



COMMITTEE ON ENERGY & COMMERCE

CHAIRMAN FRANK PALLONE, JR.

MEMORANDUM

September 20, 2019

To: Subcommittee on Oversight and Investigations Members and Staff

Fr: Committee on Energy and Commerce Staff

Re: Hearing on “Sounding the Alarm: The Public Health Threats of E-Cigarettes”

On Wednesday, September 25, 2019, at 10 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, “**Sounding the Alarm: The Public Health Threats of E-Cigarettes.**” The hearing will examine the public health impacts and regulatory authorities related to e-cigarette manufacturing, marketing, sales, and use.

I. BACKGROUND

Electronic nicotine delivery systems (ENDS), including e-cigarettes, often known by other names such as “vape pens” or “mods,” have been available on the U.S. market since the mid-2000s, growing to an estimated current \$19.3 billion global industry.¹ These products come in many forms, consisting of a battery-operated device that heats a liquid, containing nicotine, flavoring, additives, cannabinoids, or other chemical components, into an aerosol that users inhale.² On May 10, 2016, under the authority of 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 ENDS products.³

According to the Centers for Disease Control and Prevention (CDC), in 2017, there were nearly 6.9 million adult e-cigarette users in the United States.⁴ In 2018, CDC reported 3.6

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 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 Centers for Disease Control and Prevention, “Tobacco Product Use Among Adults – United States, 2017,” *MMWR*, 67(44): 1225 (2018).

million current e-cigarette users among middle and high school students.⁵ E-cigarettes became the most commonly used tobacco product among youth in 2014, surpassing youth use of conventional cigarettes.⁶ The rate of e-cigarette use among middle and high school students rose in recent years as well, increasing by nearly 80 percent among high school students and nearly 50 percent among middle school students from 2017 to 2018.⁷ While 3.2 percent of adults reported using e-cigarettes in 2018,⁸ CDC preliminary survey data found that in 2019, 27.5 percent of high school students reported they used e-cigarettes in the past 30 days.⁹ FDA noted that the overwhelming majority of these students, 60 percent, cited the use of popular fruit, menthol, or mint flavors.¹⁰

Beginning in July 2019, state health officials, CDC, and FDA began multistate investigations into severe lung illnesses occurring across the country among e-cigarette users.¹¹ As of September 19, 2019, 530 cases of lung illness associated with the use of e-cigarette products have been reported in 38 states and one U.S. territory. As of the same date, seven deaths related to this illness have been confirmed in California, Illinois, Indiana, Kansas, Minnesota, and Oregon.¹²

⁵ Centers for Disease Control and Prevention, “Use of Electronic Cigarettes and Any Tobacco Product Among Middle and High School Students – United States, 2011–2018,” *MMWR*, 67(45): 1276-1277 (2019). *Note* reported use of an e-cigarette within the past 30 days.

⁶ 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).

⁷ Centers for Disease Control and Prevention, *Vital Signs: Tobacco Product Use Among Middle and High School Students – United States, 2011–2018* (Feb. 15, 2019).

⁸ Centers for Disease Control and Prevention, *National Health Interview Survey–United States, 2018*. See also Layden, J. et al, “Pulmonary Illness related to E-Cigarette Use in Illinois and Wisconsin – Preliminary Report,” *New England Journal of Medicine* (Sept. 6, 2019).

⁹ 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).

¹⁰ *Id.*

¹¹ Layden, J. et al, “Pulmonary Illness related to E-Cigarette Use in Illinois and Wisconsin – Preliminary Report,” *New England Journal of Medicine* (Sept. 6, 2019); Centers for Disease Control and Prevention, *CDC, FDA, States Continue to Investigate Severe Pulmonary Disease Among People Who Use E-cigarettes*, (Aug. 21, 2019).

¹² Centers for Disease Control and Prevention, *Outbreak of Lung Disease Associated with E-Cigarette Use, or Vaping* (www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html).

