

THE VAPES OF WRATH: WHY THE FDA SHOULD BAN FRUITY AND SWEET FLAVORED E-LIQUIDS TO PRECLUDE ADOLESCENT USE OF E-CIGARETTES

MATTI ROSE VAGNONI*

Introduction	277
I. The Scope of the FDA’s Regulatory Authority	283
A. The FDA’s Rulemaking Process	283
B. The History of the FDA’s Tobacco Regulation	284
II. Both Sides of the Fence	288
III. Flavor Ban	298
Conclusion	305

INTRODUCTION

Chocolate, vanilla, strawberry, caramel, coffee, cookie dough, cotton candy, mango, crème brûlée, cheesecake, peanut butter, pistachio, pineapple, and banana split. Usually, mentioning these flavors to a teenager might activate a sweet tooth and induce cravings for dessert. Today, these and thousands¹ of other fruity and sweet flavors are just some of the e-cigarette liquid nicotine varieties prevalent in schools and readily available to young adults online and in vapor shops throughout the country.

Electronic Nicotine Delivery Systems (ENDS)—also commonly known as

* J.D. Candidate, 2020, American University, Washington College of Law. This Comment would not have been possible without the invaluable support and editorial guidance of the *Administrative Law Review* staff. I would also like to thank my family for their unwavering love and support throughout this process, especially my youngest sister Rosemary, who inspired me to write about this topic.

1. See Shu-Hong Zhu et al., *Four Hundred and Sixty Brands of E-Cigarettes and Counting: Implications for Product Regulation*, 23 *TOBACCO CONTROL* iii3, iii3 (2014) (juxtaposing the 7,764 e-cigarette flavors available by 2014 to consumers in the United States with solely tobacco and menthol flavors available in combustible cigarettes).

e-cigarettes, vaporizers, or vapes—come in various sizes and models, but ordinarily they all contain a battery, a heating element, and a cavity for e-liquid.² The heating element warms the liquid and produces an aerosol that users inhale.³ The large majority of the products contain nicotine, though there are some nicotine-free liquids available.⁴ While manufacturers removed many toxins found in traditional combustible cigarettes, e-cigarettes use a liquid that contains flavor additives such as propylene glycol, glycerol, and usually nicotine.⁵

In 2003, Chinese pharmacist Hon Lik created the first commercially successful e-cigarette.⁶ United States manufacturers did not begin selling the devices until 2007,⁷ but after two years on the market and growing controversy regarding device safety, the U.S. Food and Drug Administration (FDA) intervened.⁸ In May 2009, the FDA tested two e-cigarette brands, NJOY and Smoking Everywhere, and found low amounts of nicotine in cartridges which the manufacturers labeled as nicotine-free.⁹ Shortly thereafter, President Obama passed the Family Smoking Prevention and Tobacco Control Act (TCA), which expanded the FDA's authority to regulate not just tobacco cigarettes, but all "tobacco products."¹⁰

In the early stages of e-cigarettes, disposable models were common, but they gradually lost their appeal after rechargeable and reusable models with accompanying prefilled cartridges became more popular and practical.¹¹ At

2. See CTRS. FOR DISEASE CONTROL & PREVENTION, U.S. DEP'T OF HEALTH & HUMAN SERVS., ELECTRONIC CIGARETTES WHAT'S THE BOTTOM LINE? 1, https://www.cdc.gov/tobacco/basic_information/e-cigarettes/pdfs/Electronic-Cigarettes-Infographic-508.pdf [hereinafter WHAT'S THE BOTTOM LINE?]; *Electronic Cigarettes (E-Cigarettes)*, NAT'L INST. OF DRUG ABUSE, <https://www.drugabuse.gov/publications/drugfacts/electronic-cigarettes-e-cigarettes> (last updated June 2018).

3. See WHAT'S THE BOTTOM LINE?, *supra* note 2.

4. *Electronic Cigarettes (E-Cigarettes)*, *supra* note 2.

5. See Marc L. Rubinstein et al., *Adolescent Exposure to Toxic Volatile Organic Chemicals from E-Cigarettes*, 141 PEDIATRICS 1, 2 (2018) (noting that heating propylene glycol and glycerol can form carcinogenic compounds).

6. See *A Historical Timeline of Electronic Cigarettes*, CONSUMER ADVOC. FOR SMOKE FREE ALTERNATIVES ASS'N, <http://www.casaa.org/historical-timeline-of-electronic-cigarettes/> (last visited Jan. 2, 2019).

7. *Id.*

8. See Sandee LaMotte, *E-Cigarettes: Where Do We Stand?*, CNN (Oct. 2, 2018), <https://www.cnn.com/2015/12/31/health/where-we-stand-now-e-cigarettes/index.html>.

9. *Id.*

10. Family Smoking Prevention and Tobacco Control Act of 2009, Pub. L. No. 111-21, § 3(8), 123 Stat. 1776, 1783 (codified as amended at 21 U.S.C § 387 (2012)).

11. See Gaby Galvin, *E-Cigarette Sales Have Surged Immensely in the U.S.*, U.S. NEWS & WORLD REP. (Aug. 2, 2018), <https://www.usnews.com/news/healthiest-communities/arti>

present, one brand in particular, JUUL,¹² has dominated e-cigarette sales¹³ despite its comparatively recent introduction to the market in 2015.¹⁴ JUULs are rechargeable e-cigarettes that closely resemble a USB flash drive;¹⁵ the product's sleek design earned it the title of the "iPhone of e-cigarettes."¹⁶ The compatible flavored e-liquid is packaged in "JUULpods," flavored cartridges that contain as much nicotine as a pack of cigarettes.¹⁷ While purchasing a device and a pack of JUULpods is initially more expensive than buying a single pack of cigarettes to satisfy a traditional smoker's craving,¹⁸ the company's mission is to provide smokers an alternative to tobacco cigarettes.¹⁹

cles/2018-08-02/e-cigarette-sales-have-surged-immensely-in-the-us-cdc-study-shows (reporting that between 2012 and 2016 the price of rechargeable e-cigarettes decreased on average by nearly 50% while manufacturers saw a 154% increase in sales).

12. See generally Erin Brodwin, *An E-Cigarette with Twice the Nicotine of Comparable Devices Is Taking Over High Schools—And Scientists Are Sounding the Alarm*, BUS. INSIDER (Apr. 30, 2018), <https://www.businessinsider.com/juul-e-cig-vaping-health-effects-2018-3> (stating that JUUL "represents a third of the market share of the total e-cig category"); Jia Tolentino, *The Promise of Vaping and the Rise of the JUUL*, NEW YORKER (May 14, 2018), <https://www.newyorker.com/magazine/2018/05/14/the-promise-of-vaping-and-the-rise-of-juul> (citing a Wells Fargo study that predicts the U.S. vaporizer market to grow to \$5.5 billion dollars with 60% of that market belonging to JUUL); JUUL LABS, INC., <https://www.juul.com> (last visited Jan. 6, 2019).

13. See Laura Bach, *JUUL and Youth: Rising E-Cigarette Popularity*, CAMPAIGN FOR TOBACCO-FREE KIDS (June 8, 2018) <https://www.tobaccofreekids.org/assets/fact-sheets/0394.pdf> (reporting Wells Fargo data that JUUL's unit sales increased more than 600% in 2017, and the company's sales represent 64% of the market share).

14. See Angelica LaVito, *E-Cigarette Sales Are Booming Thanks to Juul*, CNBC (Aug. 21, 2018), <https://www.cnbc.com/2018/08/21/e-cigarette-sales-are-booming-thanks-to-juul.html>.

15. Bach, *supra* note 13, at 1.

16. Allison Eck, *The FDA Is Cracking Down on the 'iPhone of E-Cigarettes'*, PBS (Apr. 27, 2018), <http://www.pbs.org/wgbh/nova/next/body/the-fda-is-cracking-down-on-the-iphone-of-e-cigarettes/>.

17. See *Why the Rise in Youth E-Cigarette Use May Be Worse Than We Think*, TRUTH INITIATIVE (Apr. 18, 2018), <https://truthinitiative.org/news/why-rise-youth-e-cigarette-use-may-be-worse-we-think>; *Starter Kit*, JUUL LABS, INC., <https://www.juul.com/shop/devices/starter-kit> (last visited Jan. 6, 2019) (advertising that JUULpods contain five percent nicotine).

18. *Compare Device Kit*, JUUL LABS, INC., <https://www.juul.com/shop/devices/basic-kit> (last visited Jan. 23, 2019) (stating that a JUUL device costs \$34.99), and *JUUL Pods*, JUUL LABS, INC., <https://www.juul.com/shop/pods> (last visited Jan. 6, 2019) (noting that a pack of four JUULpods cartridges is \$15.99), with *Economic Trends in Tobacco*, CTRS. FOR DISEASE CONTROL & PREVENTION (May 4, 2018), https://www.cdc.gov/tobacco/data_statistics/fact_sheets/economics/econ_facts/index.htm (reporting that in 2016, the average retail price of a pack of twenty cigarettes after federal and state taxes ranged from as low as \$5.12 in Missouri to as high as \$10.66 in New York).

