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E-Cigarettes: Ban All Flavored Products and Enact Greater State and Local E-Cigarette Laws and Regulations to Protect Young People

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INTRODUCTION

The use of e-cigarettes has become epidemic among young people in the United States.¹ E-cigarettes have been portrayed as a safer alternative to conventional cigarettes, as a means to help smokers quit, and as a way to prevent non-smokers from starting to smoke conventional cigarettes in the first place.² However, none of these claims has been established, and there are many unanswered questions regarding how dangerous e-cigarettes are when used over the long-term.³

A significant public health concern is e-cigarette use by young people. The nicotine in e-cigarettes can harm brain development in adolescents and young adults and can prime young brains for future addiction to other drugs.⁴ Data show that e-cigarettes that are currently sold in the United States have become “overwhelmingly a vehicle for youth initiation, not adult cessation.”⁵ The nicotine in e-cigarettes puts young people at risk for both long- and short-term negative health consequences.⁶

¹ CDC, *Surgeon General’s Advisory on E-Cigarette Use Among Youth*, (April 9, 2019), https://www.cdc.gov/tobacco/basic_information/e-cigarettes/surgeon-general-advisory/index.html (last visited January 31, 2021); Rob Stein, *Surgeon General Warns Youth Vaping is Now an ‘Epidemic,’* NPR, (December 18, 2018), <https://www.npr.org/sections/health-shots/2018/12/18/677755266/surgeon-general-warns-youth-vaping-is-now-an-epidemic> (last visited March 29, 2021).

² Jayesh Mahendra Bhatt, Manisha Ramphul, Andrew Bush, *An Update on Controversies in E-Cigarettes*, PAEDIATR RESPIR REV, (November 2020);36:75-86.

³ FDA, *How FDA is Regulating E-Cigarettes*, (September 10, 2019), <https://www.fda.gov/news-events/fda-voices/how-fda-regulating-e-cigarettes>, (last visited March 14, 2021).

⁴ Office of the Surgeon General, *E-Cigarette Use Among Youth and Young Adults: A Report of the Surgeon General*, 2016, https://e-cigarettes.surgeongeneral.gov/documents/2016_SGR_Full_Report_non-508.pdf, (last visited February 15, 2021); Office of the Surgeon General, *Know the Risks: E-Cigarettes and Young People*, (2021), <https://e-cigarettes.surgeongeneral.gov/>, (last visited January 31, 2021); Office of the Surgeon General, *E-Cigarette Use Among Youth and Young Adults: A Report of the Surgeon General, Fact Sheet*, https://e-cigarettes.surgeongeneral.gov/documents/2016_SGR_Fact_Sheet_508.pdf (last visited January 31, 2021).

⁵ Truth Initiative, *Action Needed: E-Cigarettes*, (November 2019), <https://truthinitiative.org/sites/default/files/media/files/2019/11/Truth-Initiative-E-Cigarette-Fact-Sheet-Nov-11.pdf> (last visited February 1, 2021).

⁶ *Id.*

Recently enacted federal laws reveal the government’s recognition that tobacco use and the use of e-cigarettes among youth and young adults is not safe.⁷ These recent laws, as well as enforcement policies of the Food and Drug Administration (FDA), have begun to address the epidemic of e-cigarette use among young people. The Tobacco 21 law, which raised the federal minimum age of sale of tobacco products from 18 to 21 years of age, went into effect on December 20, 2019.⁸ In January 2020, the FDA issued an enforcement priority against the manufacture, distribution, and sale of unauthorized flavored cartridge-based products that appeal to children.⁹ Most recently, the Preventing Online Sales of E-Cigarettes to Children Act was signed into law on January 3, 2021.¹⁰ This law requires the United States Postal Service (USPS) to promulgate regulations that incorporate new statutory restrictions on the mailing of electronic nicotine delivery systems (ENDS).¹¹

While the federal government’s actions to deal with the epidemic of e-cigarette use by young people are important steps, they are not sufficient to adequately protect youth and young adults from nicotine addiction through e-cigarette use. This paper proposes two stronger measures. First, the FDA should exercise its authority to completely ban flavored e-cigarette products from the market since the availability of appealing flavors is the leading reason for

⁷ US Department of Health and Human Services, *E-Cigarette Use Among Youth and Young Adults: A Report of the Surgeon General*, (2016), https://e-cigarettes.surgeongeneral.gov/documents/2016_SGR_Full_Report_non-508.pdf (last visited February 1, 2021).

⁸ FDA, *Newly Signed Legislation Raises Federal Minimum Age of Sale of Tobacco Products to 21*, <https://www.fda.gov/tobacco-products/ctp-newsroom/newly-signed-legislation-raises-federal-minimum-age-sale-tobacco-products-21>, (last visited January 31, 2021).

⁹ FDA, *FDA Finalizes Enforcement Policy on Unauthorized Flavored Cartridge-Based E-Cigarettes That Appeal to Children, Including Fruit and Mint*, (January 2, 2020), <https://www.fda.gov/news-events/press-announcements/fda-finalizes-enforcement-policy-unauthorized-flavored-cartridge-based-e-cigarettes-appeal-children>, (last visited February 8, 2021).

¹⁰ Division FF, Title VI, Preventing Online Sales of E-Cigarettes to Children Act, §§601-603, Consolidated Appropriations Act, 2021, 116 H.R. 133, Part 6 of 6, 2020 H.R. 133, 116 H.R. 133, <https://www.govtrack.us/congress/bills/116/hr133/text>, (last visited February 8, 2021).

¹¹ 86 Fed. Reg. 10218 (February 19, 2021), <https://www.federalregister.gov/documents/2021/02/19/2021-03393/treatment-of-e-cigarettes-in-the-mail>, (last visited March 20, 2021).

e-cigarette use among adolescents and young adults,¹² and e-cigarette use is disproportionately greater among young people.¹³ Second, since state and local governments are not preempted by the federal law from imposing stricter laws in certain areas, such as retail licensure to sell e-cigarettes, enacting smoke-free indoor air laws, and imposing taxes on e-cigarettes,¹⁴ state and local governments should utilize their authority to enact stronger e-cigarette laws and regulations to prevent youth and young adults from access to e-cigarettes to protect their short- and long-term health.

Part I of this paper discusses the background of e-cigarettes and trends of e-cigarette use in the United States. Part II then turns to the current state of evidence regarding the potential harms and benefits of e-cigarettes. Part III discusses federal statutes, FDA regulation and enforcement, and state and local laws and regulations. Part IV provides an analysis and proposals for greater federal regulation and state and local laws on e-cigarettes for the protection of the health of young people.

I. BACKGROUND

A. Description and History of E-Cigarettes in the United States

E-cigarettes are electronic nicotine delivery systems (ENDS) that mimic cigarette smoking without the combustion of tobacco.¹⁵ E-cigarettes were first patented in 2003 and were

¹² Samir S. Soneji, Kristin E. Knutzen, Andrea C. Villanti, *Use of Flavored E-Cigarettes Among Adolescents, Young Adults, and Older Adults: Findings from the Population Assessment for Tobacco and Health Study*, PUBLIC HEALTH REPORTS, (2019);143(3) 282-292. <https://journals.sagepub.com/doi/pdf/10.1177/0033354919830967> (last visited February 4, 2021).

¹³ National Academies of Sciences, Engineering, and Medicine (NAS). *Public Health Consequences of E-Cigarettes* 2 (Kathleen R Stratton, Leslie Y Kwan, David L Eaton eds., Washington, DC: The National Academies Press; 2018).

¹⁴ Public Health Law Center, *supra* note 180.

¹⁵ Jayesh Mahendra Bhatt, *supra* note 2.

introduced into the North American market around 2007.¹⁶ Since then, over 400 different brand names of e-cigarettes have become available on the market.¹⁷

E-cigarettes contain nicotine usually derived from tobacco,¹⁸ and they function as delivery devices of nicotine to the brain.¹⁹ Harmful and potentially harmful constituents (HPHCs) are found in tobacco products and tobacco smoke and are “linked to the five most serious health effects of tobacco use,” i.e., cancer, cardiovascular disease, respiratory effects, reproductive problems, and addiction.²⁰ These HPHCs are known to cause or potentially cause harm to both smokers and nonsmokers from second-hand smoke, which has contributed to the perception that e-cigarette use is safer than combustible cigarette smoking.²¹ However, the long-term health consequences of e-cigarette use are not yet known.²²

Using an e-cigarette, sometimes called “vaping,” is the act of inhaling the aerosol that is produced by the e-cigarette.²³ E-cigarettes are sometimes referred to as “e-cigs,” “e-hookahs,”

¹⁶ Kate Lichtenberg, *E-Cigarettes: Current Evidence and Policy*. MO MED (September/October 2017);114(5):335-8, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6140188/pdf/ms114_p0335.pdf, (last visited January 31, 2021).

