COMMITTEE ON
ENERGY & COMMERCE
CHAIRMAN FRANK PALLONE, JR.

MEMORANDUM

October 11, 2019

To: Subcommittee on Health Members and Staff

Fr: Committee on Energy and Commerce Staff

Re: Hearing on "Legislation to Reverse the Youth Tobacco Epidemic"

On **Wednesday, October 16, 2019, at 10:30 a.m. in room 2322 of the Rayburn House Office Building**, the Subcommittee on Health will hold a legislative hearing entitled, "Legislation to Reverse the Youth Tobacco Epidemic."

I. BACKGROUND

Tobacco use remains the leading cause of preventable death, disability, and disease in the United States.[1] More than 480,000 of the preventable deaths, which are considered premature, are caused by smoking and exposure to tobacco smoke.[2] Despite these figures, the Centers for Disease Control and Prevention (CDC) estimates that 47.4 million adults in the United States continue to use tobacco products, including combustible cigarettes, cigars, electronic cigarettes (e-cigarettes), and smokeless tobacco, among others.[3]

While adult use is a noteworthy problem, nearly all tobacco use begins during youth and young adulthood.[4] In 2018, approximately 4.9 million middle and high school students indicated that they were using tobacco in some form.[5]

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[1] Centers for Disease Control and Prevention, *Data and Statistics, Smoking & Tobacco Use* (accessed Oct. 8, 2019).

[2] *Id.*

[3] Centers for Disease Control and Prevention, *Tobacco Product Use Among Adults — United States, 2017* (November 9, 2018).

[4] Centers for Disease Control and Prevention, *Vital Signs: Tobacco Product Use Among Middle and High School Students – United States, 2011–2018* (Feb. 15, 2019).

[5] *Id.*

Multiple studies, including the 2018 National Youth Tobacco Survey (NYTS), indicate that the Nation is seeing a significant increase in youth use of tobacco products.[6,7] Further contributing to this public health issue is the popularity of electronic nicotine delivery systems (ENDS), such as e-cigarettes. According to the most recent CDC data, more than one in four high school students say they have used an e-cigarette in the past 30 days.[8] The 2018 Monitoring the Future (MTF) survey—which offers a look into the drug use and attitudes of the Nation's 8th, 10th, and 12th graders—found that between 2017 and 2018, the percentage of 12th graders who reported vaping nicotine nearly doubled.[9] Numerically, this translates to an increase of 1.5 million more students who used e-cigarettes in 2018 compared to 2017.[10] This year-over-year increase was the most significant increase for any substance since the survey began in 1975.[11]

The availability and appeal of flavored products plays a role in the widespread youth use of tobacco products, including e-cigarettes. According to the 2018 MTF survey, the percentage of 12th graders who say they vaped "just flavoring" in the past year substantially increased.[12] Data from the CDC also found that nearly two-thirds of middle and high school student tobacco users reported using a flavored tobacco product[13] while the NYTS from 2016 reported that one-third of the study's respondents who had used an e-cigarette said the reason for their use was the availability of flavors such as mint, candy, fruit, or chocolate.[14]

Among the various options available on the market, cigarette flavors such as menthol, which has cooling and analgesic effects, are associated with increased smoking initiation by

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[6] *Id.*

[7] Food and Drug Administration, *Youth Tobacco Use: Results from the National Youth Tobacco Survey* (accessed Oct. 8, 2019).

[8] Centers for Disease Control and Prevention, *Flavored Tobacco Product Use Among Middle and High School Students — United States, 2014–2018* (Oct. 4, 2019).

[9] Institute for Social Research, University of Michigan, *Monitoring the Future National Survey Results on Drug Use 1975-2018* (January 2019).

[10] *See* note 7.

[11] National Institute on Drug Abuse. *Monitoring the Future Survey Results Show Alarming Rise in Teen Vaping,* Nora's Blog (December 17, 2018).