19. See *Our Mission*, JUUL LABS, INC., <https://www.juul.com/> (last visited Jan. 6, 2019).

One potential explanation for JUUL's instant popularity is the product's ability to mimic the user experience of traditional cigarettes.²⁰ Though JUUL has a relatively limited selection of flavors compared to some competing brands,²¹ the company's line of e-liquids incorporates salt into the concoction, which is similar to the natural ingredients of a tobacco plant and results in a stronger e-liquid.²² JUUL e-liquids produce a vapor that is smoother than other products on the market, creating a more enjoyable vaping experience for users.²³

Strategic marketing has also set the company apart from competitors. JUUL's initial marketing campaign successfully distinguished the product from other, more recognized brands, such as R.J. Reynolds, which were already established in the industry and sold numerous other tobacco products.²⁴ The company's advertisements, which used colorful, attention-grabbing designs and often featured young adults dancing, appeared on billboards in Times Square, in YouTube videos, and in *Vice* magazine.²⁵ Although it has since updated its marketing code with the goal of limiting youth exposure to its advertisements, JUUL continues to effectively advertise on social media, maintaining a strong presence on both Instagram and Twitter.²⁶

20. Tolentino, *supra* note 12 (describing JUUL as an “uncanny simulacrum” of a traditional cigarette, but without the “disgusting accoutrements . . . the tar, the carbon monoxide, the garbage mouth, [and] the smell”).

21. See, e.g., *Myblu Liquidpods*, BLU, <https://www.blu.com/en/US/flavors/myblu-liquid-pods> (last visited Dec. 27, 2018) (advertising flavors such as melon time, blueberry, green apple, and mango apricot); *Shop Pods*, JUNO VAPOR, <http://junovapor.com/Shop-JUNO-Pods> (last visited Jan. 23, 2018) (advertising flavors such as cucumber freeze, cinnamon menthol, key lime pie, and strawberry watermelon); see also *E-Liquid*, SMOKING VAPOR, <https://smokingvapor.com/e-liquid> (last visited Jan. 23, 2018). Numerous e-cigarette devices, such as the Mi-pod, now take refillable pods or cartridges so the users have access to e-liquid available at any online or brick and mortar vape shop retailer. *FAQ Mi-pod*, MI-ONE, <http://mi-one.com/faq/> (last visited Jan. 23, 2018) (stating that Mi-pod cartridges are refillable with any e-juice).

22. See Brodwin, *supra* note 12; see also Anna K. Duell et al., *Free-Base Nicotine Determination in Electronic Cigarette Liquids by ¹H NMR Spectroscopy*, CHEMICAL RES. TOXICOLOGY 431, 432–33 (2018) (finding that JUUL e-liquids contain the highest amounts of nicotine compared to competing e-liquids, but lower levels of overall nicotine freebase).

23. See Brodwin, *supra* note 12. Instead of using “straight liquid nicotine,” JUUL patented a unique formula that combines freebase liquid nicotine with salt. *Id.*

24. See Kate Keller, *Ads for E-Cigarettes Today Hearken Back to the Banned Tricks of Big Tobacco*, SMITHSONIAN.COM (Apr. 27, 2018), <https://www.smithsonianmag.com/history/electronic-cigarettes-millennial-appeal-ushers-next-generation-nicotine-addicts-180968747/> (comparing JUUL's marketing to that of Big Tobacco companies in the 1990s).

25. Bach, *supra* note 13, at 3.

26. *Id.*; see also Carolyn Crist, *Social Media Offer Insights into Teen Juul Use, Popularity*,

Unlike the documented risks associated with cigarette smoking,²⁷ there is generally a lack of conclusive evidence about the long-term effects of e-cigarette use.²⁸ A 2017 National Institutes of Health-funded study posited the potential for e-cigarettes to help one consumer group, while simultaneously putting another group at risk.²⁹ E-cigarettes might help the nearly 40 million adult smokers quit using traditional combustible cigarettes.³⁰ Conversely, the products might also lead adolescents and young adults who were never smokers to begin smoking combustible cigarettes.³¹ While the evidence about the

REUTERS (May 16, 2018, 2:11PM), <https://www.reuters.com/article/us-health-juul-social-media/social-media-offer-insights-into-teen-juul-use-popularity-idUSKCN1IH2LC> (analyzing JUUL's prominence on Twitter, where teens feel freer to discuss and promote JUUL than they do on Facebook, where their parents might see their posts). In attempt to prevent its ads from infiltrating the accounts of minor users, JUUL implemented age-restrictions for its Instagram account. See Bach, *supra* note 13, at 3. However, its Twitter account does not have these same restrictions, and there are no restrictions on JUUL-sponsored posts advertising the products or other user-generated posts. *Id.* Posts using hashtags that promote the company such as "#JUULvapor" or "#doitforJUUL" are not subject to age-restrictions, so they are still present in the social media feeds of younger users. *Id.* JUUL's "iconicity" came at a rapid pace, partially fueled by users' posts describing and displaying personal accounts of use. Amos Barshad, *The JUUL Is Too Cool*, N.Y. TIMES (Apr. 7, 2018), <https://www.nytimes.com/2018/04/07/style/the-juul-is-too-cool.html>. Social media platforms are now filled with posts demonstrating "creative" ways to use JUULs without adults noticing, such as at the dining room table during family dinner, or during class while a teacher's back is turned. *Id.* According to JUUL chief executive officer Ashely Gould, although the company has nothing to do with these posts, it has still actively tried to remove them. *Id.* Since the devices are so easily accessible and because the sweet flavors entice young consumers—evidenced by JUULs wild popularity in middle and high schools—the advertisements and the products are still making their way to young consumers. Bach, *supra* note 7, at 3.

27. See generally *Health Effects of Cigarette Smoking*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/tobacco/data_statistics/fact_sheets/health_effects/effects_cig_smoking/index.htm (lasted visited Oct. 21, 2018) (detailing the harmful effects of tobacco use).

28. WHAT'S THE BOTTOM LINE?, *supra* note 2, at 3. Since e-cigarettes are still relatively new, the U.S. Food and Drug Administration (FDA) is not entirely certain about the potential long-term health effects of the products. *Id.* at 3–4. The FDA is aware that most e-cigarettes contain nicotine, some e-cigarette aerosol can contain harmful substances, and that the devices can lead to accidental injuries. *Id.* at 2.

29. See Samir S. Soneji et al., *Quantifying Population-Level Health Benefits and Harms of E-Cigarette Use in the United States*, PLOS ONE 1, 1 (Mar. 14, 2018), <https://doi.org/10.1371/journal.pone.0193328> (positing that, as of now, e-cigarette use poses more of a population-level harm than benefit).

30. See *Current Cigarette Smoking Among Adults in the United States*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/tobacco/data_statistics/fact_sheets/adult_data/cig_smoking/index.htm (last visited Jan. 3, 2019).

31. Soneji et al., *supra* note 29, at 1.

long-term use of e-liquids is uncertain, the long-term risks associated with nicotine addiction are clear and undisputed.³² Additionally, while scientists have not yet determined all of the risks linked to e-cigarette use, existing information about the flavor additives raises red flags.³³

Even though e-cigarettes have become increasingly popular among all consumer age groups, the large contingent of adolescent users is particularly worrisome.³⁴ As of 2017, e-cigarettes were the most commonly used tobacco products among middle and high school students.³⁵ Although the numbers remained consistent to those in the 2016 study,³⁶ accurately measuring youth e-cigarette use is difficult because of the variation of products, terminology,³⁷

32. See *Know the Risks: E-Cigarettes & Young People*, U.S. SURGEON GEN., <https://e-cigarettes.surgeongeneral.gov/knowtherisks.html> (last visited Jan. 23, 2018). Until around age twenty-five, the brain is still growing and forming synapses, which form faster in adolescent brains than in adult brains. *Id.* Nicotine alters the formation of brain synapses, which control attention and learning functions and can increase the likelihood of addiction to other drugs, such as cocaine. *Id.*; see also Benjamin J. Apelberg et al., *Potential Public Health Effects of Reducing Nicotine Levels in Cigarettes in the United States*, 378 NEW ENG. J. MED. 1725, 1725 (2018) (noting that addiction to nicotine in tobacco products is the proximate cause of the majority of smoking-related diseases because it “sustains smoking behavior”).

33. Soneji et al., *supra* note 29, at 12. The aerosols carry high levels of organic compounds called aldehydes, which can inhibit cardiovascular function. *Id.* E-cigarette use can also produce fine particles that can accelerate the onset of heart disease. *Id.*

34. U.S. DEP’T OF HEALTH & HUMAN SERVS., *E-CIGARETTE USE AMONG YOUTH AND YOUNG ADULTS: A REPORT OF THE SURGEON GENERAL* vii (2016), https://e-cigarettes.surgeongeneral.gov/documents/2016_sgr_full_report_non-508.pdf (reporting that since 2011, e-cigarette use among youths has increased by 900%).

35. See Teresa W. Wang et al., *Tobacco Product Use Among Middle and High School Students—United States, 2011–2017*, 67 CDC MORBIDITY & MORTALITY WKLY. REP. 629, 629 (2018), <https://www.cdc.gov/mmwr/volumes/67/wr/pdfs/mm6722a3-H.pdf>. The 2017 National Youth Tobacco Survey reported that roughly 1.73 million high schoolers and 390,000 middle schoolers were currently using e-cigarettes nationwide. *Id.*

36. See Press Release, Food & Drug Admin., Statement from FDA Statement of Commissioner Scott Gottlieb, M.D., on 2017 National Youth Tobacco Survey Results and Ongoing FDA Efforts to Protect Youth From the Dangers of Nicotine and Tobacco Products (June 7, 2018), <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm610206.htm> [hereinafter Press Release, Statement of Scott Gottlieb] (noting that the FDA is dedicated to decreasing the “disturbingly high number” of adolescents using vape and e-cigarette products).