¹⁷ *Id.*

¹⁸ FDA, *Commonly Asked Questions: About the Center for Tobacco Products*, <https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp/commonly-asked-questions-about-center-tobacco-products>, (last visited January 31, 2021). “E-liquids that do not contain nicotine or other substances made or derived from tobacco may still be components or parts and, therefore, subject to FDA’s tobacco control authorities. However, . . . a disposable, closed system device that contains an e-liquid with truly zero nicotine (or synthetic nicotine) [might] not be regulated by the FDA as a tobacco product, if it is not intended or reasonably be expected to be used in such a fashion. FDA intends to make these determinations on a case-by-case basis, based on a totality of the circumstances.” *Id.*

¹⁹ National Institute on Drug Abuse, *Vaping Devices (Electronic Cigarettes) Drug Facts*, <https://www.drugabuse.gov/publications/drugfacts/vaping-devices-electronic-cigarettes>, (last visited January 31, 2021); Hussein Traboulsi et al., *Inhalation Toxicology of Vaping Products and Implications for Pulmonary Health*, INT J MOL SCI (May 15, 2020);21(10):3495, <https://www.mdpi.com/1422-0067/21/10/3495/htm>, (last visited February 6, 2021).

²⁰ FDA, *Harmful and Potentially Harmful Constituents (HPHCs)*, (October 7, 2019), <https://www.fda.gov/tobacco-products/products-ingredients-components/harmful-and-potentially-harmful-constituents-hphcs>, (last visited March 14, 2021).

²¹ *Id.*

²² FDA, *supra* note 3.

²³ CDC, *About Electronic Cigarettes (E-Cigarettes) Smoking & Tobacco*, https://www.cdc.gov/tobacco/basic_information/e-cigarettes/about-e-cigarettes.html#what-are-e-cigarettes, (last visited January 31, 2021).

“mods,” “vape pens,” “vapes,” “tank systems,” and ENDS.²⁴ Most e-cigarettes have a battery, a heating element, and a place to hold a liquid.²⁵ An aerosol is produced by heating the liquid, which typically contains nicotine, flavorings, and other chemicals that help create the aerosol.²⁶ Some are made to look like regular cigarettes, cigars, or pipes, while others resemble pens or USB sticks.²⁷ E-cigarettes shaped like USB flash drives and other similar devices have gained popularity and have likely contributed to uptake of e-cigarettes by young people.²⁸ Individuals can use these types of devices discreetly.²⁹ Tank systems, or “mods,” which are larger devices, do not resemble conventional tobacco products.³⁰ Disposable e-cigarettes are designed to be used one time, are not rechargeable or refillable, and are discarded when they run out of charge or e-liquid.³¹

B. E-cigarette Use Trends in the United States

i. E-Cigarette Use Among Youth and Young Adults

E-cigarette use is greatest among young adults.³² Few adults who are not already smokers ever start using e-cigarettes.³³ Historically, most tobacco product use has been initiated during adolescence.³⁴ Almost all adults who smoke every day began smoking when they were 26 or

²⁴ *Id.*

²⁵ *Id.*

²⁶ *Id.*

²⁷ *Id.*

²⁸ Karen A. Cullen et al., *E-Cigarette Use Among Youth in the United States*, 2019. *JAMA*, (November 5, 2019);322(21):2095–2103.

²⁹ *Id.*

³⁰ CDC, *supra* note 23.

³¹ CDC, *E-Cigarette, or Vaping, Products Visual Dictionary*, https://www.cdc.gov/tobacco/basic_information/e-cigarettes/pdfs/ecigarette-or-vaping-products-visual-dictionary-508.pdf, (last visited March 6, 2021).

³² NAS, *supra* note 13.

³³ *Id.*

³⁴ CDC, *Youth and Tobacco Use*, https://www.cdc.gov/tobacco/data_statistics/fact_sheets/youth_data/tobacco_use/index.htm, (last visited February 1, 2021).

younger.³⁵ Although the tobacco industry has asserted to health authorities that e-cigarettes are intended for use by, and marketed to, adult smokers, the data have shown that it is young people who use e-cigarettes at the highest rates.³⁶ From 2017 to 2019, the increase of e-cigarette use among high school students more than doubled to 27.5%.³⁷ Based on the National Youth Tobacco Survey (NYTS) results from only part of 2020 (January to March),³⁸ 19.6% of high school students (estimated 3.02 million) and 4.7% of middle school students (estimated 550,000) reported they were currently using e-cigarettes.³⁹ In 2019, by comparison, the NTYS results showed that 27.5% (4.11 million) of high school students and 10.5% (1.24 million) of middle school students reported e-cigarette use.⁴⁰ Although the rate decreased, approximately 3.6 million young people in the U.S. were still using e-cigarettes in 2020.⁴¹

ii. E-Cigarette Flavors

The Monitoring the Future (MTF) survey results for 2019 reported by the National Institute on Drug Abuse⁴² “underscore that youth are particularly attracted to e-cigarette flavors, such as fruit and mint, much more so than tobacco or menthol flavored e-cigarettes.”⁴³ Based on

³⁵ US Department of Health and Human Services, *Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General*, (2012),

https://www.ncbi.nlm.nih.gov/books/NBK99237/pdf/Bookshelf_NBK99237.pdf (last visited February 1, 2021).

³⁶ Truth Initiative, *Action Needed on E-Cigarettes*, (November 2020), <https://truthinitiative.org/research-resources/emerging-tobacco-products/action-needed-e-cigarettes>, (last visited February 1, 2021).

³⁷ Campaign for Tobacco-Free Kids, *Ending the Sale of Flavored Tobacco Products*, (January 4, 2021), <https://www.tobaccofreekids.org/what-we-do/us/flavored-tobacco-products>, (last visited March 4, 2021).

³⁸ Teresa W. Wang et al., *E-cigarette Use Among Middle and High School Students — United States, 2020*, *MORB MORTAL WKLY REP.*, (September 9, 2020);69:1310–1312.

<https://www.cdc.gov/mmwr/volumes/69/wr/mm6937e1.htm#suggestedcitation> (last visited March 14, 2021). “CDC and FDA analyzed nationally representative data from the 2020 National Youth Tobacco Survey (NYTS), a cross-sectional, school-based, self-administered survey of U.S. middle school (grades 6–8) and high school (grades 9–12) students conducted during January 16–March 16, 2020. . . The data collection timeline was truncated because of widespread school closures during the coronavirus disease 2019 pandemic.” *Id.*

³⁹ *Id.*

⁴⁰ Teresa W. Wang, *supra* note 38; Karen A. Cullen, *supra* note 28.

⁴¹ Teresa W. Wang, *supra* note 38.

⁴² National Institute on Drug Abuse, *Monitoring the Future*, <https://www.drugabuse.gov/drug-topics/trends-statistics/monitoring-future> (last visited February 2, 2021).

⁴³ FDA News Release, *FDA Finalizes Enforcement Policy on Unauthorized Flavored Cartridge-Based E-Cigarettes That Appeal to Children, Including Fruit and Mint*, (January 02, 2020), <https://www.fda.gov/news-events/press->

data from the Population Assessment for Tobacco and Health (PATH) Study, which is a nationally representative longitudinal cohort study conducted by the National Institute on Drug Abuse and the FDA’s Center for Tobacco Products (CTP), the leading reason for e-cigarette use among adolescents and young adults is the availability of appealing flavors.⁴⁴ In 2020, more than 8 in 10 youth e-cigarette users reported using “flavored e-cigarettes, with fruit, mint, candy, and menthol flavors among the most commonly used.”⁴⁵ One analysis looked at e-cigarette flavors used by adolescents (aged 12-17), young adults (aged 18-24), and older adults (aged ≥25) and the relevance of the availability of appealing flavors as a reason for e-cigarette use across these groups.⁴⁶ The leading reason for e-cigarette use among adolescents (n=414) and young adults (n=961) was the availability of appealing flavors (77.9% adolescents; 90.3% young adults).⁴⁷ By contrast, the leading reasons for e-cigarette use among older adults (n=1711) were the belief that e-cigarettes might be less harmful to persons around them than cigarettes (81.9%) and that e-cigarette use is acceptable in places where cigarette smoking is not allowed (79.3%).⁴⁸ The availability of appealing flavors was only the seventh most commonly reported reason (66.4%) for e-cigarette use among adults.⁴⁹

By late 2019, Juul Labs suspended sales of most of its flavored products, including mango, fruit, crème, cucumber, and mint; currently, the only flavor pods available for the JUUL device are tobacco and menthol.⁵⁰ Manufacturers and distributors of other e-cigarette device

[announcements/fda-finalizes-enforcement-policy-unauthorized-flavored-cartridge-based-e-cigarettes-appeal-children](#), (last visited February 2, 2021).