[12] *See* note 9.

[13] *See* note 8.

[14] *See* note 7.

youth and young adults.[15] As cause for additional concern, while some flavorings used in e-cigarettes are generally recognized as safe for oral consumption, inhalation of the same flavored products require further research to fully understand safety risks.[16]

In addition to the appeal of flavors, tobacco product advertising and promotion are strong factors that influence the use of e-cigarettes and other tobacco products by youth. Studies from multiple public health agencies demonstrated the influence of tobacco marketing on youth.[17,18] A 2012 Surgeon General report on youth and tobacco use also highlighted the causal relationship between tobacco advertising and promotion and increased tobacco use.[19] In the age of social media, an investigation led by CNN found that platforms such as Instagram, which is the second most popular social media platform among teens,[20] were leveraged to promote e-cigarettes.[21] Of note, in 2017, the Federal Trade Commission (FTC) reported that on cigarettes alone, advertising and promotional expenditures totaled $8.637 billion.[22]

II. FEDERAL REGULATORY AUTHORITY AND ACTIONS

In 2009, the Food and Drug Administration (FDA) was given authority to regulate tobacco products in the Family Smoking Prevention and Tobacco Control Act of 2009 (TCA).[23] Although traditional cigarettes and other tobacco products, including smokeless tobacco, were statutorily deemed to be regulated by FDA through the TCA, the legislation provided the Secretary of Health and Human Services with the authority to extend its regulatory oversight to additional tobacco products. Using this authority, FDA finalized its 2016 "deeming rule" to

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[15] Food and Drug Administration, *Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol versus Nonmenthol Cigarettes* (2013).

[16] National Academies of Sciences, Engineering, and Medicine, *Public health consequences of e-cigarettes* (2018).

[17] National Cancer Institute, *The Role of the Media in Promoting and Reducing Tobacco Use. Tobacco Control Monograph No. 19* (June 2008).

[18] Centers for Disease Control and Prevention, *Executive Summary - Preventing tobacco use among young people: a report of the Surgeon General* (1994).

[19] U.S. Health and Human Services, *Preventing Tobacco Use among Youth and Young Adults: A Report of the Surgeon General* (2012).

[20] Pew Research Center, *Teens, Social Media & Technology 2018* (May 31, 2018).

[21] *#JUUL: How social media hyped nicotine for a new generation,* CNN Health (December 19, 2018).

[22] Federal Trade Commission, *Cigarette Report for 2017* (2019).

[23] Pub. L. No. 111-31 (2009).

encompass all tobacco products, including ENDS products, with the goal of reducing death and disease from tobacco products.[24]

Under the deeming rule, ENDS products must undergo FDA review.[25] Through the submission of a premarket tobacco application (PMTA), manufacturers must include reports of health risk investigations, a complete statement of product ingredients, a complete description of the manufacturing and processing methods, and proposed product labeling.[26] For FDA to issue a PMTA marketing order, the manufacturer must demonstrate that the product is "appropriate for the protection of public health."[27] FDA will also consider the risks and benefits of the product to the population as a whole, including tobacco product users as well as non-users.[28]

Although ENDS products were deemed under the regulatory authority of FDA, when finalizing the deeming rule, the agency announced that ENDS products already on the market as of August 8, 2016, could remain on the market, but the product manufacturers were required to submit a PMTA by August 8, 2018.[29] In August 2017, FDA extended the compliance deadlines for several products, including a four-year extension for e-cigarettes, to August 8, 2022.[30] Following litigation, a district court judge ordered manufacturers of e-cigarettes and other ENDS products on the market under FDA's enforcement discretion authority to submit PMTAs for these products within 10 months, by May 2020.[31] In response to the court order, FDA clarified that manufacturers do not need to wait 10 months to submit PMTAs and the agency encouraged the industry to use available FDA guidance for their submissions.[32] FDA has since issued a

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[24] 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).