37. *Why the Rise in Youth E-Cigarette Use May Be Worse Than We Think*, *supra* note 17 (“But accurately measuring youth vaping is challenging because of the variety of products and their rapid growth in recent years [T]he terminology surrounding these electronic devices continues to evolve and may not be accurately captured in survey options [A] young person who says they ‘vape’ or ‘JUUL’ may not consider the products they use to be e-cigarettes and may not report use on a survey . . .”).

its rapid growth over the last few years,³⁸ and because most of the data is self-reported and based on survey results.³⁹

Part I of this Comment briefly provides a synopsis of the FDA's rulemaking authority under the Administrative Procedure Act (APA) and reviews the Advance Notice of Proposed Rulemaking issued in March 2018 about the role of flavors in attracting youth e-cigarette users. It then examines the scope of the FDA's regulatory authority over e-cigarettes in light of the 2016 Deeming Rule, discussing the relevant portions of the TCA and the Food, Drug, and Cosmetic Act (FDCA). Part II outlines the viewpoints and major arguments of both proponents and opponents of banning flavored e-cigarettes. In Part III, this Comment argues that while there is some evidence that e-cigarettes are beneficial to cigarette smokers trying to quit, flavored e-cigarettes are attracting youth users and current regulatory efforts are ineffective, so the FDA should restrict available flavors to only menthol and tobacco.

I. THE SCOPE OF THE FDA'S REGULATORY AUTHORITY

A. *The FDA's Rulemaking Process*

Under the APA, the FDA has the authority to create rules.⁴⁰ The FDA promulgates such regulations in the *Federal Register* through notice-and-comment rulemaking.⁴¹ The first step is usually a Notice of Proposed Rulemaking, which explains how the agency intends to use its regulatory authority and the scientific and medical bases for the action it intends to take.⁴² Citizens are then able to submit comments that are public and accessible on the *Federal Register* website.⁴³ When the FDA wants more input before promulgating a rule, it issues an Advance Notice of Proposed Rulemaking

38. *Id.* (reporting that youth e-cigarette use increased tenfold between 2011 and 2015, causing the surgeon general to declare e-cigarette use among young people a “public health concern” in 2016).

39. *Id.*

40. See Administrative Procedure Act, 5 U.S.C. § 553 (2012). Notice-and-comment rulemaking occurs when the FDA publishes a new rule in the *Federal Register* and gives the public the opportunity to weigh in before codifying the rule. *FDA Rules and Regulations*, FOOD & DRUG ADMIN. (Mar. 28, 2018), <https://www.fda.gov/regulatoryinformation/rulesregulations/default.htm>. Formal rulemaking is less common and only necessary when a statute explicitly requires a hearing on the record. See TODD GARVEY, CONG. RESEARCH SERV., R41546, A BRIEF OVERVIEW OF RULEMAKING AND JUDICIAL REVIEW 3 (2017). The hearing is before an administrative law judge and the agency must present evidence, as the burden is on the proponent of the rule. See *id.*; 5 U.S.C. § 553.

41. *FDA Rules and Regulations*, *supra* note 40.

42. *Id.*

43. *Id.*

(ANPRM), asking for public comments and requesting data and research about particular topics.⁴⁴ The FDA uses this information to formulate a proposed rule, considering the public's opinion in conjunction with the relevant scientific and medical evidence.⁴⁵ The next step after issuing a proposed rule and reviewing the public comments is either to terminate the rulemaking process or to issue a final rule.⁴⁶ When the FDA promulgates final rules, it addresses the public comments.⁴⁷ The *Federal Register* publishes final rules, while the *Code of Federal Regulations* publishes the codified portion in Title 21.⁴⁸

B. *The History of the FDA's Tobacco Regulation*

The FDA first exercised regulatory jurisdiction over tobacco products in 1996 through the “drug-device” provision of the FDCA, asserting that nicotine was a “drug,” and cigarettes and smokeless tobacco products were “devices that deliver nicotine to the body.”⁴⁹ The Supreme Court rejected the FDA's authority to regulate tobacco products and held that Congress intended to exclude tobacco products from the FDA's jurisdiction under the FDCA because ruling otherwise would contradict congressional intent.⁵⁰ Instead, the Court interpreted the FDCA as aiming to protect commerce and the national economy by requiring consumers be informed about any potentially adverse health effects that could result from use of the products, and directed the FDA to weigh the probable therapeutic benefits of the devices to the consumer against the potential risks.⁵¹

A decade later, the FDA attempted to assert regulatory authority over e-cigarettes through the FDCA. In *Smoking Everywhere v. FDA*,⁵² Smoking Everywhere, an e-cigarette distributor, challenged the FDA's authority under the drug-device provision of the FDCA.⁵³ The court held that the drug-device provision did not apply to e-cigarettes because they were sold for “customary

44. *Id.*

45. *Id.*

46. *Id.*

47. *Id.*

48. *Id.*

49. *See* *FDA v. Brown & Williamson Corp.*, 529 U.S. 120, 120 (2000).

50. *Id.* at 121–22 (noting that interpreting the Food, Drug, and Cosmetic Act (FDCA) to give the FDA authority to regulate tobacco products would contradict congressional intent).

51. *Id.* at 140–41 (ruling that the FDA's job was to strike a balance between the benefits of the use of certain products, not to weigh the risks of leaving products on the market against the risk of taking them off the market).

52. 680 F. Supp. 2d 62 (D.D.C. 2010).

53. *Id.* at 63. Plaintiffs brought action against the FDA after United States Customs denied entry of a shipment of their e-cigarettes. *Id.* at 64.

recreational use” like combustible cigarettes.⁵⁴ This ruling was a victory for tobacco companies at the time because it established that e-cigarettes were not subject to FDA regulation under the drug-device provision of the FDCA.⁵⁵

Despite the result in *Smoking Everywhere* and similar decisions,⁵⁶ the FDA was eventually victorious in regulating e-cigarettes through the TCA.⁵⁷ The TCA amended the FDCA with the goal of discouraging minors and youth from smoking tobacco products⁵⁸ and gave the FDA more regulatory authority over the tobacco industry.⁵⁹ Following the TCA’s passage, the FDA had the authority to regulate the manufacturing, distributing, and marketing of tobacco products, including e-cigarettes.⁶⁰

In August 2016, after the explosion of e-cigarettes onto the market, the FDA finalized the Deeming Rule.⁶¹ Most recently, the United States District Court for the District of Columbia had the opportunity to rule on the Deeming Rule as it pertained to Nicopure Labs, the manufacturer of a battery-

54. *Id.* at 73.

55. *Id.* *But cf. id.* at 72 (“Congress enacted the Tobacco Act to confer FDA jurisdiction over any tobacco product—whether traditional or not—that is sold for customary recreational use, as opposed to therapeutic use.”).

56. *See, e.g.,* *Sottera, Inc. v. FDA*, 627 F.3d 891, 898–99 (D.C. Cir. 2010) (establishing that the FDA could only regulate products which claimed therapeutic effect under the drug-device provision of the FDCA).

57. Family Smoking Prevention and Tobacco Control Act of 2009, Pub. L. No. 111-31, § 3(4), 123 Stat. 1776, 1782 (codified as amended at 21 U.S.C § 387 (2018)).

58. *Id.* § 3(2).

59. *Id.* § 3(8); *A Historical Timeline of Electronic Cigarettes*, *supra* note 6.

60. *See* Family Smoking Prevention and Tobacco Control Act § 3; *see, e.g.,* 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; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 81 Fed. Reg. 28,975, 29,073 (May 10, 2016) (to be codified at 21 C.F.R. pts. 1100, 1140, 1143) (promulgating a rule stating that the FDA has authority to regulate e-cigarettes) [hereinafter Deeming Rule]; *see also* *Family Smoking Prevention and Tobacco Control Act- An Overview*, U.S. FOOD & DRUG ADMIN. (Jan. 17, 2018), <https://www.fda.gov/tobaccoproducts/guidancecomplianceinformation/ucm246129.htm> (establishing a special rule for combustible cigarettes banning characterizing flavors, except for tobacco and menthol flavors, and vesting the FDA with the authority to protect public health through the implementation of product standards and regulation of nicotine and ingredient levels).

61. Deeming Rule, 81 Fed. Reg. at 29,073. This amendment to the TCA expanded the FDA’s authority to all categories of “tobacco products,” including e-cigarettes. *Id.* at 29,074. After the FDA deems a product to be a tobacco product, it can then restrict its sale, distribution, and advertisement. *Id.* at 28,975. While this action was a significant step toward regulating e-cigarettes, the Deeming Rule did not implement any rules applying to flavors. *Id.* at 29,055.

powered closed-system e-cigarette.⁶² The court ruled in favor of the FDA and held that the agency had acted within the scope of its authority under the TCA and the APA when it classified e-cigarettes and nicotine-free e-liquids as “tobacco products” subject to its regulation.⁶³ The case is currently on appeal.⁶⁴

In 2018, the FDA addressed the issue of youth e-cigarette use directly. FDA Commissioner Scott Gottlieb announced the implementation of the Youth Tobacco Prevention Plan in March 2018.⁶⁵ Later, in September, the FDA announced “critical and historic” actions impacting the e-cigarette industry.⁶⁶ In a statement to the public, Commissioner Gottlieb characterized the youth e-cigarette use as reaching “epidemic proportions.”⁶⁷ The FDA

62. See *Nicopure Labs v. FDA*, 266 F. Supp. 3d 360 (D.D.C. 2017). Closed-system e-cigarettes are devices that users cannot modify because the battery, coil, and chamber that hold the e-liquid are self-contained. See *About Electronic Cigarettes*, CONSUMER ADVOC. FOR SMOKE FREE ALTERNATIVES ASS’N, <http://www.casaa.org/electronic-cigarettes/> (last visited Jan. 5, 2019).

63. *Nicopure Labs*, 266 F. Supp. 3d at 368.