⁴⁴ Samir S. Soneji, *supra* note 12.

⁴⁵ Teresa W. Wang, *supra* note 38.

⁴⁶ *Id.*

⁴⁷ *Id.*

⁴⁸ *Id.*

⁴⁹ *Id.*

⁵⁰ Allison Aubrey, *Juul Suspends Sales of Flavored Vapes And Signs Settlement To Stop Marketing To Youth*, NPR, (October 17, 2019), <https://www.npr.org/sections/health-shots/2019/10/17/771098368/juul-suspends-sales-of-flavored-vapes-and-signs-settlement-to-stop-marketing-to->, (last visited March 6, 2021); Dennis Thompson, *Juul*

types, such as disposable e-cigarettes and devices that use refillable cartridges, continue to sell youth-appealing flavored liquid nicotine, such as cotton candy, gummy bear, “O.M.G. (orange, mango, guava),” and sour apple.⁵¹ During 2019–2020, the use of disposable e-cigarettes increased approximately 1,000% (from 2.4% to 26.5%) among high school e-cigarette users and approximately 400% (from 3.0% to 15.2%) among middle school e-cigarette users.⁵²

II. CURRENT STATE OF EVIDENCE OF POTENTIAL HARMS AND BENEFITS

The hazards of e-cigarette use over the long-term are unknown,⁵³ but considerable amounts of data exist that provide information about potential harms and benefits of e-cigarette use. Whether e-cigarettes are effective in helping addicted adults quit smoking combustible tobacco cigarettes or whether e-cigarettes are less harmful than traditional cigarettes has not been established.⁵⁴ The extent to which e-cigarettes can serve as a “gateway” to the use of combustible cigarettes is also unknown.⁵⁵ The CTP was directed by Congress in 2016 to conduct an in-depth evaluation of the available evidence of health effects of e-cigarettes and to make recommendations for future federally-funded research.⁵⁶ In accordance with this directive, the CTP contracted with the National Academies of Sciences, Engineering, and Medicine (“NAS”) to convene an ad hoc committee (“NAS Committee”) to conduct the evaluation.⁵⁷ The NAS

Stops Sales of Mint-Flavored E-Cigarettes, HEALTHDAY NEWS, (November 8, 2019), <https://www.webmd.com/smoking-cessation/news/20191108/juul-stops-sales-of-mint-flavored-e-cigarettes>, (last visited March 6, 2021).

⁵¹ Truth Initiative, *What Vape Products Are Still Allowed Under the New E-Cigarette Policy?* (February 20, 2020), <https://truthinitiative.org/research-resources/emerging-tobacco-products/what-vape-products-are-still-allowed-under-new-e>, (last visited March 6, 2021).

⁵² Teresa W. Wang, *supra* note 38.

⁵³ FDA, *supra* note 3.

⁵⁴ *Id.*

⁵⁵ *Id.*

⁵⁶ NAS, *supra* note 13, at 24.

⁵⁷ NAS, *supra* note 13, at 24-25. The NAS Committee on the Review of the Health Effects of Electronic Nicotine Delivery Systems included experts in toxicology, nicotine pharmacology, adolescent and adult tobacco use patterns, epidemiology, public health, inhalation toxicology/pulmonology, cardiology, pediatrics, obstetrics, and oncology. *Id.*

Committee conducted a comprehensive and systematic assessment and review of the available literature,⁵⁸ reviewed more than 800 peer-reviewed scientific studies on ENDS, and drew nearly 50 conclusions.⁵⁹ Some of the key conclusions on the potential harms and benefits are described in the following sections.

A. Potential Harms Associated with E-Cigarettes

i. Nicotine and Nicotine Addiction

Nicotine, the chemical in tobacco products that has a major role in development of dependence,⁶⁰ “meets the established criteria for a drug that produces symptoms of addiction, specifically, dependence, withdrawal, and craving.”⁶¹ “Nicotine is well-recognized as one of the most addictive substances” and is regarded “as addictive as heroin and cocaine.”⁶² There is substantial evidence that e-cigarette use leads to symptoms of dependence on e-cigarettes.⁶³

The developing brains of children and adolescents are especially vulnerable to nicotine exposure.⁶⁴ The majority (90%) of combustible cigarette smokers start before 18 years old, a fact that tobacco companies have exploited in advertising, marketing, and product designs targeted to

⁵⁸ NAS, *supra* note 13, at 666. The NAS Committee conducted a series of searches to identify all literature on e-cigarettes in six databases—PubMed, Scopus, Web of Science, PsycINFO (ProQuest), MEDLINE (Ovid), and Embase (Ovid)—between February 1, 2017, and August 31, 2017. *Id.*

⁵⁹ Society for the Study of Addiction (SSA), *The Public Health Consequences of E-Cigarettes: A Review by the National Academies of Sciences. A Call for More Research, a Need for Regulatory Action*, (2018), ADDICTION, 114:587-589, <https://onlinelibrary.wiley.com/doi/epdf/10.1111/add.14478>, (last visited February 20, 2021).

⁶⁰ *Id.*

⁶¹ Lorena M. Siqueira & Committee on Substance Use and Prevention, *Nicotine and Tobacco as Substances of Abuse in Children and Adolescents*, PEDIATRICS, (January 2017);139(1), <https://pediatrics.aappublications.org/content/139/1/e20163436>, (last visited February 4, 2021).

⁶² Brian P. Jenssen & Rachel Boykan, *Electronic Cigarettes and Youth in the United States: A Call to Action (at the Local, National, and Global Levels)*, CHILDREN (BASEL), (February 20, 2019);6(2):30, <https://www.mdpi.com/2227-9067/6/2/30/htm> (last visited February 4, 2021).

⁶³ NAS, *supra* note 13, at 333. “Substantial evidence: There are several supportive findings from good-quality observational studies or controlled trials with few or no opposing findings. A firm conclusion can be made, but minor limitations, including chance, bias, and confounding factors, cannot be ruled out with reasonable confidence.” *Id.* at 5.

⁶⁴ American Academy of Pediatrics, *Public Policy to Protect Children from Tobacco, Nicotine, and Tobacco Smoke*, PEDIATRICS NOVEMBER (2015);136(5): 998-1007, <https://pediatrics.aappublications.org/content/136/5/998> (last visited February 4, 2021).

teens.⁶⁵ Brain development continues until about the age of 25, and nicotine exposure has been shown to harm the developing brain.⁶⁶ Exposure to nicotine “during adolescence can impact learning, memory, and attention” and “can also increase risk for future addiction to other drugs.”⁶⁷

E-cigarettes can deliver nicotine at levels comparable to or exceeding that of combustible tobacco cigarettes.⁶⁸ The labeling on e-cigarette products “is not always a reliable indicator of nicotine content, as studies have found mislabeling to be a common issue in the category.”⁶⁹ E-cigarette devices that use pre-filled cartridges or pods “typically use nicotine salts rather than the freebase nicotine used in most other e-cigarette, or vaping, products.”⁷⁰ Because nicotine salts have a lower pH than freebase nicotine, these devices “allow particularly high levels of nicotine to be inhaled more easily and with less irritation to the throat than freebase nicotine.”⁷¹

ii. E-Liquid and Inhalation of E-Cigarette Aerosols

In addition to nicotine, e-cigarette liquid contains a solvent, usually propylene glycol and vegetable glycerin, as well as various additives including flavors.⁷² Most of the flavorings in e-cigarette liquids are generally recognized as safe (GRAS) by the FDA; however, GRAS designations for flavorings are for oral consumption in food.⁷³ Most of the flavorings used in e-cigarettes have never been studied for toxicity when inhaled.⁷⁴

⁶⁵ Brian P. Jenssen, *supra* note 62.

