addition to nicotine, most e-cigarette products contain and emit numerous potentially toxic substances.”⁴⁰ According to CDC, e-cigarettes can contain nicotine and other substances that have known harmful health effects.⁴¹ Additional research can help health officials and the public to better understand these and other long-term health effects.⁴²

³⁶ U.S. Department of Health and Human Services, Office of the Surgeon General, *Smoking Cessation: A Report of the Surgeon General Executive Summary* (2020).

³⁷ National Academies of Sciences, Engineering, and Medicine, *Public Health Consequences of E-Cigarettes* (Jan. 23, 2018);

³⁸ Bhatta, Dharma N., et al, *Association of E-Cigarette Use With Respiratory Disease Among Adults: A Longitudinal Analysis*, *AJPM* (Dec. 16, 2019); Osei, A.D., et al, *Association Between E-Cigarette Use and Cardiovascular Disease Among Never and Current Combustible-Cigarette Smokers*, *Am J Med.* (Aug. 2019).

³⁹ U.S. Centers for Disease Control and Prevention, *About Electronic Cigarettes (E-Cigarettes)* (Jan. 3, 2020) (www.cdc.gov/tobacco/basic_information/e-cigarettes/about-e-cigarettes.html).

⁴⁰ National Academies of Sciences, Engineering, and Medicine, *Public Health Consequences of E-Cigarettes* (Jan. 23, 2018).

⁴¹ U.S. Centers for Disease Control and Prevention, *About Electronic Cigarettes (E-Cigarettes)* (Jan. 3, 2020) (www.cdc.gov/tobacco/basic_information/e-cigarettes/about-e-cigarettes.html).

⁴² U.S. Centers for Disease Control and Prevention, *About Electronic Cigarettes (E-Cigarettes)* (Jan. 3, 2020) (www.cdc.gov/tobacco/basic_information/e-cigarettes/about-e-cigarettes.html).

IV. LEADING E-CIGARETTE MANUFACTURERS

Five e-cigarette manufacturers operating in the United States represent approximately 97 percent of the U.S. market.⁴³ JUUL Labs, Inc. holds more than two-thirds of the yearly market share, followed by Reynolds American Inc., NJOY, LLC, Fontem U.S., and Japan Tobacco International, U.S. (Logic Technology Development, LLC).⁴⁴ These five companies manufacture their own closed cartridge devices and respective compatible e-liquid units (pods).⁴⁵ The nicotine content of the e-cigarettes varies across these companies and their products, ranging from a nicotine-free option to products with six percent nicotine content.⁴⁶ All five manufacturers have at one time sold, or currently sell, mint-, fruit-, or dessert-flavored e-cigarette products in addition to tobacco and menthol flavors.⁴⁷ Of the five manufacturers, both NJOY and Fontem sell fruit- or dessert-flavored disposable e-cigarette products in addition to their closed-cartridge devices not automatically subject to FDA's priority enforcement guidance regarding certain flavored e-cigarette products.⁴⁸

V. WITNESSES

The following witnesses have been invited to testify:

K.C. Crosthwaite
CEO
JUUL Labs, Inc.

Ricardo Oberlander
President & CEO
Reynolds American Inc.

Ryan Nivakoff
CEO
NJOY, LLC

⁴³ Winston-Salem Journal, *Nielsen report finds electronic cigarette sales remaining on downward trend*, (Oct. 15, 2019).

⁴⁴ *Id.*

⁴⁵ Companies' website product pages (Jan. 24, 2020) (Product homepages available at: www.blu.com/en/US; www.juul.com/; www.logicvapes.us/; <https://njoy.com/>; and <https://vusevapor.com/>).

⁴⁶ *Id.*

⁴⁷ *Id.*

⁴⁸ *Id.*; NJOY DAILY (accessed Jan. 27, 2020) (<https://njoy.com/shop/devices/daily/>); blu Disposable (accessed Jan. 27, 2020) (www.blu.com/en/US/blu-disposable); U.S. Food and Drug Administration, *Enforcement Priorities for Electronic Nicotine Delivery System (ENDS) and Other Deemed Products on Market Without Premarket Authorization; Guidance for Industry; Availability*, 85 Fed. Reg. 720 (Jan. 7, 2020).

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