64. Notice of Appeal, *Nicopure Labs*, 266 F. Supp. 3d 360 (No. 1:16-cv-0878-ABJ).

65. Press Release, Food & Drug Admin., Statement from FDA Commissioner Scott Gottlieb, M.D., on New Enforcement Actions and a Youth Tobacco Prevention Plan to Stop Youth Use of, and Access to, JUUL and Other E-Cigarettes (Apr. 24, 2018), <https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm605432.htm> [hereinafter Press Release, April Statement from FDA Commissioner Scott Gottlieb]. The first step of the plan was to crack down on brick and mortar retailers through a large-scale undercover blitz, which, even at its early stages, revealed many violations of the law. *Id.*; Editorial Board, *The FDA Should Let E-Cigarettes Help Adults—But Not Hook Kids*, WASH. POST (May 7, 2018), https://www.washingtonpost.com/opinions/the-fda-should-let-e-cigarettes-help-adults-but-not-hook-kids/2018/05/07/4faceb8e-4d75-11e8-b725-92c89fe3ca4c_story.html?utm_term=.81677d7634af (reporting that the FDA employed underage decoys to buy e-cigarettes and e-liquids from gas stations and other retailers which resulted in at least forty citations). The next step in the plan was to reach out to online retailers about listings advertising the sale of e-cigarettes, and then to contact manufacturers to hold them directly accountable. Press Release, Food & Drug Admin., 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. 12, 2018), <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm620184.htm> [hereinafter Press Release, FDA Takes New Steps to Address Epidemic of Youth E-Cigarette Use]. The plan also aims to shape additional enforcement actions against manufacturer campaigns that intentionally mislead youth consumers. *Id.*; see *infra* Part III.

66. Press Release, FDA Takes New Steps to Address Epidemic of Youth E-Cigarette Use, *supra* note 65.

67. *Id.* (describing how over 1300 warning letters and fines resulted from the FDA’s retailer blitz conducted in March); see also Sheila Kaplan & Jan Hoffman, *FDA Targets Vaping, Alarmed by Teenage Use*, N.Y. TIMES (Sept. 12, 2018), <https://www.nytimes.com/2018/09/12/health/juul-fda-vaping-ecigarettes.html> (quoting Commissioner Gottlieb) (“[W]e are

required five of the top-selling brands to submit a plan detailing how they will address the widespread youth access to their products.⁶⁸ The agency gave these retailers sixty days to produce plans.⁶⁹ Failing to produce plans or submitting inadequate plans might result in the FDA removing the flavored products from the market.⁷⁰

In October 2018, in response to Commissioner Gottlieb's September announcement and orders for plans to address youth access, tobacco giant Altria Group announced that it was removing its flavored e-cigarette products from the market until the FDA is able to review and approve the company's flavored e-liquids.⁷¹ Altria was the first of the five companies named in the FDA's September demand to respond with plans addressing the e-cigarette epidemic impacting the nation's youth.⁷² Less than a month later, JUUL suspended the sale of most of its flavored pods in retail stores.⁷³ The company also suspended its Facebook and Instagram accounts to prevent ads from reaching underage users.⁷⁴ The announcement came with a caveat that

going to have to contemplate . . . actions that may narrow the off-ramp for adults who see e-cigarettes as a viable alternative to tobacco in order to close the on ramp for kids It's an unfortunate trade-off.”)

68. Press Release, FDA Takes New Steps to Address Epidemic of Youth E-Cigarette Use, *supra* note 65.

69. *Id.*

70. *Id.* (acknowledging that flavored products have amplified youth e-cigarette use); see also M.B. Harrell et al., *Flavored E-Cigarette Use: Characterizing Youth, Young Adult, and Adult Users*, 5 PREVENTATIVE MED. REP. 33, 34 (2016) (noting that youth e-cigarette users are attracted to novel flavors of e-cigarettes).

71. See Letter from Howard A. Willard III, Chairman and Chief Exec. Officer, Altria Grp., Inc., to Scott Gottlieb, Comm'r, FDA (Oct. 25, 2018), <http://www.altria.com/About-Altria/Federal-Regulation-of-Tobacco/Regulatory-Filing/FDAFilings/Altria-Response-to-FDA-E-vapor-October-25-2018.pdf>; see also Craig Giammona, *Altria Pulls E-Cig Flavors After FDA Cracks Down on Youth Usage*, BLOOMBERG (Oct. 25, 2018), <https://www.bloomberg.com/news/articles/2018-10-25/altria-pulls-e-cig-flavors-after-fda-cracks-down-on-youth-usage> (reporting that Altria was removing all flavors except tobacco, menthol, and mint).

72. See Angelica LaVito, *Altria Has More to Gain Than Lose in Voluntarily Pulling E-Cigarette Pods and Most Flavors, as FDA Cracks Down on Teen Use*, CNBC (Oct. 25, 2018), <https://www.cnbc.com/2018/10/25/altria-voluntarily-pulls-e-cigarette-pods-flavors-amid-fda-crackdown.html> (observing that Altria is the first company to publicly share its response to the FDA); see also *supra* Section I.A (describing the FDA's rulemaking process).

73. See Sheila Kaplan & Jan Hoffman, *Juul Suspends Selling Most E-Cigarette Flavors in Stores*, N.Y. TIMES (Nov. 13, 2018), <https://www.nytimes.com/2018/11/13/health/juul-e-cigarettes-vaping-teenagers.html> (reporting that JUUL would continue to sell mint, tobacco, and menthol flavored pods in retail stores, but that the company would remove characterizing flavors and advertisements from the market).

74. Jia Tolentino, *Goodbye to JUUL Season*, NEW YORKER (Nov. 15, 2018), <https://www.newyorker.com/news/news-desk/goodbye-to-juul-season>.

JUUL would renew sales to retailers that invested in age-verification technology,⁷⁵ which would not prevent the company from eventually putting the flavors back on shelves.⁷⁶

Through its authority granted by the Deeming Rule, the FDA has taken further action to regulate e-cigarettes. On March 21, 2018, the agency issued an ANPRM regarding the regulation of flavors in e-cigarettes titled Regulation of Flavors in Tobacco Products.⁷⁷ The purpose of this ANPRM was to gather information about the role that flavored tobacco products play in attracting youth users.⁷⁸ The FDA also considered whether flavors contain or have the ability to form toxic compounds, as some of these chemicals in flavor additives that are safe for ingestion become poisonous once e-cigarette users heat and inhale them.⁷⁹ Potential regulatory action that could result from the ANPRM is the implementation of tobacco product standards and restrictions on the sale and distribution of flavored tobacco products.⁸⁰

II. BOTH SIDES OF THE FENCE

The comment period for the Regulation of Flavors in Tobacco Products Proposed Rule officially closed on July 19, 2018.⁸¹ Public input was a mix of former smokers chiming in to note the role that flavored vaping products played in their cessation and concerned parents and medical professionals urging the FDA to remove flavors from the marketplace before a new generation becomes addicted to nicotine.⁸² Many smokers voiced their outrage that the FDA would ban flavored e-cigarettes, which some credited as the reason for successful cessation and expressed fear that this change would cause their own relapse to combustible cigarettes.⁸³ Conversely, other comments came from parents demanding FDA intervention because of fears that

75. See Kaplan & Hoffman, *supra* note 73.

76. *Id.*

77. See Regulation of Flavors in Tobacco Products, 83 Fed. Reg. 12,294 (proposed Mar. 21, 2018) (to be codified at 21 C.F.R. pts. 1100, 1140, 1143).

78. *Id.*

79. See *id.* at 12,298. Certain substances that the FDA has previously considered “generally recognized as safe” (GRAS) do not also possess a GRAS status for inhalation. *Id.* The effects of chemical exposure via inhalation can be drastically different than exposure via ingestion. *Id.*

80. *Id.* at 12,294 (providing the FDA with authority to drastically alter the e-cigarette industry).

81. Regulation of Flavors in Tobacco Products, REGULATIONS.GOV, <https://www.regulations.gov/docketBrowser?rpp=50&so=DESC&sb=postedDate&po=0&dct=PS&D=FDA-2017-N-6565> (last visited Jan. 6, 2019).

82. *Id.*

83. See Anonymous, Comment on Regulation of Flavors in Tobacco Products (May 22, 2018), <https://www.regulations.gov/document?D=FDA-2017-N-6565-8298> (“Flavors in e-

the tobacco industry is targeting their children.⁸⁴ Commenters, regardless of their respective opinions, delivered consistently passionate input among the more than 23,000 comments, demonstrating that this issue remains important and in contentious debate among the American public.⁸⁵

Much like these ANPRM commentators, many proponents of e-cigarette regulation consistently point to the “epidemic” of use in schools and among youth.⁸⁶ Particularly with flavored varieties, e-cigarettes are extremely alluring, with statistics showing that over eighty percent of youth e-cigarette users continue to use the products because of the available flavors.⁸⁷ Unlike a traditional combustible cigarette, e-cigarettes do not produce smoke.⁸⁸ Instead, the devices emit sometimes unnoticeable and odorless vapor making their use extremely difficult for school administrators and parents to detect, so much so that some students are even vaping in class.⁸⁹ Even though these

liquid are the only reason I had the drive to quit smoking. If there were only tobacco flavors I would still be smoking cigarettes. Please don't ban flavors.”); Anonymous, Comment on Regulation of Flavors in Tobacco Products (May 23, 2018), <https://www.regulations.gov/document?D=FDA-2017-N-6565-10025> (“Please don't ban flavors. If it weren't for all the flavors I would've never been successful in quitting . . . and if flavors are banned, I would more than likely end up smoking again. Banning flavors will not stop children from wanting to rebel and use tobacco products, but it will negatively affect probably the majority of people who vape.”).