⁶⁶ CDC, *Surgeon General’s Advisory on E-cigarette Use Among Youth*, https://www.cdc.gov/tobacco/basic_information/e-cigarettes/surgeon-general-advisory/index.html (last visited February 4, 2021).

⁶⁷ *Id.*

⁶⁸ SSA, *supra* note 59; Truth Initiative, *E-Cigarettes: Facts, Stats and Regulations*, (November 11, 2019), <https://truthinitiative.org/research-resources/emerging-tobacco-products/e-cigarettes-facts-stats-and-regulations>, (last visited March 5, 2021).

⁶⁹ Truth Initiate, *supra* note 68.

⁷⁰ CDC, *supra* note 31.

⁷¹ *Id.*

⁷² Hussein Traboulsi, *supra* note 19.

⁷³ NAS, *supra* note 13, at 4.

⁷⁴ *Id.*

The chemical composition of the aerosol produced by e-cigarettes varies, “depending on parameters such as the device, voltage used, and the composition of the e-liquid.”⁷⁵ The NAS Committee determined that substantial evidence exists that aerosol from e-cigarettes contains metals.⁷⁶ The metals in e-cigarette aerosol could originate from the metallic coil used to heat the e-liquid, other parts of the e-cigarette device, or the e-liquids themselves.⁷⁷ E-cigarette aerosol also contains other toxic and carcinogenic substances, although at lower levels than in combustible tobacco cigarettes.⁷⁸ Substantial evidence exists that the aerosols from the e-cigarettes “can induce acute endothelial cell dysfunction, although the long-term consequences and outcomes on these parameters with long-term exposure to e-cigarette aerosol are uncertain.”⁷⁹ Substantial evidence exists that e-cigarette aerosols also contain chemicals such as formaldehyde and acrolein, which can cause DNA damage and mutagenesis.⁸⁰ This evidence “supports the biological plausibility that long-term exposure to e-cigarette aerosols could increase the risk of cancer and adverse reproductive outcomes.”⁸¹ It has not been determined, however, whether the exposure levels from e-cigarette aerosols are high enough to promote human carcinogenesis.⁸²

iii. EVALI (E-Cigarette or Vaping Use-Associated Lung Injury)

While nicotine is a key component of e-cigarettes, e-cigarette users have increasingly used e-cigarette devices to inhale cannabis products, such as those containing

⁷⁵ Hussein Traboulsi, *supra* note 19.

⁷⁶ NAS, *supra* note 13, at 18.

⁷⁷ *Id.*

⁷⁸ SSA, *supra* note 59.

⁷⁹ NAS, *supra* note 13, at 18.

⁸⁰ *Id.*

⁸¹ *Id.* at 18-19.

⁸² *Id.* at 19.

tetrahydrocannabinol (THC), the primary psychoactive cannabinoid in marijuana.⁸³ Inhalation of cannabis-based products can cause unique types of lung injury.⁸⁴

Among the hospitalized patients with e-cigarette or vaping use-associated lung injury (EVALI), 80% reported using THC-containing e-cigarettes, most frequently illicit THC-containing products.⁸⁵ As of February 18, 2020, the number of hospitalized EVALI cases or deaths reported to the CDC was 2,807 from all 50 states, the District of Columbia, and two U.S. territories (Puerto Rico and U.S. Virgin Islands); sixty-eight deaths were confirmed in 29 states and the District of Columbia.⁸⁶ Laboratory data showed strong links to the EVALI outbreak from vitamin E acetate, an additive in some THC-containing e-cigarette or vaping products.⁸⁷ National emergency department data and case reporting from state health departments across the country showed a sharp increase in symptoms or cases of EVALI in August 2019, a peak in September 2019, followed by a gradual decline.⁸⁸ The reasons for the decline may be related to the increase in public awareness of the risks associated with THC-containing e-cigarettes, vitamin E acetate being removed from some products, and law enforcement actions related to the unlawful products.⁸⁹

⁸³ Hussein Traboulsi, *supra* note 19.

⁸⁴ *Id.*

⁸⁵ Matthew J. Lozier et al., *Update: Demographic, Product, and Substance-Use Characteristics of Hospitalized Patients in a Nationwide Outbreak of E-cigarette, or Vaping, Product Use-Associated Lung Injuries—United States, December 2019*, MORB MORTAL WKLY REP, (December 13, 2019);68(49):1142-1148, https://www.cdc.gov/mmwr/volumes/68/wr/mm6849e1.htm?s_cid=mm6849e1_w, (last visited February 6, 2021).

⁸⁶ CDC, *Outbreak of Lung Injury Associated with the Use of E-Cigarette, or Vaping, Products*, (last updated February 25, 2020), https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html, (last visited February 6, 2021).

⁸⁷ *Id.*

⁸⁸ *Id.*

⁸⁹ *Id.*

iv. Initiation to and Progression of Combustible Tobacco Cigarettes

The use of e-cigarettes by adolescents and young adults may impact their health by changing their behavior through initiation to, or progression of, combustible tobacco cigarette smoking.⁹⁰ Among youth and young adults, there is substantial evidence that e-cigarette use increases the risk of “ever using” combustible tobacco cigarettes—i.e., starting cigarette smoking.⁹¹ Moderate evidence exists that among youth and young adult e-cigarette users who have used combustible tobacco cigarettes, e-cigarette use increases the frequency (i.e., days used in the past 30 days) and intensity (i.e., cigarettes per day on smoking day) of subsequent combustible tobacco cigarette smoking.⁹²

v. Other Potential Harms Associated with E-Cigarettes

a. E-Cigarette Emissions and Airborne Particulate Matter

Conclusive evidence exists that “most e-cigarette products contain and emit numerous potentially toxic substances.”⁹³ The evidence is also conclusive “that e-cigarette use increases airborne concentrations of particulate matter and nicotine in indoor environments compared with background levels.”⁹⁴ Conclusive evidence exists “that, other than nicotine, the number, quantity, and characteristics of potentially toxic substances emitted from e-cigarettes are highly variable and depend on product characteristics (including device and e-liquid characteristics) and how the

⁹⁰ NAS, *supra* note 13, at 494.

⁹¹ *Id.* at 494, 532.

⁹² *Id.* at 498, 535-36. “Moderate evidence: There are several supportive findings from fair-quality studies with few or no credible opposing findings. A general conclusion can be made, but limitations, including chance, bias, and confounding factors, cannot be ruled out with reasonable confidence.” *Id.* at 5.

⁹³ *Id.* at 6. “Conclusive evidence: There are many supportive findings from good-quality controlled studies (including randomized and non-randomized controlled trials) with no credible opposing findings. A firm conclusion can be made, and the limitations to the evidence, including chance, bias, and confounding factors, can be ruled out with reasonable confidence.” *Id.* at 5.

⁹⁴ *Id.* at 17.

device is operated.”⁹⁵ Moderate evidence exists “that secondhand exposure to nicotine and particulates is lower from e-cigarettes compared with combustible tobacco cigarettes.”⁹⁶

b. Device Explosions

Conclusive evidence exists that e-cigarette devices can explode, although rare, and the explosions can cause burns and projectile injuries.⁹⁷ The risk of such injuries is significantly increased when the batteries in the devices are of poor quality or are stored improperly or modified.⁹⁸

c. Contact with E-Liquid

Contact with e-liquid directly through the skin or by ingestion can cause harm, including death.⁹⁹ Conclusive evidence exists “that intentional or accidental exposure to e-liquids (from drinking, eye contact, or dermal contact) can result in adverse health effects including but not limited to seizures, anoxic brain injury, vomiting, and lactic acidosis” and “that intentionally or unintentionally drinking or injecting e-liquids can be fatal.”¹⁰⁰

B. Potential Benefits Associated with E-Cigarettes

i. Smoking Cessation

E-cigarettes have been portrayed as smoking cessation aids, but the scientific evidence from research studies documenting the effectiveness of e-cigarette use for smoking cessation is limited or insufficient.¹⁰¹ Although some adults have used e-cigarettes to switch completely from combustible tobacco cigarettes, the FDA has not approved any e-cigarette for smoking

⁹⁵ *Id.*

⁹⁶ *Id.* at 19.

⁹⁷ SSA, *supra* note 59; NAS, *supra* note 13, at 17.

⁹⁸ NAS, *supra* note 13, at 17.

⁹⁹ SSA, *supra* note 59.

¹⁰⁰ NAS, *supra* note 13, at 17-18.