II. FEDERAL REGULATORY AUTHORITY

Following finalization of the 2016 deeming rule, ENDS products must undergo FDA review.¹³ One pathway to review is through submission of a premarket tobacco application (PMTA). These applications must include, among other things, 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.¹⁴ In order for FDA to issue a PMTA marketing order, the manufacturer must demonstrate that the product is “appropriate for the protection of public health.”¹⁵ Additionally, FDA will consider the risks and benefits of the product to the population as a whole, including tobacco product users as well as non-users.¹⁶

Under the deeming rule, manufacturers of ENDS products already on the market as of August 8, 2016, could continue marketing their products under FDA’s enforcement discretion, but were required to submit a PMTA by August 8, 2018.¹⁷ In August 2017, FDA extended the compliance deadlines for several products, including a four-year extension for e-cigarettes, to August 8, 2022.¹⁸ Following litigation, a district court judge ordered manufacturers of e-cigarettes and other ENDS products on the market under FDA’s enforcement discretion to submit their PMTAs within ten months, by May 2020.¹⁹ Responding to the court order, FDA indicated that manufacturers do not need to wait ten months to submit PMTAs and it encouraged the industry to use available FDA guidance for their submissions.²⁰ On September 20, 2019,

¹³ 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).

¹⁴ FFDCA Section 910(b)(1). *See also* FDA, *Draft Guidance: Applications for Premarket Review of New Tobacco Products* (Sept. 2011).

¹⁵ FFDCA Section 910(c)(4).

¹⁶ Food and Drug Administration, *Premarket Tobacco Product Applications* (www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/premarket-tobacco-product-applications).

¹⁷ 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).

¹⁸ 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).

¹⁹ 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).

²⁰ *Id.*

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.²¹

In the meantime, other provisions of the deeming rule went into immediate effect, leading to the prohibition of e-cigarette sales to young people under the age of 18 and allowing FDA to conduct inspections of ENDS manufacturers and retailers to enforce compliance with other aspects of the Tobacco Control Act.²² In addition to conducting inspections, FDA also exercises its enforcement authority through letters to manufacturers and retailers of products and product recalls.²³ For example, in September 2018, FDA issued letters to e-cigarette retailers and manufacturers, including more than 1,300 letters to retailers who illegally sold e-cigarette products to minors, and five letters to e-cigarette manufacturers regarding their plans to address youth access and use of their products.²⁴ In September 2019, FDA 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.²⁵

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 unauthorized non-tobacco-flavored e-cigarettes, including mint and menthol e-cigarettes.²⁶ FDA indicated it will finalize a policy in "the coming weeks."²⁷

²¹ Food and Drug Administration, *Premarket Tobacco Product Applications and Recordkeeping Requirements* (Sept. 20, 2019).

²² FDA, *How FDA is Regulating E-Cigarettes* (www.fda.gov/news-events/fda-voices-perspectives-fda-leadership-and-experts/how-fda-regulates-e-cigarettes).

²³ FFDCa, Section FDA, *How FDA is Regulating E-Cigarettes* (www.fda.gov/news-events/fda-voices-perspectives-fda-leadership-and-experts/how-fda-regulates-e-cigarettes); FFDCa Section 908(c) (authorizing FDA to issue mandatory recalls); 21 C.F.R. § 7.40(b) (voluntary recalls may be undertaken at the request of FDA).

²⁴ 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); U.S. Food and Drug Administration, *Statement from FDA Commissioner Scott Gottlieb, M.D., on new steps to address epidemic of youth e-cigarette use* (Sept. 11, 2018) (press release).

²⁵ 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).

²⁶ 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).