84. See Anonymous, Comment on Regulation of Flavors in Tobacco Products (Apr. 25, 2018), <https://www.regulations.gov/document?D=FDA-2017-N-6565-4405> (“I am a high school biology teacher. I have confiscated over a dozen vaporizers in less than a month that contain 30–50mg nicotine. 100% of the kids I took them from said they started to use the devices because they LOVE the flavors. HIGH SCHOOL KIDS ARE NOW NICOTINE ADDICTS.”); Anonymous, Comment on Regulation of Flavors in Tobacco Products (Aug. 7, 2018), <https://www.regulations.gov/document?D=FDA-2017-N-6565-21047> (“Just as Marlboro used the Marlboro man to convince teenagers that smoking was cool, now tobacco companies are targeting youth with flavored products that get them addicted to nicotine young. It's the same trick for a different generation, and it is ruining the health of our youth.”).

85. See *supra* note 84 and accompanying text; Anonymous, Comment on Regulation of Flavors in Tobacco Products (May 22, 2018), *supra* note 83; *Regulation of Flavors in Tobacco Products*, *supra* note 81.

86. See Anne Marie Chaker, *Schools and Parents Fight a Juul E-Cigarette Epidemic*, WALL ST. J. (Apr. 4, 2018, 4:49 p.m.), <https://www.wsj.com/articles/schools-parents-fight-a-juul-e-cigarette-epidemic-1522677246>.

87. See Harrell et al., *Flavored E-Cigarette Use*, *supra* note 70, at 34 (suggesting that flavors contribute to the novelty of the e-cigarettes and make them more attractive to youth users). Equally problematic, e-cigarettes, especially JUULs, are often manufactured to look like USB drives, and users can charge the devices in a computer's USB port. Chaker, *supra* note 86.

88. See *About Electronic Cigarettes*, *supra* note 62 (describing e-cigarette vapor as “smoke-like”).

89. See Kate Zernike, *'I Can't Stop': Schools Struggle with Vaping Explosion*, N.Y. TIMES (Apr. 2, 2018), <https://www.nytimes.com/2018/04/02/health/vaping-cigarettes-addiction-teen>.

devices are already small enough to fit in a closed fist, some businesses have jumped at the chance to market a line of products that are specifically designed to disguise use of e-cigarettes.⁹⁰

School administrations nationwide have also implemented preventative measures to discourage students from using e-cigarettes.⁹¹ Most commonly, schools confiscate the devices and suspend students caught using them.⁹² Since there are some e-cigarettes that teens can use to smoke marijuana, several schools have instated policies that require drug testing any student caught using e-cigarettes.⁹³ Additionally, because e-cigarette use is especially common in school bathrooms, some schools elected to remove bathroom

html. Some schools have gone to such lengths as to ban USB drives on school campuses because administrators are unable to differentiate e-cigarettes from the memory devices. *See* Shawnette Wilson, *School District Bans Flash Drives Over Confusion with E-Cigarette Brand*, FOX 29 (Feb. 23, 2018), <http://www.fox29.com/news/upper-dublin-school-district-bans-flash-drives-over-confusion-with-e-cigarette-brand>. After reports that students were using school computers to charge JUULs, Upper Dublin Pennsylvania school district decided to ban flash drives because “they look too much like an e-cigarette brand.” *Id.* Administrators also noted the size and concealability of the products and the resulting ability of students to successfully trick teachers into believing that the devices are USB drives. *Id.*

90. *See, e.g.*, RIP TECHS. LLC, <https://www.rip-store.com> (last visited Jan. 6, 2019) (detailing accessories meant for decorating and holding JUULs). VaprWear produced a line of hooded sweatshirts and backpacks designed to conceal e-cigarettes. *See* VAPRWEAR, <https://vaprwear.com> (last visited Jan. 6, 2019); Zernike, *supra* note 89. MightySkins manufactures decals customized for various vape devices. *Vape Skins*, MIGHTYSKINS, <https://mightyskins.com/pages/e-cigs-vapes> (last visited Jan. 6, 2019). One of the stickers copycats the exterior of a USB device, demonstrating how these decals make JUULs even easier to conceal. *Americana Collection Pax Juul Skin*, MIGHTYSKINS, <https://mightyskins.com/collections/pax-juul-skins/products/paxjuul-par-americana?variant=13841902141499> (last visited Jan. 6, 2019).

91. *See generally* Collin Binkley, *Schools Fret as Teens Take to Vaping, Even in Class Rooms*, U.S. NEWS & WORLD REP. (Apr. 29, 2018), <https://www.usnews.com/news/healthiest-communities/articles/2018-04-29/schools-fret-as-teens-take-to-vaping-even-in-classrooms> (detailing school officials’ alarm at the wave of teenage vape use); Vicki Ortiz Healy, *More Teens Sneaking Vaping Devices That Look like Flash Drives, Markers into Suburban High School*, CHI. TRIB. (Feb. 20, 2018), <http://www.chicagotribune.com/news/ct-met-juul-ecigarettes-at-schools-20180209-story.html> (discussing the preventative efforts of school administrators across the country and demonstrating that the problem is widespread); Zernike, *supra* note 89 (describing the growing use of e-cigarettes in schools).

92. *See Schools Are Handing Out Harsh Punishments for E-Cigarette Use*, FOX NEWS (Mar. 26, 2018), <http://www.foxnews.com/us/2015/02/15/schools-handing-out-harsh-punishments-for-e-cigarette-use.html>. Other punishments include detention, a letter home, tobacco education class, suspension, mandatory drug testing, and possession of drug paraphernalia listed on the student’s record. *Id.*

93. Binkley, *supra* note 91.

stall doors and have installed vaping alarms and detectors.⁹⁴

A recent lawsuit blames JUUL for youth nicotine addiction⁹⁵ through false claims of safety via the company's advertising and labeling.⁹⁶ The complaint points out that JUULpods contain three times more nicotine than the necessary amount to satisfy an adult smoker's nicotine craving, and that the product delivers the nicotine through an aerosolized vapor deliberately designed to taste like candy.⁹⁷ The plaintiff, D.P., was a fifteen-year-old high school freshman when he first used a JUUL in September 2017.⁹⁸ He quickly became addicted to the nicotine in the product.⁹⁹

Legislators are concerned that high levels of nicotine will lead to addiction or serve as a "gateway to combustible tobacco cigarettes," encouraging experiential use of other tobacco products among youth users.¹⁰⁰ Because the majority of cigarette-smoking adults in the United States began smoking during their youth,¹⁰¹ proponents are passionate about preventing a new generation from becoming addicted to tobacco products.¹⁰² Furthermore, since

94. See Lynh Bui, *Juuling: If You Don't Know What It Is, Ask Your Kids*, WASH. POST. (May 10, 2018), https://www.washingtonpost.com/local/public-safety/juuling-if-you-dont-know-what-it-is-ask-your-kids/2018/05/09/37e2f026-4d65-11e8-84a0-458a1aa9ac0a_story.html?utm_term=.6c4a9f32d8c5. A high school principal in Annapolis, Maryland approved the removal of bathroom stall doors to prevent students from vaping in bathrooms, and an entire school system in New Jersey installed vape detectors in its high schools. *Id.* At a high school in Placerville, California, administrators closed all but two bathrooms. Zernike, *supra* note 89 (explaining that JUULs are easy to share and that students commonly use them in bathroom stalls). The school has an employee monitor how many students are in the bathroom at once to reduce the occurrence of vaping in school bathrooms. *Id.*

95. See Complaint & Demand for Jury Trial ¶ 41, *D.P. v. JUUL Labs Inc.*, No. 7:18-cv-05758 (S.D.N.Y. June 26, 2018). Even the e-liquids that are tobacco-free still contain nicotine, which has known negative health effects. WHAT'S THE BOTTOM LINE?, *supra* note 2, at 3. The drug is highly addictive, potentially harmful to adolescent brain development, and can be very dangerous to pregnant women and their developing fetuses. *Id.*

96. See Complaint & Demand for Jury Trial ¶¶ 2, 35, 41, *D.P. v. JUUL Labs Inc.*, No. 7:18-cv-05758.

97. *Id.* ¶ 1. Neither the products, nor their packaging, contained warnings about the existence of nicotine or the risk of nicotine addiction. *Id.* at ¶ 12.

98. *Id.* ¶¶ 2, 45, 46 (noting that D.P.'s high school was an environment where JUUL usage was pervasive and that other students offered him "hits" of their JUULs throughout the day).

99. *Id.* ¶¶ 2, 46, 47 (articulating that the minor's addiction drastically changed his behavior and his performance in school).

100. See *Aggressive E-Cigarette Marketing and Potential Consequences for Youth: Hearing Before the Subcomm. on Commerce, Sci., & Transp.*, 113th Cong. 5 (2014) (statement of North Dakota Sen. John Thune).

101. Apelberg et al., *supra* note 32, at 1725.

102. See Zernike, *supra* note 89 (quoting Dr. Mark L. Rubinstein, "I'm afraid that we're going to be hooking a new generation of kids on nicotine, with potentially unknown risks");

the age that a person begins smoking can dictate the frequency of his or her smoking and the individual's proneness to tobacco-related disease and death,¹⁰³ now is the time to promulgate a rule to prevent these avoidable deaths.