¹⁰¹ Lorena M. Siqueira, *supra* note 61.

cessation.¹⁰² Products that the FDA has approved for smoking cessation include over-the-counter nicotine replacement therapy (NRT) (patch, gum, lozenge), prescription NRT (nasal spray, inhaler), and prescription medications (varenicline, bupropion).¹⁰³

The NAS Committee concluded that the evidence on whether e-cigarettes may be effective aids to promote smoking cessation is limited.¹⁰⁴ Insufficient evidence from randomized controlled trials exists regarding “the effectiveness of e-cigarettes as cessation aids compared with no treatment or with [FDA]-approved smoking cessation treatments.”¹⁰⁵ There is moderate evidence from randomized controlled trials that nicotine-containing e-cigarettes “are more effective than e-cigarettes without nicotine for smoking cessation.”¹⁰⁶ The overall evidence from observational studies is mixed; however, moderate evidence from observational studies exists “that more frequent use of e-cigarettes is associated with an increased likelihood of [tobacco smoking] cessation.”¹⁰⁷

One recent randomized study showed that e-cigarettes were more effective for smoking cessation than nicotine replacement therapy after one year.¹⁰⁸ However, all subjects in the study, regardless of treatment, received four weeks of weekly one-on-one behavioral support, and treatment was not blinded,¹⁰⁹ which may have biased the results. Additional “longitudinal

¹⁰² Truth Initiative, *Action Needed on E-Cigarettes*, (November 13, 2020), <https://truthinitiative.org/research-resources/emerging-tobacco-products/action-needed-e-cigarettes>, (last visited February 6, 2021).

¹⁰³ FDA, *Smoking: Medicines to Help You Quit*, (2017), <https://www.fda.gov/media/86936/download>, (last visited February 20, 2021).

¹⁰⁴ NAS, *supra* note 13, at 584. “Limited evidence: There are supportive findings from fair-quality studies or mixed findings with most favoring one conclusion. A conclusion can be made, but there is significant uncertainty due to chance, bias, and confounding factors.” *Id.* at 5.

¹⁰⁵ *Id.* “Insufficient evidence: There are mixed findings or a single poor study. No conclusion can be made because of substantial uncertainty due to chance, bias, and confounding factors.” *Id.* at 5.

¹⁰⁶ *Id.*

¹⁰⁷ *Id.*

¹⁰⁸ Peter Hajek et al., *A Randomized Trial of E-Cigarettes Versus Nicotine-Replacement Therapy*, *N ENGL J MED*, (February 14, 2019);380:629-637, <https://www.nejm.org/doi/full/10.1056/nejmoa1808779>, (last visited February 6, 2021).

¹⁰⁹ *Id.*

population-level studies are needed to identify whether the use of e-cigarettes as a method to quit cigarettes is associated with increased successful cigarette cessation at the population level.”¹¹⁰

In the PATH study, individuals who used e-cigarettes as a tobacco smoking cessation method “had similar 12+ months cigarette abstinence rates, assessed 1-2 years after the quit attempt, compared to those who used FDA-approved cessation aids or no product at all.”¹¹¹

However, more than half of those who used e-cigarettes to attempt to quit smoking still used e-cigarettes one year later.¹¹²

E-cigarette manufacturers are not required to conduct research on e-cigarettes to determine whether they are effective smoking cessation aids.¹¹³ When the FDA extended its authority to regulate e-cigarettes in 2016, it prohibited sales of e-cigarettes to minors, but many states had already enacted such laws.¹¹⁴ The FDA requires smoking cessation claims to undergo a drug evaluation review, and, to date, no company has sought such review for e-cigarettes.¹¹⁵ E-cigarette manufacturers have no incentive to invest in submitting applications for FDA approval of therapeutic claims for smoking cessation, because they can continue to sell e-cigarettes freely under the current regulatory scheme.¹¹⁶

ii. Harm Reduction

The evidence on harm reduction of e-cigarette use “suggests that over a range of studies and outcomes, e-cigarettes pose less risk to an individual than combustible tobacco cigarettes.”¹¹⁷

¹¹⁰ John P. Pierce et al., *Role of E-Cigarettes and Pharmacotherapy During Attempts to Quit Cigarette Smoking: The PATH Study 2013-16*. PLOS ONE, (September 2, 2020);15(9):e0237938, <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0237938> (accessed January 18, 2021).

¹¹¹ *Id.*

¹¹² *Id.*

¹¹³ SSA, *supra* note 59.

¹¹⁴ *Id.*

¹¹⁵ *Id.*

¹¹⁶ *Id.*

¹¹⁷ NAS, *supra* note 13, at 487.

Conclusive evidence exists “that completely substituting e-cigarettes for combustible tobacco cigarettes reduces users’ exposure to numerous toxicant and carcinogens present in combustible tobacco cigarettes.”¹¹⁸ Substantial evidence exists “that completely switching from regular use of combustible tobacco cigarettes to e-cigarettes results in reduced short-term adverse health outcomes in several organ systems.”¹¹⁹ According to the CDC, in 2018, 3.2% of U.S. adults were current users of e-cigarettes, about half of whom also smoked regular cigarettes (dual users).¹²⁰ However, the CDC does not report what percentage of adult e-cigarette users switch from combustible tobacco cigarettes to e-cigarettes.

Among smokers who continue to smoke combustible tobacco cigarettes and use e-cigarettes (dual users), insufficient evidence exists “that e-cigarette use changes short-term adverse health outcomes in several organ systems.”¹²¹ No available evidence exists as to whether “long-term e-cigarette use among smokers (dual use) changes morbidity or mortality compared with those who only smoke combustible tobacco cigarettes.”¹²²

¹¹⁸ *Id.* at 604.

¹¹⁹ *Id.* at 617.

¹²⁰ CDC, *Adult Smoking Cessation – The Use of E-Cigarettes*, https://www.cdc.gov/tobacco/data_statistics/sgr/2020-smoking-cessation/fact-sheets/adult-smoking-cessation-e-cigarettes-use/index.html, (last visited January 31, 2021).

¹²¹ NAS, *supra* note 13, at 619.

¹²² *Id.* “No available evidence: There are no available studies; health endpoint has not been studied at all. No conclusion can be made.” *Id.* at 5.

III. LAWS AND REGULATIONS

This section describes federal laws related to tobacco and e-cigarettes; FDA regulations and enforcement priorities; the impact of the Tobacco 21 law and FDA enforcement activities; and state and local laws and regulations.

A. Federal Statutes

i. Tobacco Control Act

The Family Smoking Prevention and Tobacco Control Act of 2009 (“Tobacco Control Act”) granted the FDA authority to regulate tobacco products that are manufactured, marketed, and distributed in the United States.¹²³ The Tobacco Control Act’s controlling purpose is to protect the public health through reducing tobacco use and harms.¹²⁴ The purposes of the Tobacco Control Act include, *inter alia*:

- (1) to provide authority to the Food and Drug Administration to regulate tobacco products under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), by recognizing it as the primary Federal regulatory authority with respect to the manufacture, marketing, and distribution of tobacco products as provided for in this division;
- (2) to ensure that the Food and Drug Administration has the authority to address issues of particular concern to public health officials, especially the use of tobacco by young people and dependence on tobacco; ...¹²⁵

The Tobacco Control Act considers a “tobacco product” to be “any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in

¹²³ *Id.* at 34.

¹²⁴ Eric N. Lindblom, *What is “Appropriate for the Protection of the Public Health” Under the U.S. Tobacco Control Act?* FOOD & DRUG LAW J, (June 8, 2020);74(4):523-585 <https://www.fdi.org/wp-content/uploads/2020/06/LINDBLOM-Final-1.pdf> (last visited February 9, 2021).