[25] *Id.*

[26] *See* 21 U.S.C. § 387j(b)(1); Section 910(b)(1). *See also* Food and Drug Administration, *Draft Guidance: Applications for Premarket Review of New Tobacco Products* (Sept. 2011).

[27] 21 U.S.C. § 387j(c)(4); Section 910(c)(4).

[28] Food and Drug Administration, *Premarket Tobacco Product Applications* (accessed Oct 10, 2019).

[29] *See* note 22.

[30] 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).

[31] Memorandum Opinion and Order, American Academy of Pediatrics v. FDA, Doc. 127, No. 18-cv-00883 (D. Md. July 12, 2019).

[32] *Id.*

proposed rule on the content and formatting requirements for PMTAs, as well as the agency's review and communications procedures for PMTA submissions.[33]

On September 11, 2019, after seeing data that indicated a dramatic increase in youth usage of flavored e-cigarette products, FDA announced that it intends to finalize a new enforcement policy for addressing flavored e-cigarette products, including mint and menthol, that lack premarket authorization moving forward.[34] Under the announced policy, FDA has said that it expects flavored e-cigarette products, other than those with tobacco flavor, to exit the market unless and until manufacturers provide scientific evidence that demonstrates that marketing these products is appropriate for the protection of the public health.[35]

Driven by its mission to protect consumers by preventing deceptive business practices, among other things, the FTC is also using its current authority to investigate the tobacco industry, including the industry's product marketing, advertising, and promotion of its products. Recently, the agency issued orders to six e-cigarette manufactures to study the companies' business practices.[36] Similar to the agency's studies on smokeless tobacco products and cigarettes, this inquiry is aimed at obtaining a better understanding of the rapidly growing e-cigarette market.[37]

III. LEGISLATION

On April 18, 2019, Committee on Energy and Commerce Chairman Frank Pallone, Jr. (D-NJ) and Rep. Donna E. Shalala (D-FL) introduced H.R. 2339, the "Reversing the Youth Tobacco Epidemic Act of 2019". Below is a section-by-section summary of the legislation.

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[33] Food and Drug Administration, *Premarket Tobacco Product Applications and Recordkeeping Requirements* (Sept. 20, 2019).

[34] 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).

[35] Food and Drug Administration, *Statement of Acting Commissioner Norman E. Sharpless, M.D., Sounding the Alarm: The Public Health Threats of E-Cigarettes: Hearing before the S. Comm. On Oversight and Investigations of the Comm. on Energy and Commerce*, 116th Cong. 1 (2019).

[36] Federal Trade Commission, *FTC to Study E-Cigarette Manufacturers' Sales, Advertising, and Promotional Methods*. (Oct. 2, 2019) (press release).

[37] *Id.*

SECTION 1. Short Title.

This Act may be cited as the "Reversing the Youth Tobacco Epidemic Act of 2019".

TITLE I – FOOD AND DRUG ADMINISTRATION

Sec. 101 – Cigarette Graphic Health Warnings.

This section requires FDA to finalize a rulemaking to implement graphic health warnings for cigarette packages within 12 months.

The TCA required graphic health warnings to be added to cigarette packages and in cigarette advertisements. However, ongoing litigation has delayed finalizing this requirement. Studies around the world have shown that graphic health warnings are an effective way to inform consumers about the health risks of smoking and a mechanism to prevent children and other nonsmokers from beginning to smoke.

Sec. 102 – Advertising and Sales Parity for All Deemed Tobacco Products.

This section extends FDA's 2010 final rule on the sale, distribution, and use of cigarettes and smokeless tobacco to all deemed tobacco products, including e-cigarettes. This provision ensures manufacturers of newly deemed tobacco products are held to the same advertising and sales requirements currently applied to traditional cigarettes. This includes prohibiting the distribution of non-tobacco merchandise that bears a tobacco product brand name or logo; prohibiting brand sponsorship of athletic, music, or other concert events by tobacco product manufacturers; prohibiting offering free gifts in consideration of purchasing a tobacco product; and prohibiting advertising or labeling of tobacco products in nontraditional mediums without first notifying FDA. FDA is required to promulgate a final rule amending these regulations that will take effect two years after the date of enactment.