Proponents also argue that many young consumers are often unaware that the e-liquids they are using contain nicotine.¹⁰⁴ Because some have dubbed e-cigarettes as the "safer alternative" to combustible cigarettes, many children use them under the incorrect perception that they are harmless and without knowledge that the products still contain nicotine.¹⁰⁵ While there are some varieties of e-liquids that do not contain nicotine,¹⁰⁶ most do.¹⁰⁷ There have even been some instances where products were labeled as nicotine-free, but actually contained nicotine.¹⁰⁸

The evidence about the dangers of nicotine addiction in general and especially in children is fairly straightforward.¹⁰⁹ However, consumers fail to

Press Release, Statement of Scott Gottlieb, *supra* note 36 (warning that without intervention into e-cigarettes, a new generation of kids could become hooked to nicotine and tobacco products); *see also* U.S. DEP'T OF HEALTH & HUMAN SERVS., *supra* note 34, at v (suggesting "cost-effective, evidence-based, lifesaving strategies . . . [to] protect the health of our nation's young people")

103. *See* Apelberg, *supra* note 32, at 1725.

104. *See* JUUL E-Cigarettes Gain Popularity Among Youth, But Awareness of Nicotine Presence Remains Low, TRUTH INITIATIVE (Apr. 18, 2018), <https://truthinitiative.org/news/juul-e-cigarettes-gain-popularity-among-youth> (reporting that 63% of JUUL users were not aware that product always contains nicotine even though all of the flavor varieties have always contained nicotine).

105. *See* Janine Wolf, *Teens Love Vaping Flavors, and It's a Regulatory Nightmare*, BLOOMBERG (Apr. 26, 2018), <https://www.bloomberg.com/news/articles/2018-04-26/teens-love-vaping-flavors-and-it-s-a-regulatory-nightmare> (explaining that kids often believe they are only vaping flavors, but that the nicotine content is "considerably higher" than what the packaging states); WHAT'S THE BOTTOM LINE?, *supra* note 2, at 3 (noting how nicotine is highly addictive, toxic to developing fetuses, can alter adolescent brain development even into the mid-twenties, and is dangerous for pregnant women).

106. *See* Diana Crow, *Some E-Cigarette Flavors May Be More Harmful Than Others*, ATLANTIC (Nov. 28, 2017), <https://www.theatlantic.com/health/archive/2017/11/e-cigarette-flavors/546914/>.

107. *Why the Rise in Youth E-Cigarette Use May Be Worse Than We Think*, *supra* note 17. Despite data indicating that 99% of e-cigarette products sold in 2015 contained nicotine, 36% of twelfth graders participating in a University of Michigan survey reported vaping, but only one quarter of those high school seniors said they vaped nicotine. *Id.*

108. WHAT'S THE BOTTOM LINE?, *supra* note 2, at 2.

109. Lucinda J. England et al., *Nicotine and the Developing Human: A Neglected Element in the Electronic Cigarette Debate*, 49 AM. J. PREVENTATIVE MED. 286, 289-90 (2015) (detailing the detrimental impact of nicotine exposure to the adolescent brain); *Electronic Cigarettes (E-Cigarettes)*, *supra* note 2 (discussing how nicotine is highly addictive and can alter the brain's reward system which puts e-cigarette users at risk for addiction to other drugs).

consider the chemical ingredients of the e-liquids they are inhaling with each puff of an e-cigarette.¹¹⁰ While e-cigarette users are not inhaling many of the cancer-causing chemicals found in tobacco cigarettes, they are instead inhaling aerosol, which contains other potentially harmful substances.¹¹¹ Aside from the ultrafine particles that are inhaled deep into smokers' lungs, there is also unsettling research about the possibly harmful effects of the flavor additives.¹¹² Many of these chemicals have been found safe to ingest in small amounts, but once e-cigarette devices vaporize the compounds, they become unsafe to inhale.¹¹³

Even in nicotine-free e-liquids, researchers have observed the damaging effects on users' lungs.¹¹⁴ Scientific evidence indicates that e-cigarette use

110. WHAT'S THE BOTTOM LINE?, *supra* note 2, at 2 (noting that consumers do not know what chemicals are in an e-cigarette); *see also* Regulation of Flavors in Tobacco Products, 83 Fed. Reg. 12,294, 12,298 (Mar. 21, 2018) (to be codified at 21 C.F.R. pts. 1100, 1140, 1143) (naming some toxic compounds found in e-cigarettes).

111. WHAT'S THE BOTTOM LINE?, *supra* note 2, at 2 (listing volatile organic compounds, ultrafine particles, cancer-causing chemicals, heavy metals such as nickel, tin, and lead, nicotine, and diacetyl).

112. Rubinstein et al., *supra* note 5, at 2, 8 (mentioning that e-cigarettes often contain additives such as propylene glycol or glycerol that can form carcinogenic compounds when heated). This study determined that a flavored e-cigarette user is exposed to volatile organic compounds like propylene oxide, acrylamide, acrylonitrile, and crotonaldehyde, regardless of whether the e-liquid contains nicotine. *Id.* Based on their results, Rubinstein and his co-authors challenge the idea that e-cigarette vapor is safe to inhale. *Id.*

113. *See* Sara Shipley Hiles, *Nicotine Isn't the Only Hazard to be Found in E-Cigarettes*, CHI. TRIB. (Sept. 20, 2015), <http://www.chicagotribune.com/lifestyles/health/ct-cigarette-hazards-20150918-story.html> (cautioning that cinnamon-flavored e-liquids contain cinnamaldehyde, which lab tests have demonstrated is highly toxic to human cells and can cause swollen throats and mouth sores, and that vanilla-flavored e-liquids contain aldehydes, which can cause respiratory irritation and constriction); *see also* *Know the Risk*, *supra* note 32, at 99 (identifying diacetyl and benzene, a volatile organic compound found in car exhaust and heavy metals); *Myths: Are Nicotine-Free E-Cigarettes Harmful?*, CTR. ON ADDICTION (Oct. 2018), <https://www.centeronaddiction.org/e-cigarettes/tobacco-replacement/are-nicotine-free-e-cigarettes-harmful> (stating that the chemicals found in most flavored e-cigarettes are safe to ingest, but become dangerous when users repeatedly inhale them).

114. *See* Lisa Rapaport, *Even Without Nicotine, E-Cigarettes Can Still Damage Lungs*, REUTERS (Feb. 9, 2018), <https://www.reuters.com/article/us-health-ecigarettes/even-without-nicotine-e-cigarettes-can-still-damage-lungs-idUSKBN1FT2QE>. Researchers exposed white blood cells to the chemicals used to flavor popular nicotine-free e-cigarette liquids and found that this chemical exposure caused many cells to die and also produced biomarkers for inflammation and tissue damage. *Id.* Cinnamon and vanilla flavors appeared to be the most toxic to lungs, but the study did not examine more complex flavors with flashy names and a mixture of many flavoring chemicals that are often even more enticing to youth. *Id.*; *see also* Eck, *supra* note 16 (noting that cinnamaldehyde is effective in shutting down immune cells that protect the body against invading pathogens); *Myths*, *supra* note 113 (reporting that once heated, many

increases risk for developing serious long-term health conditions such as heart disease, lung cancer, and bladder cancer.¹¹⁵ Other studies have reported that e-cigarette usage is linked to dangerous, potentially permanent conditions like “popcorn lung.”¹¹⁶ E-cigarettes have not been on the market for very long, so there is limited long-term evidence about their health effects.¹¹⁷ However, given the available data it is understandable why medical professionals and lawmakers are in favor of regulation.¹¹⁸

Conversely, the opponents of e-cigarette regulation consistently argue that there are no known negative long-term health effects associated with e-cigarette use.¹¹⁹ However, the risks associated with nicotine addiction and early

of the chemicals used in nicotine-free e-liquid have serious health consequences such as cancer, lung disease, and respiratory disease).

115. See Janine Wolf, *E-Cigarettes May Lead to Cancer and Heart Disease, New Study Finds*, BLOOMBERG (Jan. 29, 2018), <https://www.bloomberg.com/news/articles/2018-01-29/e-cigarettes-may-lead-to-cancer-and-heart-disease-new-study-finds>; Hyun-Wook Lee et al., *E-Cigarette Smoke Damages DNA and Reduces Repair Activity in Mouse Lung, Heart, and Bladder, As Well as in Human Lung and Bladder Cells*, PNAS 1, 7–8 (2018), <http://www.pnas.org/content/pnas/115/7/E1560.full.pdf>.

116. See Joseph G. Allen et al., *Flavoring Chemicals in E-Cigarettes: Diacetyl, 2-3-Pentanedione, and Acetoin in a Sample of 51 Products, Including Fruit-, Candy-, and Cocktail-Flavored E-Cigarettes*, 124 ENVTL. HEALTH PERSP. 733, 734 (2016), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4892929/pdf/ehp.1510185.pdf>. Bronchiolitis obliterans, along with other similar respiratory diseases of the small airways, became collectively known as “popcorn lung.” *Id.* The name is due to its prevalence in microwave popcorn manufacturing plant workers where diacetyl was prominent in butter flavorings and workers inhaled the chemical. *Id.* Bronchiolitis obliterans is an irreversible loss of pulmonary function. *Id.* In some cases, the only cure is a lung transplant. *Id.* at 733. Milder manifestations of symptoms include chronic cough, shortness of breath, asthma, and prevalence of airway obstruction. *Id.*

117. See Erin Brodwin, *Vaping Every Day Could Double Your Risk of a Heart Attack, New Research Suggests*, BUS. INSIDER (Aug. 22, 2018), <https://www.businessinsider.com/vaping-e-cigs-heart-attack-risk-2018-8>. There is little research available about the long-term effects of e-cigarette use, but an August 2018 study became the first to show the long-term impact of e-cigarettes. *Id.* While there were still some limitations, researchers found that vaping was linked to heart attacks, and that dual-users of e-cigarettes and traditional combustible cigarettes faced approximately five times more of a risk of heart attack than non-smokers. *Id.*