¹²⁵ Family Smoking Prevention and Tobacco Control Act of 2009, Pub. L. No. 111-31, 123 Stat. 1776, (June 22, 2009), <https://www.govinfo.gov/content/pkg/PLAW-111publ31/pdf/PLAW-111publ31.pdf>, (last visited February 7, 2021).

manufacturing a component, part, or accessory of a tobacco product).”¹²⁶ Products that meet the statutory definition of drug, device, or combination product are excluded from the definition of a tobacco product of the Food, Drug and Cosmetic Act (“FD&C Act”), as amended by the Tobacco Act.¹²⁷

ii. Tobacco 21 Law

The FD&C Act was amended again on December 20, 2019, to raise the federal minimum age on the sale of tobacco products from 18 to 21 years.¹²⁸ The Tobacco 21 law took immediate effect on December 20, 2019 and makes it illegal for retailers to sell any tobacco products—including e-cigarettes and e-liquids—to anyone under 21 years of age.¹²⁹ The new federal minimum age applies, without exception, to all retail establishments and persons.¹³⁰

iii. Preventing Online Sales of E-Cigarettes to Children Act

The Preventing Online Sales of E-Cigarettes to Children Act (“Act”) was signed into law on January 3, 2021, and goes into effect 90 days after its enactment.¹³¹ This Act is an amendment to “An Act to assist States in collecting sales and use taxes on cigarettes,” which was approved October 19, 1949 (commonly known as the “Jenkins Act”) (15 U.S.C. § 375 et seq.), to include ENDS in the definition of “cigarette” and to define ENDS in 15 U.S.C. § 375.¹³² The Act also includes a provision for non-mailability of ENDS products; this provision requires the USPS to promulgate regulations not later than 120 days after the date of enactment “to clarify the

¹²⁶ 21 U.S.C. § 321(rr)(1).

¹²⁷ FDA, Guidance for Industry, *FDA Deems Certain Tobacco Products Subject to FDA Authority, Sales and Distribution Restrictions, and Health Warning Requirements for Packages and Advertisements (Revised)**, (October 2020), <https://www.fda.gov/media/143049/download>, (last visited February 7, 2021).

¹²⁸ FDA, *supra* note 8.

¹²⁹ FDA, *Tobacco 21*, (February 12, 2020), <https://www.fda.gov/tobacco-products/retail-sales-tobacco-products/tobacco-21>, (last visited February 8, 2021).

¹³⁰ *Id.*

¹³¹ Preventing Online Sales of E-Cigarettes to Children Act, *supra* note 10.

¹³² *Id.*

applicability of the prohibition on mailing of cigarettes ..., to [include] electronic nicotine delivery systems,” consistent with the amended definition of “cigarette.”¹³³ On February 19, 2021, the USPS issued for public comment its proposed rule on the “Treatment of E-Cigarettes in the Mail,” which incorporates the new statutory restrictions on the mailing of electronic nicotine delivery systems.¹³⁴

Currently, federal and state laws restricting consumer access to online purchases and shipment of commercial tobacco products do so, in large part, by requiring age verification checks at the time an individual places an online order and then at the point of delivery.¹³⁵ However, age verification laws have not effectively prevented underage access to e-cigarettes and e-liquids.¹³⁶ The significant challenges to federal, state, and local governments to prevent youth access to e-cigarettes convinced some states to completely prohibit direct-to-consumer online retail sales and shipments.¹³⁷

Before the Act, there were essentially two different sets of rules for online purchases of combustible tobacco cigarettes and e-cigarettes.¹³⁸ For traditional cigarettes, an online buyer needed to sign and show identification at the time of delivery, just as a buyer would for an in-person purchase.¹³⁹ But for e-cigarettes, individuals could go online and buy e-cigarettes and have them delivered to their front door, with no questions asked and no age verification or ID required.¹⁴⁰ The new law applies the same safeguards to e-cigarettes that are currently in place

¹³³ *Id.*

¹³⁴ 86 Fed. Reg. 10218, *supra* note 11.

¹³⁵ Public Health Law Center at Mitchell Hamline School of Law, *JUUL and the Guinea Pig Generation Revisited*, (July 2020), <https://www.publichealthlawcenter.org/sites/default/files/resources/JUUL-and-the-Guinea-Pig-Generation-Revisited.pdf>, (last visited February 8, 2021).

¹³⁶ *Id.*

¹³⁷ *Id.*

¹³⁸ E-cigarettes (Executive Session), 166 Cong Rec S 7028, November 17, 2020.

¹³⁹ *Id.*

¹⁴⁰ *Id.*

for combustible tobacco cigarettes and ensures that only adults can take delivery of e-cigarettes purchased online.¹⁴¹

B. FDA Regulations

i. Final Deeming Rule

Products such as cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco were immediately covered by the FDA’s tobacco product authority in chapter IX of the FD&C Act when the Tobacco Control Act went into effect in 2009.¹⁴² For other kinds of tobacco products, the statute authorized the FDA to issue regulations “deeming” them to be subject to FDA regulation.¹⁴³ Once a tobacco product is deemed, the FDA may put restrictions in place to regulate “the sale and distribution of a tobacco product, including age-related access restrictions and advertising and promotion restrictions, if FDA determines the restrictions are appropriate for the protection of the public health.”¹⁴⁴ In May 2016, FDA published the final Deeming Rule that deemed e-cigarettes to be a tobacco product under the law.¹⁴⁵ The final Deeming Rule, which went into effect on August 8, 2016, gives the FDA authority to regulate e-cigarettes.¹⁴⁶

ii. FDA Market Authorization for E-Cigarettes Products

E-cigarettes that are deemed “new tobacco products” are subject to premarket authorization by the FDA.¹⁴⁷ Any tobacco product that was on the market as of February 15,

¹⁴¹ Hannah Prokop, *Congress Passes Bill to Prevent Online Underage E-Cig Sales*, (January 4, 2021), <https://www.cspdailynews.com/tobacco/congress-passes-bill-prevent-online-underage-e-cig-sales>, (last visited February 8, 2021).

¹⁴² 81 Fed. Reg. 28973 (May 10, 2016), <https://www.federalregister.gov/documents/2016/05/10/2016-10685/deeming-tobacco-products-to-be-subject-to-the-federal-food-drug-and-cosmetic-act-as-amended-by-the>, (last visited February 8, 2021).

¹⁴³ *Id.*

¹⁴⁴ *Id.*

¹⁴⁵ *Id.*

¹⁴⁶ FDA, *Perspective: FDA’s Preparations for the September 9 Submission Deadline*, (February 19, 2021), <https://www.fda.gov/tobacco-products/ctp-newsroom/perspective-fdas-preparations-september-9-submission-deadline>, (last visited February 1, 2021).

¹⁴⁷ *Id.*

2007, is considered “grandfathered” under the FDA’s final Deeming Rule. “New tobacco products” are those that are not grandfathered, i.e., those that were introduced to the market or modified on or after February 15, 2007. The first e-cigarettes were introduced in the United States sometime around 2007.¹⁴⁸ Thus, most if not all e-cigarette products fall within the category of “new tobacco products,” and e-cigarette manufacturers are required to submit an application to the FDA for market authorization.¹⁴⁹

When the FDA performs a premarket review of a new tobacco product, it conducts a science-based evaluation to determine whether the product meets the applicable statutory standard for marketing authorization.¹⁵⁰ For e-cigarettes, the FDA considers whether the “product is appropriate for the protection of public health with respect to the risks and benefits to the population as a whole, including users and nonusers.”¹⁵¹ Manufacturers must show that the product “would be appropriate for the protection of public health,” based on considerations such as the increase or decrease in the likelihood that those who do not use tobacco products will start using the products.¹⁵²

As of August 31, 2020, no e-cigarette product had received marketing authorization from the FDA, and the FDA had not issued a grandfathered status determination for any e-cigarette product.¹⁵³ All premarket applications for ENDS products that had been accepted by the FDA by

¹⁴⁸ Kate Lichtenberg, *supra* note 16

¹⁴⁹ FDA, *supra* note 146.

¹⁵⁰ FDA, Guidance for Industry, *Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised)*, (April 2020), <https://www.fda.gov/media/133880/download>, (last visited February 11, 2021).

¹⁵¹ *Id.*

¹⁵² *Id.*

¹⁵³ FDA, *supra* note 146.

August 31, 2020, were submitted through the Premarket Tobacco Product Application (PMTA) pathway.¹⁵⁴

E-cigarettes that were on the market as of August 8, 2016, were subject to FDA compliance policies that deferred enforcement for the lack of premarket authorization.¹⁵⁵ In July 2019, a U.S. District Court in Maryland ordered that for deemed tobacco products, such as e-cigarettes, that were on the market as of August 8, 2016, applications had to be submitted to the FDA no later than May 12, 2020.¹⁵⁶ The court order also provided a one-year period in which products with timely-filed applications could remain on the market, pending FDA review.¹⁵⁷ The court order, however, clarified that the FDA had the discretion to enforce the premarket review provisions against deemed products prior to May 12, 2020, or during the one-year review period.¹⁵⁸

iii. FDA Enforcement of E-Cigarettes Regulations

The FDA established enforcement priorities in a final Guidance for Industry in April 2020.¹⁵⁹ The FDA prioritizes enforcement against:

- Any flavored, cartridge-based ENDS product (other than a tobacco- or menthol-flavored ENDS product);
- All other ENDS products for which the manufacturer has failed to take (or is failing to take) adequate measures to prevent minors' access; and
- Any ENDS product that is targeted to minors or whose marketing is likely to promote use of ENDS by minors.¹⁶⁰

¹⁵⁴ FDA, *supra* note 146; *See generally* Jim McDonald, *How Will the PMTA Deadline Affect Vapers and the Industry?* VAPING360, (September 7, 2020), <https://vaping360.com/vape-news/105656/how-will-the-pmta-deadline-affect-vapers-and-the-industry/>, (last accessed March 14, 2021).