²⁷ *Id.*

III. RECENT STATE EXECUTIVE ACTION

Some states have also exercised their authorities to regulate e-cigarettes, including through efforts aimed at taxation, product packaging, youth access, retail licensing requirements, and smoke-free restrictions.²⁸ On September 4, 2019, Michigan became the first state in the nation to prohibit the sale of flavored nicotine e-cigarette products when Governor Gretchen Whitmer ordered the state’s Department of Health and Human Services to issue emergency rules to ban the sale of these products in retail stores and online, as well as to ban misleading marketing claims that indicate the products are harmless and restrict advertisement of such products.²⁹ Similarly, on September 15, 2019, Governor Andrew Cuomo of New York announced emergency executive action to ban all flavored e-cigarette products, except tobacco and menthol.³⁰ This followed a previously-announced plan to introduce legislation to prohibit flavored e-cigarette products and other measures, including directing the New York State Department of Health to conduct investigations into companies producing vaping substances and to issue emergency regulations requiring those that sell vaping products to post signs regarding the dangers of vaping.³¹

IV. PUBLIC HEALTH IMPLICATIONS

A. Public Health Research and Scientific Review Findings

Research on the public health impacts of e-cigarette usage for all ages is ongoing, though several key scientific reviews in recent years have produced concerning findings.³² For instance, a 2016 Surgeon General Report stated that the use of tobacco products in any form—including e-cigarettes—is not safe for youth and young adults.”³³ The same report noted that young people may be trying e-cigarette products based on the belief that e-cigarettes are less harmful than other tobacco products.³⁴ In 2018, the National Academies of Sciences, Engineering, and Medicine found that while the long-term health effects of e-cigarettes are not yet clear, there is “conclusive evidence that in addition to nicotine, most e-cigarette products contain and emit

²⁸ Public Health Law Center at Mitchell Hamline School of Law, *U.S. E-Cigarette Regulation: A 50-State Review* (June 15, 2019).

²⁹ The Office of Governor Gretchen Whitmer, *Governor Whitmer Takes Bold Action to Protect Michigan Kids from Harmful Effects of Vaping* (Sept. 4, 2019) (press release).

³⁰ *New York Set to Join Michigan in Banning Some E-Cigarettes*, NPR (Sept. 16, 2019).

³¹ The Office of Governor Andrew M. Cuomo, *Governor Cuomo Takes Aggressive Action to Protect New Yorkers from Harmful and Addictive Vaping Products Following Rise in Vaping-Associated Illnesses Nationwide* (Sept. 9, 2019) (press release).

³² U.S. Department of Health and Human Services, *Researchers Explore Health Effects of E-Cigarettes* (Nov. 6, 2018).

³³ 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).

³⁴ *Id.*

numerous potentially toxic substances.”³⁵ The study also concluded “there is substantial evidence that e-cigarette use increases risk of ever using combustible tobacco cigarettes among youth and young adults.”³⁶ Additionally, a U.S. Preventive Services Task Force review in 2015 concluded there was insufficient evidence to recommend e-cigarettes for smoking cessation in adults.³⁷ Studies have also found that many adults are using e-cigarettes to try to quit smoking, yet research has determined that current smokers do not stop smoking cigarettes, but instead continue to use both, known as “dual use.”³⁸

B. Reports and Investigations of Adverse Health Effects and Reactions

Prior to the recent numerous reports of severe lung illnesses associated with vaping, other adverse health effects of e-cigarette use have been documented. For example, from January 2009 to December 31, 2016, there were reports of 195 e-cigarette fire and explosion incidents resulting in 133 acute injuries.³⁹ Though the causes of the incidents are not clear, evidence points to battery-related issues leading to the vape explosions.⁴⁰ Additionally, in April 2019, FDA announced it was investigating reports that some people, especially youth and young adults, had experienced seizures, a potential side effect of nicotine poisoning, following the use of e-cigarette products.⁴¹ These reports are particularly concerning given the high level of nicotine concentration in many e-cigarette products.⁴²

Investigations continue at all levels of government into the drivers of the severe lung illnesses associated with vaping, with individual states, CDC, and FDA utilizing laboratory

³⁵ National Academies of Sciences, Engineering, and Medicine, *Public Health Consequences of E-Cigarettes* (Jan. 23, 2018).