Sec. 103 – Reducing Child and Adolescent Nicotine Addiction.

(a) Applicability to All Tobacco Products.—

This section codifies the FDA's authority over all tobacco products, pursuant to the 2016 final deeming rule, into the Federal Food, Drug, and Cosmetic Act.

Pursuant to the TCA, cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco were immediately covered by FDA's tobacco product authorities upon enactment. However, all other tobacco products were deemed under FDA's authority by regulation. This provision codifies the final regulation to statutorily extend FDA's "tobacco product" authorities to all tobacco products in the Federal Food, Drug, and Cosmetic Act.

(b) Minimum Age Restrictions.—

This section raises the minimum age for purchasing tobacco products to 21 and makes it unlawful for any retailer to sell a tobacco product to any person younger than 21 years of age. The provision does not preempt the authority of a state or locality to increase age restrictions for the purchase of tobacco products beyond age 21. This section shall go into effect 180 days after the date of enactment.

(c) Prohibition Against Remote Retail Sales.—

This section directs FDA to issue final regulations that prohibit non-face-to-face sales of all tobacco products, including e-cigarettes and e-cigarette accessories.

Given the lack of sufficient protections to prevent youth access to tobacco products online and the inability to ensure the same level of face-to-face identification and age verification with remote sales, this provision is intended to enhance protections against underage youth sales.

(d) Prohibiting Flavoring of Tobacco Products.—

This section prohibits all characterizing flavors of tobacco products, including menthol. This provision includes a narrow pathway for the use of characterizing flavors that decrease smoking should FDA determine that a flavor would be appropriate for the protection of public health.

Sec. 104 – Fees Applicable to All Tobacco Products.

This section provides FDA with explicit authority to collect user fees from all classes of tobacco products, including newly deemed products such as e-cigarettes. It also increases the total amount of fees collected by $100 million. This proposal was included in the President's fiscal year (FY) 2020 budget.

Sec. 105 – Regulation of Products Containing Synthetic Nicotine.

This section directs FDA to issue an interim final rule within one year and a final rule within two years on the regulation of products containing synthetic nicotine or nicotine that is not made or derived from tobacco.

TITLE II—FEDERAL TRADE COMMISSION

Sec. 201 – Advertising of Tobacco Products.

(a) Advertising of Electronic Nicotine Delivery Systems.—

This section makes it unlawful to market, advertise, or promote any e-cigarette products to individuals under the age of 21 or to market, advertise, promote, or endorse any e-cigarette product without clearly disclosing that the communication is an advertisement. This section would give the FTC the authority to issue rules under notice-and-comment rulemaking to

implement these prohibitions. It would also allow FTC to seek civil penalties for violations of statute, and it would allow state authorities to enforce the law.

(b) Report to Congress on Tobacco Product Advertising.—

This section requires FTC to issue a report to Congress within two years, and annually thereafter, on the domestic sales, advertising, and promotional activity of cigarette, cigar, smokeless tobacco, and e-cigarette manufacturers.

IV. WITNESSES

Dorian Fuhrman
Co-founder and Parent
Parents Against Vaping e-cigarettes (PAVe)

Phillip Gardiner, Dr. P.H.
Senior Program Officer
Tobacco Related Disease Research Program
University of California Office of the President

Matthew L. Myers
President
Campaign for Tobacco-Free Kids

Michael Siegel, M.D., M.P.H.
Professor
Department of Community Health Sciences
Boston University School of Public Health

Susanne E. Tanski, M.D., M.P.H.
Associate Professor of Pediatrics
American Academy of Pediatrics