¹⁵⁵ FDA, *supra* note 3.

¹⁵⁶ *Id.*

¹⁵⁷ *Id.*

¹⁵⁸ *Id.*

¹⁵⁹ FDA, *supra* note 150.

¹⁶⁰ FDA, *supra* note 150.

The FDA stated that it intended to prioritize enforcement of ENDS products offered for sale after September 9, 2020, and for which the manufacturer had not submitted a premarket application, or after a negative action by the FDA on a submitted application.¹⁶¹ The FDA “make[s] enforcement decisions on a case-by-case basis, recognizing that it is unable, as a practical matter, to take enforcement action against every illegally marketed tobacco product, and that it needs to make the best use of Agency resources.”¹⁶²

iv. Regulation of Flavors in E-Cigarettes

As of January 2020, the FDA accepted and began reviewing premarket applications for flavored ENDS products.¹⁶³ Before the FDA grants marketing authorization, a company must demonstrate that a specific ENDS product meets the applicable statutory standard and considers how product marketing might affect youth initiation and use.¹⁶⁴ The FDA prioritizes “enforcement against certain unauthorized flavored e-cigarette products that appeal to kids, including fruit and mint flavors.”¹⁶⁵ The FDA’s enforcement policy affects only cartridge-based e-cigarette products, which involve “a cartridge or pod that holds liquid that is to be aerosolized when the product is used.”¹⁶⁶

In its Guidance for Industry (April 2020), the FDA called for flavored e-liquid “cartridges/pods (all but menthol and tobacco) to be removed from the marketplace, (namely, flavored Juul pods and similar cartridges designed for use with rechargeable vaping devices like

¹⁶¹ *Id.*

¹⁶² *Id.*

¹⁶³ FDA, *FDA Finalizes Enforcement Policy on Unauthorized Flavored Cartridge-Based E-Cigarettes That Appeal to Children, Including Fruit and Mint*, (January 2, 2020), <https://www.fda.gov/news-events/press-announcements/fda-finalizes-enforcement-policy-unauthorized-flavored-cartridge-based-e-cigarettes-appeal-children>, (last visited February 11, 2021).

¹⁶⁴ *Id.*

¹⁶⁵ FDA, *supra* note 9.

¹⁶⁶ *Id.*

Juul).¹⁶⁷ The FDA did not prioritize enforcement action against other types of flavored e-cigarette products, as data showed that cartridge-based products were the most common types of e-cigarette products used among youth.¹⁶⁸ The FDA does not currently restrict sales of flavored e-liquids or cartridges designed for use with disposable or refillable e-cigarette devices.¹⁶⁹

v. FDA and Tobacco 21

Under the Tobacco 21 law, retailers cannot sell tobacco products to anyone under the age of 21.¹⁷⁰ The FDA recognized that both the agency and retailers would need to update current practices to implement the new law; the FDA stated on its website that it would “need time to do outreach and education to retailers and update the Agency’s programmatic work to reflect this change in law.”¹⁷¹ During the transition period, the FDA expects retailers to comply with the law and to take necessary measures to ensure that any individual purchasing any tobacco product is 21 years or older.¹⁷²

C. Impact of Federal Statutes and Regulations

The federal statutes and regulations, such as the Tobacco 21 law and FDA’s enforcement activities, are potentially having an impact on the rate of e-cigarette use among young people. The CDC and FDA analyze data each year from the National Youth Tobacco Survey (NYTS) on e-cigarette use among high school and middle school students.¹⁷³ The NYTS data from 2020 showed a decrease in the rates of e-cigarette use among young people compared with 2019, with a decrease from 27.5% to 19.6% among high school students, and from 10.5% to 4.7% among

¹⁶⁷ Public Health Law Center, *supra* note 135.

¹⁶⁸ FDA, *supra* note 165.

¹⁶⁹ Public Health Law Center, *supra* note 135.

¹⁷⁰ FDA, *supra* note 8.

¹⁷¹ *Id.*

¹⁷² *Id.*

¹⁷³ CDC, *National Youth Tobacco Survey (NYTS)*, (December 21, 2020), https://www.cdc.gov/tobacco/data_statistics/surveys/nyts/index.htm, (last visited March 20, 2021).

middle school students.¹⁷⁴ The observed decrease in the rates of e-cigarette use among young people from 2019 to 2020 could be due to several factors. In 2020, because of the widespread school closures during the coronavirus pandemic, NYTS data were collected only from January to March.¹⁷⁵ In addition, the federal Tobacco 21 law, which prohibited the sale of tobacco products, including e-cigarettes, to anyone under 21 years old, took effect in December 2019.¹⁷⁶ Also, at the end of 2019, Juul labs, which sells JUUL, one of the most popular e-cigarette devices among young people, stopped selling most of its flavored products, including mango, fruit, crème, cucumber, and mint.¹⁷⁷ Juul Labs took this action just ahead of the FDA’s January 2020 enforcement priority regarding e-cigarettes, which prohibited the sale of certain flavored e-cigarette products, specifically, flavored pre-filled cartridges and pods.¹⁷⁸

D. State and Local Laws and Regulations

The preemption provision of the Tobacco Control Act¹⁷⁹ “expressly preempts state and local governments from regulating tobacco product standards, premarket review, manufacturing practices, labeling, and product registration.”¹⁸⁰ However, the Tobacco Control Act does not “preempt state and local communities from enacting more stringent tobacco sales and distribution restrictions; youth possession restrictions; use restrictions (typically, smoke-free

¹⁷⁴ Teresa W. Wang, *supra* note 38.

¹⁷⁵ *Id.*

¹⁷⁶ FDA, *supra* note 8.

¹⁷⁷ Allison Aubrey, *supra* note 50; Dennis Thompson, *supra* note 50.

¹⁷⁸ FDA, *supra* note 9.

¹⁷⁹ 15 U.S. Code § 1334

¹⁸⁰ Public Health Law Center at Mitchell Hamline School of Law, *Preemption: The Biggest Challenge to Tobacco Control*, TOBACCO CONTROL LEGAL CONSORTIUM, (October 2014), <https://publichealthlawcenter.org/sites/default/files/resources/tclc-fs-preemption-tobacco-control-challenge-2014.pdf>, (last visited February 20, 2021).

laws); fire safety standards for products; or taxes on tobacco products.”¹⁸¹ Some states have also banned all flavored e-cigarette products.¹⁸²

State and local governments have increasingly taken steps to regulate the sale, marketing, and use of e-cigarettes.¹⁸³ State legislatures have enacted laws that include restrictions on sales of e-cigarettes to underage persons, requirements for retail licensure on e-cigarettes, smoke-free indoor air laws that include e-cigarettes, and taxation on e-cigarettes.¹⁸⁴

All 50 states, the District of Columbia, and several U.S. territories have passed legislation prohibiting the sale of e-cigarettes to underage persons.¹⁸⁵ As noted previously, the Tobacco 21 law raised the federal minimum legal sales age for commercial tobacco products from 18 to 21 years.¹⁸⁶ This law applies to sales of all tobacco products, including nicotine-based e-cigarettes, and affects all retail establishments.¹⁸⁷ States and localities may pass or strengthen their own age laws to ensure that state and local agencies have enforcement authority and appropriate community-level oversight.^{188,189}

The US Surgeon General called on states and localities to include e-cigarettes in smoke-free policies.¹⁹⁰ The Surgeon General’s report on e-cigarettes noted that “[s]uch policies will maintain current standards for clean indoor air, reduce the potential for renormalization of tobacco product use, and prevent involuntary exposure to nicotine and other aerosolized

¹⁸¹ *Id.*

¹⁸² Campaign for Tobacco-Free Kids, *supra* note 37.

¹⁸³ Public Health Law Center at Mitchell Hamline School of Law, *E-Cigarettes*, <https://www.publichealthlawcenter.org/topics/commercial-tobacco-control/e-cigarettes>, (last visited February 11, 2021).