³⁶ *Id.*

³⁷ 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).

³⁸ 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).

³⁹ U.S. Fire Administration, *Electronic Cigarette Fires and Explosions in the United States 2009–2016* (July 2017).

⁴⁰ Food and Drug Administration, *Tips to Help Avoid “Vape” Battery Explosions* (Dec. 20, 2017) (www.fda.gov/tobacco-products/products-ingredients-components/tips-help-avoid-vape-battery-explosions#blue).

⁴¹ Food and Drug Administration, *Some E-cigarette Users Are Having Seizures, Most Reports Involving Youth and Young Adults* (Apr. 10, 2019); Food and Drug Administration, *Statement from FDA Commissioner Scott Gottlieb, M.D., and Principal Deputy Commissioner Amy Abernethy, M.D., Ph.D.* (Apr. 3, 2019).

⁴² *JUUL ramped up nicotine levels, and competitors followed, study says*, CNN (Feb. 7, 2019).

resources and coordinating to identify common sources contributing to the dangerous illnesses.⁴³ While vitamin E acetate within e-cigarette liquid that also contained tetrahydrocannabinol (THC) oil has been identified as one common factor among many, though not all, of those who fell ill in New York, federal officials stress that there may be multiple causes.⁴⁴ The investigations have also made clear that the vaping lung illnesses have not been tied to a single product.⁴⁵ On August 30, 2019, CDC issued a health advisory that, among other recommendations for clinicians, public health officials, and the public, stated that regardless of the ongoing investigation, “[y]outh, young adults, pregnant women, as well as adults who do not currently use tobacco products should not use e-cigarettes.”⁴⁶ On September 16, 2019, CDC announced that it was activating its Emergency Operations Center to provide increased support to the inter-agency response to the outbreak of lung injury associated with vaping.⁴⁷ Additionally, on September 19, 2019, officials disclosed that the enforcement arm of the FDA has been conducting a probe related to the illnesses within its Office of Criminal Investigations focused on the supply chain.⁴⁸

V. WITNESSES

The following witnesses have been invited to testify:

Panel I

Norman E. Sharpless, MD

Acting Commissioner
Food and Drug Administration

Anne Schuchat, MD (RADM, USPHS, RET)

Principal Deputy Director
Centers for Disease Control and Prevention

⁴³ Food and Drug Administration, *Lung Illnesses Associated with Use of Vaping Products* (Sept. 13, 2019) (www.fda.gov/news-events/public-health-focus/lung-illnesses-associated-use-vaping-products).

⁴⁴ *Vitamin E named as primary culprit in vaping illness, but feds urge caution*, Politico (Sept. 5, 2019).

⁴⁵ Centers for Disease Control and Prevention, *Outbreak of Lung Disease Associated with E-Cigarette Use, or Vaping* (Sept. 12, 2019) (www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html).

⁴⁶ Centers for Disease Control and Prevention, *Severe Pulmonary Disease Associated with Using E-Cigarette Products* (Aug. 30, 2019) (health advisory).

⁴⁷ Centers for Disease Control and Prevention, *Investigation of Lung Injury Associated with E-cigarette product Use, or Vaping: CDC Activates Emergency Operations Center* (Sept. 16, 2019).

⁴⁸ *Vaping-related illnesses surge as FDA discloses criminal probe*, Washington Post (Sept. 19, 2019).

Panel II

Joneigh Khaldun, MD, MPH,

Chief Deputy Director for Health and Chief Medical Executive
Michigan Department of Health and Human Services

Elizabeth Cuervo Tilson, MD, MPH

State Health Director and Chief Medical Officer
North Carolina Department of Health and Human Services

Lee Norman, MD, MHS, MBA

Secretary
Kansas Department of Health and Environment

Monica Bharel, MD, MPH

Commissioner
Massachusetts Department of Public Health