118. See *supra* notes 113–117 and accompanying text.

119. See Michael Siegel, *Real Talk About Vaping*, U.S. NEWS & WORLD REP. (Jan. 25, 2018), <https://www.usnews.com/opinion/policy-dose/articles/2018-01-25/new-vaping-report-shows-there-are-no-known-long-term-health-effects>; Joel L. Nitzkin, *The Case in Favor of E-Cigarettes for Tobacco Harm Reduction*, 11 INT’L J. OF ENVTL. RES. & PUB. HEALTH 6459, 6463–66 (2014) (asserting that e-cigarettes are a feasible tobacco harm reduction modality because they are significantly more effective than other smoking cessation tools, they have not attracted non-smoking teens and adults, and their vapor poses “no discernable risk to bystanders”). *But see* Soneji et al., *supra* note 29, at 1–2 (estimating that e-cigarette use in 2014 would lead to 1,510,000 years of life lost and concluding that e-cigarette use poses more population-level

nicotine exposure are well-established.¹²⁰ Challengers also frequently argue that removing the distinguishing flavored products from the tobacco would have drastic results for current and former combustible cigarette smokers.¹²¹ Additionally, opponents contend that a flavor ban would create a gray market of e-cigarettes and e-liquids,¹²² harm the livelihood of small business owners who rely on the sale of flavored e-liquids,¹²³ and create unduly burdensome restrictions for tobacco companies.¹²⁴

Both sides agree that youth access should be regulated and prevented, but opponents of regulation draw the line at ridding flavors from the market.¹²⁵ Because this option would limit adult choice, vapers feel that greater stress should be placed on restricting youth access rather than entirely banning the flavored varieties.¹²⁶ Since there is a population of users who rely on flavored e-cigarettes to help them quit smoking traditional combustible cigarettes, challengers of flavor regulation feel that the original purpose of the products would be diminished,¹²⁷ negatively impacting those who greatly benefit from e-cigarette use.

harm than benefit).

120. See *supra* notes 32 and 109 and accompanying text. In the 2016 Surgeon General's report on e-cigarette use among youth and young adults, results showed that e-cigarettes are potentially addictive, and that early nicotine addiction can alter brain development and nerve functioning. See U.S. DEP'T OF HEALTH & HUMAN SERVS., *supra* note 34, at vii.

121. See Daniel DiMartino, *Banning Flavored E-Cigarettes Could Blow Up in the FDA's Face*, WASH. EXAMINER (Sept. 21, 2018), <https://www.washingtonexaminer.com/red-alert-politics/banning-flavored-e-cigarettes-could-blow-up-in-the-fdas-face> (positing that a lack of e-cigarette flavors may discourage current cigarette smokers from using the products to quit, and cause some users who utilized the products for smoking cessation to revert back to traditional combustible cigarette usage).

122. See Janine Wolf & Olivia Zaleski, *JUUL Warns If U.S. Bans Flavored Tobacco, Illicit 'Gray Market' Could Take Its Place*, BLOOMBERG (Aug. 2, 2018), <https://www.bloomberg.com/news/articles/2018-08-02/juul-warns-u-s-banning-flavors-could-fuel-illicit-gray-market> (perceiving the potential consequences of a gray market as an "uptick in online purchases, local illegal sales or buying on Native American reservations").

123. See Olga R. Rodriguez, *Tobacco Giant Fights San Francisco's Proposed Ban on Flavored Products*, BLOOMBERG (May 28, 2018), <https://www.bloomberg.com/news/articles/2018-05-28/san-francisco-mulls-ban-on-flavored-vaping-liquids-menthols>.

124. See Lauren H. Greenberg, *The Deeming Rule: The FDA's Destruction of the Vaping Industry*, 83 BROOK. L. REV. 777, 778 (2018).

125. See Madison Park, *San Francisco Bans Sales of Flavored Tobacco Products*, CNN (Jun. 6, 2018), <https://www.cnn.com/2018/06/06/health/san-francisco-flavored-cigarettes-proposition-e/index.html> (stating that removing flavors infringes on adult choice, in part because "flavored products are helpful to smokers who are trying to quit").

126. *Id.*

127. See *Flavor Bans: E-Vapor Flavor Bans Deprive Adults of the Freedom to Choose*, VAPER RTS., <https://vaperrights.com/flavor-bans/> (last visited Jan 6, 2019) (outlining the ways that a flavor ban would "deprive adults of the freedom to choose").

Unlike traditional smoking cessation products such as nicotine gum or patches, e-cigarettes simulate smoking.¹²⁸ The products are able to deliver nicotine with the same sensory experience of smoking a combustible cigarette.¹²⁹ Manufacturers created products that look and feel like a traditional cigarette, but because the products do not contain tobacco, users are able to satisfy their nicotine craving without inhaling all of the carcinogenic toxins in a combustible cigarette.¹³⁰ Despite the removal of these toxins, the existing scientific data is insufficient to clinically recommend e-cigarettes as successful cessation tools.¹³¹

Opponents to e-cigarette regulation also frequently cite to statistics in a 2015 study conducted by Saul Schiffman, which found that flavors in e-cigarettes will not entice youth users and that adults use flavors more than adolescents.¹³² However, this particular study is highly controversial because NJOY, an e-cigarette company that sued the FDA, funded it.¹³³ Further, the study contradicts the findings of the 2016 National Youth Tobacco Survey¹³⁴ and numerous other studies that reached the exact opposite conclusions.¹³⁵ As such, whether flavors contribute to youth e-cigarette use is a source of contention among both sides.

Regulation opponents caution that FDA action could have a devastating

128. Nick Dantonio, Comment, *Vape Away: Why a Minimalist Regulatory Structure is the Best Option for FDA E-Cigarette Regulation*, 48 U. RICH. L. REV. 1319, 1351 (2014) (attributing e-cigarettes' success to the ability to "provide the nicotine as well as simulate the physical act of smoking, creating a psychological placebo effect increasing the rate of cigarette abstinence").

129. Soneji et al., *supra* note 29, at 2.

130. See Rubinstein et al., *supra* note 5, at 2; *Electronic Cigarettes (E-Cigarettes)*, *supra* note 2 (providing that e-cigarettes often resemble traditional tobacco cigarettes, cigars, pipes, or everyday items such as USB drives or pens).

131. Soneji et al., *supra* note 29, at 13.

132. See Saul Shiffman et al., *The Impact of Flavor Descriptors on Nonsmoking Teens' and Adult Smokers' Interest in Electronic Cigarettes*, 17 NICOTINE & TOBACCO RES. 1255 (2015). But see Shanton A. Glantz, *Shiffman et al., Paper in Nicotine & Tobacco Research Is Not a Reliable Estimate of Effects of Ecig Flavors*, U.C.S.F. CTR. FOR TOBACCO CONTROL RES. & EDUC. (Feb. 18, 2015), <https://tobacco.ucsf.edu/shiffman-et-al-paper-nicotine-tobacco-research-not-reliable-estimate-effects-ecig-flavors> (arguing that e-cigarette flavors did not appeal to adult or youth users).

133. See Glantz, *supra* note 133; *Sottera, Inc. v. FDA*, 627 F.3d 891, 898–99 (D.C. Cir. 2010).

134. James Tsai et al., *Reasons for Electronic Cigarette Use Among Middle and High School Students—National Youth Tobacco Survey, United States, 2016*, 67 CDC MORBIDITY & MORTALITY WKLY. REP. 6, 197–98 (2018), <https://www.cdc.gov/mmwr/volumes/67/wr/pdfs/mm6706a5-H.pdf> (finding that 31% of students reported that the reason for their e-cigarette use was because of the availability of flavors).

135. See Glantz, *supra* note 132.

effect on public health.¹³⁶ In July 2017, the FDA delayed the compliance deadline for regulating e-cigarettes mandated by the Deeming Rule to 2022, giving the industry five more years to file applications demonstrating that their products are safe alternatives to conventional cigarettes and that the products are not targeting minors.¹³⁷ Commissioner Gottlieb justified the delay as a chance for manufacturers to bring their current practices up to par while not depriving adult access to smoking cessation products.¹³⁸ However, public health advocates did not approve of the extension¹³⁹ and in the meantime teen e-cigarette use has increased to epidemic proportions.¹⁴⁰ While virtually all levels of government could intervene, the FDA is best-equipped through its Comprehensive Plan for Tobacco and Nicotine Regulation.¹⁴¹

Tobacco companies agree that youth access to e-cigarettes is problematic and call for regulation.¹⁴² JUUL's CEO expressed support of the FDA's efforts because the company maintains that it never intended that children use JUULs.¹⁴³ Additionally, Reynolds Tobacco, which owns Newport, Camel,

136. Rich Barlow, *Will the Government Ban E-Cigarettes?*, BU TODAY (Sept. 17, 2018), <http://www.bu.edu/today/2018/will-the-government-ban-e-cigarettes/> (cautioning that an FDA ban on e-cigarettes would jeopardize the health of adults in America, and equating a ban of flavored products to a ban of vaping products altogether). *But see* U.S. DEP'T OF HEALTH & HUMAN SERVS., *supra* note 34, at 183 ("Public health will be harmed if the availability of e-cigarettes: increases exposure to nicotine among youth and young adults; leads to the initiation of combustible tobacco smoking; slows or prevents cessation of combustible products by nicotine-addicted smokers; or increases the likelihood that former smokers will again become addicted to nicotine and/or use combustible products after being reintroduced to nicotine by e-cigarettes.").

137. *See* Julia Belluz, *FDA: We Might Have to Ban Some E-Cigarettes to Stop Teens from Vaping*, VOX (Sept. 21, 2018), <https://www.vox.com/2018/9/12/17850598/fda-juul-vaping>.