¹⁸⁴ CDC, *STATE System E-Cigarette Fact Sheet*, (November 18, 2020), <https://www.cdc.gov/statesystem/factsheets/ecigarette/ECigarette.html>, (last visited February 11, 2021)

¹⁸⁵ *Id.*

¹⁸⁶ FDA, *supra* note 129.

¹⁸⁷ Public Health Law Center, *supra* note 135.

¹⁸⁸ CounterTobacco.Org, *Tobacco 21*, <https://countertobacco.org/policy/tobacco-21/>, (last visited February 11, 2021).

¹⁸⁹ Public Health Law Center, *supra* note 135.

¹⁹⁰ Brian P. Jenssen, *supra* note 62; CDC, *supra* note 1.

emissions from e-cigarettes.”¹⁹¹ As of September 30, 2020, 15 states, the District of Columbia and Puerto Rico have passed comprehensive smoke-free indoor air laws that include a prohibition on e-cigarette use in indoor areas such as private worksites, restaurants, and bars.¹⁹²

Thirty states, the District of Columbia and Puerto Rico have passed legislation that requires retailers to obtain a license to sell e-cigarettes over the counter.¹⁹³ As of September 30, 2020, 26 states, the District of Columbia, Puerto Rico, and the U.S. Virgin Islands have passed legislation that taxes e-cigarettes; 12 states have a tax on e-cigarettes per milliliter of liquid or consumable material; and 11 states, the District of Columbia, and the U.S. Virgin Islands have a tax on e-cigarettes as a percentage of a specified cost.¹⁹⁴

Some state and local governments have banned the sale of all flavored e-cigarettes, including Massachusetts, California, New York, New Jersey, and Rhode Island.¹⁹⁵ Cities and localities that prohibit the sale of flavored e-cigarettes include San Francisco, New York City, Chicago, Sacramento, and Los Angeles County.¹⁹⁶

V. PROPOSALS

The use of e-cigarettes has become epidemic among young people in the United States.¹⁹⁷ One obvious danger of e-cigarette use by young people is the risks associated with nicotine, which damages brain development during adolescence and can impact learning, memory, and attention.¹⁹⁸ Nicotine is known to be highly addictive,¹⁹⁹ and nicotine addiction through e-

¹⁹¹ Office of the Surgeon General, (2016), *supra* note 4.

¹⁹² CDC, *supra* note 184.

¹⁹³ *Id.*

¹⁹⁴ *Id.*

¹⁹⁵ Campaign for Tobacco-Free Kids, *supra* note 37.

¹⁹⁶ *Id.*

¹⁹⁷ CDC, *supra* note 1.

¹⁹⁸ CDC, *supra* note 66.

¹⁹⁹ Brian P. Jenssen, *supra* note 62.

cigarettes can increase the risk of future addiction to other substances.²⁰⁰ The long-term health effects of e-cigarettes are not known.²⁰¹ The highest rates of e-cigarette use are among young people in the United States.²⁰² Unless further government measures are taken to prevent youth access to e-cigarettes, the short-term and long-term health of young people who use e-cigarettes is imperiled.

Proposal 1: The FDA should exercise its authority to completely ban all flavored e-cigarette products from the market.

While there is some evidence of a decline in youth e-cigarette use rates from 2019 to 2020, there were still an estimated 3.6 million young people using e-cigarettes in 2020.²⁰³ The availability of appealing flavors is the leading reason for e-cigarette use among adolescents and young adults.²⁰⁴ Young people are attracted to e-cigarette flavors, such as fruit and mint, much more so than to tobacco- or menthol-flavored e-cigarettes.²⁰⁵ While Juul Labs stopped selling all flavors except tobacco and menthol at the end of 2019, disposable and other e-cigarette devices that use refillable cartridges continue to be sold with youth-appealing flavors.²⁰⁶ From 2019 to 2020, the use of disposable e-cigarettes among high school e-cigarette users rose by approximately 1,000% (from 2.4% to 26.5%) and among middle school e-cigarette users by approximately 400% (from 3.0% to 15.2%).²⁰⁷ It appears that young people who can no longer buy one type of flavored e-cigarette product (flavored pre-filled cartridges or pods), whose

²⁰⁰ *Id.*

²⁰¹ FDA, *supra* note 3.

²⁰² NAS, *supra* note 13.

²⁰³ Teresa W. Wang, *supra* note 38.

²⁰⁴ Samir S. Soneji, *supra* note 12.

²⁰⁵ FDA News Release, *supra* note 43.

²⁰⁶ Truth Initiative, *supra* note 51.

²⁰⁷ Teresa W. Wang, *supra* note 38.

manufacture, distribution, and sale is prohibited by the FDA, will indeed switch to other flavored e-cigarette products (disposables and refillable cartridges/tanks) that are not prohibited.

One might argue that banning all flavored e-cigarette products (except menthol and tobacco flavors) would eliminate options for some adult tobacco smokers who want the option of buying flavored e-cigarette products to help them quit smoking or to reduce harm through either substituting e-cigarettes for combustible cigarettes or dual use. However, first, the evidence on whether e-cigarettes are effective in promoting smoking cessation is limited at best.²⁰⁸ E-cigarette manufacturers cannot claim that their e-cigarette products are effective for smoking cessation unless they undergo a drug evaluation review by the FDA, and no company has yet sought such review.²⁰⁹ Second, as for harm reduction, substituting e-cigarettes for combustible cigarettes does reduce users' exposure to all the toxicants and carcinogens present in tobacco cigarettes,²¹⁰ and substantial evidence exists that complete switching to e-cigarettes reduces short-term adverse health outcomes.²¹¹ However, evidence is insufficient whether there is a benefit with dual use and whether e-cigarettes change short-term health outcomes.²¹² In addition, banning flavored e-cigarettes will not likely affect many adult cigarette smokers. The availability of flavored e-cigarette products is not a leading reason for adult e-cigarette use.²¹³ In 2018, at a time when there were no bans on flavored e-cigarette products, only 3.2% of adults were current users of e-cigarettes, about half of whom were dual users of e-cigarettes and tobacco cigarettes.²¹⁴

²⁰⁸ Lorena M. Siqueira, *supra* note 61.

²⁰⁹ SSA, *supra* note 59.

²¹⁰ NAS, *supra* note 13 at 604.

²¹¹ *Id.* at 617.

²¹² *Id.* at 619.

²¹³ Teresa W. Wang, *supra* note 38.

²¹⁴ CDC, *supra* note 120.

Proposal 2: To supplement federal laws and regulations in preventing young people from accessing and using e-cigarettes, more state and local governments should enact stronger e-cigarette laws and regulations.

The rationale for greater state and local government action is that, even if the FDA were to implement a policy and prioritize enforcement against all flavored e-cigarette products, its ability to enforce the policy against all the manufacture, distribution, and sale of such products would likely be hampered by lack of agency resources. As noted earlier in this paper, the FDA needs to make enforcement decisions on a case-by-case basis, recognizing that as a practical matter, it is not able to take enforcement action against every illegally marketed tobacco product and must make best use of its resources.²¹⁵ Some state and local governments have already taken steps to impose greater restrictions on the sale of e-cigarette products to underaged persons; to require licensure for selling e-cigarettes, to include e-cigarettes in indoor smoke-free policies; and to ban the sale of all flavored e-cigarettes.²¹⁶ State and local governments, where they are not federally preempted, should therefore take advantage of their sovereign powers to enact laws and regulations in these areas to protect young people from the harms of e-cigarettes.

CONCLUSION

Recent federal laws and regulations implemented to deal with the epidemic of e-cigarette use by young people have been important steps in helping reduce the rate of e-cigarette use. However, they are not sufficient. Two proposals are put forward in this paper. First, the FDA should exercise its authority to completely ban all flavored e-cigarette products from the market, since the availability of appealing flavors is the leading reason for e-cigarette use among

²¹⁵ FDA, *supra* note 150.

²¹⁶ CDC, *supra* note 184; Campaign for Tobacco-Free Kids, *supra* note 37.

adolescents and young adults. Second, more state and local governments should enact stronger laws and regulations in areas where they are not federally preempted, such as retail licensing to sell e-cigarettes, enacting smoke-free indoor air laws, imposing taxes on e-cigarettes, and banning all flavored e-cigarette products. Implementation of these proposals will serve to protect the short- and long-term health of youth and young adults by preventing exposure to nicotine through e-cigarette use.