138. *Id.*

139. *Id.* (stating that opponents of the delay perceived the extension as an opportunity for the e-cigarette market to exploit youth users).

140. *See* Press Release, FDA Takes New Steps to Address Epidemic of Youth E-Cigarette Use, *supra* note 66.

141. *See* FDA's *Comprehensive Plan for Tobacco and Nicotine Regulation*, FOOD & DRUG ADMIN. (Nov. 2, 2018), <https://www.fda.gov/tobaccoproducts/newsevents/ucm568425.htm#2> (outlining the agency's next steps through a multi-year roadmap with the goal of protecting youth while simultaneously helping addicted adult smokers quit and reducing tobacco-related disease and death). In addition to the notice-and-comment period for the March 2018 Advance Notice of Proposed Rulemaking (ANPRM), the FDA scheduled a public hearing on December 5, 2018 for additional public input. *Id.*

142. *See* Roni Selig et al., *JUUL and the Vape Debate: Choosing Between Smokers and Teens*, CNN (Aug. 9, 2018), <https://www.cnn.com/2018/08/09/health/juul-teen-vape-debate/index.html> ("[N]o usage of our product by youth is acceptable to us.").

143. *See* *Teens Are Hooked on JUUL, But a Top Exec Insists That Was Never the Company's Intention*, CBS NEWS (Jun. 14, 2018), <https://www.cbsnews.com/news/juul-ecigarette-executive->

and Pall Mall, stated that it “supports the responsible approaches to regulating flavors and balancing the growing evidence that flavors play an important role in helping adult smokers switch to alternatives that potentially present less risk than cigarettes.”¹⁴⁴

On June 5, 2018, San Francisco voters made history when they elected to ban flavored vaping products and menthol cigarettes.¹⁴⁵ While the city is the first to adopt a flavor ban of e-liquids,¹⁴⁶ other cities such as Chicago, New York, and Providence have taken steps to regulate e-liquids by restricting the sale of products to adult-only stores and city lawmakers have begun discussing the implementation of their own flavor bans.¹⁴⁷ Georgetown Law professor and former FDA official Eric Lindblom predicted that soon other states and cities will take the same approach as San Francisco and refuse to compromise on the issue,¹⁴⁸ electing instead to ban flavored e-liquids entirely.¹⁴⁹

III. FLAVOR BAN

Although the FDA has already taken some active measures to prevent youth access to e-cigarettes, the products are increasingly popular among middle and high schoolers, and the availability of flavors is partially to

addresses-concerns-product-appeals-directly-to-teens-vaping/ (reporting that JUUL is spending \$30 million on youth prevention programs); Matt Richtel & Sheila Kaplan, *Did JUUL Lure Teenagers and Get ‘Customers for Life?’*, N.Y. TIMES (Aug. 27, 2018), <https://www.nytimes.com/2018/08/27/science/juul-vaping-teen-marketing.html> (acknowledging that JUUL changed the names of its flavors in an attempt to deter teenage use).

144. Angelica LaVito, *The FDA Is Going After Menthol Cigarettes—And Maybe Even Fruity E-Cigs Flavors*, CNBC (Mar. 20, 2018), <https://www.cnbc.com/2018/03/20/fda-considering-restricting-menthol-and-other-flavors-from-tobacco-products.html>; see Jan Hoffman, *San Francisco Voters Uphold Ban on Flavored Vaping Products*, N.Y. TIMES (June 6, 2018), <https://www.nytimes.com/2018/06/06/health/vaping-ban-san-francisco.html>. Ironically, this statement came at the same time that Reynolds actively contributed to, and essentially funded, the ultimately unsuccessful campaign against the recent San Francisco Flavor Ban. *Id.* Reynolds spokesman, Jacob McConnico, also argued that this change would be a major setback for tobacco harm reduction efforts because it removes many potentially reduced-risk alternatives to tobacco from the market. *Id.*

145. Hoffman, *supra* note 144.

146. Robert King, *San Francisco First City to Ban E-Cigarette Flavors*, WASH. EXAMINER (June 26, 2018), <https://www.washingtonexaminer.com/policy/healthcare/san-francisco-first-city-to-ban-e-cigarette-flavors>.

147. See Hoffman, *supra* note 144.

148. *Id.*; see also Eric N. Lindblom, *Effectively Regulating E-Cigarettes and Their Advertising—And the First Amendment*, 70 FOOD & DRUG L. J. 55, 58 (2015) (noting that under the TCA, individual states or local jurisdictions could ban all or select e-cigarettes).

149. See Hoffman, *supra* note 144.

blame.¹⁵⁰ By creating flavors that are sweet and dessert flavored, tobacco companies are able to target the youth demographic when they manufacture candy-flavored e-liquids, sometimes in nearly-identical packaging to the products they imitate.¹⁵¹ Additionally, younger e-cigarette users are more likely to begin smoking combustible cigarettes after using e-cigarettes.¹⁵² To stop this epidemic, the FDA should restrict the sale of flavored e-liquids and allow only menthol and tobacco flavors because unique flavors are attracting adolescent and youth users, increasing their chances of eventually switching to combustible cigarettes.¹⁵³

150. See Hanan Qasim et al., *Impact of Electronic Cigarettes on the Cardiovascular System*, 8 J. AM. HEART ASS'N 1, 1–2 (2017), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5634286/pdf/JAH3-6-e006353.pdf>. Youth e-cigarette usage is primarily linked to the “appealing” flavored nature of e-liquids and adolescent curiosity. *Id.*; see also *Why the Rise in Youth E-Cigarette Use May Be Worse Than We Think*, *supra* note 17. The 2016 National Youth Tobacco Survey found that among students who used e-cigarettes, the three most common reasons for their use were because a friend or family member used them (39%); the “availability of flavors such as mint, candy, fruit, or chocolate” (31%); and “the belief that [e-cigarettes] are less harmful than other forms of tobacco such as cigarettes” (17.1%). *Youth Tobacco Use: Results from the National Youth Tobacco Survey*, FOOD & DRUG ADMIN. (June 7, 2018), <https://www.fda.gov/TobaccoProducts/PublicHealthEducation/ProtectingKidsfromTobacco/ucm405173.htm>.

151. See Laurie McGinley, *Feds Crack Down on E-Liquid Packaging That Looks Like Candy, Juice Boxes*, WASH. POST (May 1, 2018), https://www.washingtonpost.com/news/to-your-health/wp/2018/05/01/liquid-nicotine-for-e-cigs-looks-like-kids-juice-boxes-and-candy-government-says/?noredirect=on&utm_term=.7130165dc8f8. Several e-cigarette companies created packaging that closely resembles juice boxes, Sour Patch Kids candy, Trolli Sour Crawlers candy, WarHeads candy, Nilla Wafer cookies, Golden Oreo cookies, and Redi Whip whipped cream. *Id.* The products utilize similar fonts and colors, and feature cartoon-like images. *Id.* One flavor, “Twirly Pop,” physically resembles a Unicorn Pop lollipop. *Id.* Manufacturers also ship the e-liquid with a Unicorn Pop lollipop. *Id.*; see also Deanna Paul, *E-Cigarette Maker JUUL Targeted Teens With False Claims of Safety, Lawsuit Says*, WASH. POST (July 30, 2018), https://www.washingtonpost.com/news/to-your-health/wp/2018/07/30/e-cigarette-maker-juul-targeted-teens-with-false-claims-of-safety-lawsuit-claims/?utm_term=.5a93fd8a95c7 (quoting Robert Jackler, the principal investigator at a Stanford University School of Medicine program who is studying the impact of tobacco advertising) (“If you walk down the cereal aisle in the grocery store, where the Cocoa Krispies and Sugar Puffs are at knee level and Cornflakes and Life are up high where adults see them, there’s a different appeal of sweet and fruity flavors to young people”).

152. See *E-Cig Use Increases Risk of Beginning Tobacco Cigarette Use in Young Adults*, SCI. DAILY (Dec. 11, 2017), <https://www.sciencedaily.com/releases/2017/12/171211090733.htm> (“Young adults who use electronic cigarettes are more than four times as likely to begin smoking tobacco cigarettes within 18 months as their peers who do not vape . . . [E]-cigarettes are serving as a gateway to traditional smoking, contrary to their purported value as a smoking cessation tool.”)

153. See Meghan E. Morean et al., *Preferring More E-Cigarette Flavors Is Associated with E-*

The ready availability of flavors and the evidence proving the influence of these flavors on adolescents¹⁵⁴ suggest that the FDA should issue a rule banning the sale of these products from the market until tobacco companies are able to prove that making these sweet and fruity flavors serves more benefits than harms.¹⁵⁵ Combustible cigarettes are the leading cause of preventable deaths in the United States over the last fifty years.¹⁵⁶ While e-cigarettes have the potential to be a valuable cessation tool for cigarette smokers¹⁵⁷ and have already assisted some former cigarette smokers in quitting,¹⁵⁸ e-cigarette use

Cigarette Use Frequency Among Adolescents But Not Adults, PLOS ONE (Jan. 4, 2018), <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0189015>. Data revealed that compared to adolescents, a larger portion of adults preferred tobacco flavored e-liquid and more adolescents preferred fruit flavored e-liquids. *Id.*; see also Brian A. Primack et al., *Initiation of Traditional Cigarette Smoking After Electronic Cigarette Use Among Tobacco-Naïve US Young Adults*, 131 AM. J. MED. 443.e1, 443.e5 (2018) (categorizing e-cigarettes as an “ideal transition vehicle” to combustible cigarettes because of the devices’ ability to “mimic many powerful behavioral cues of cigarette smoking” and comparing the use of tobacco products to alcohol use, in which users usually prefer sweet and sugary beverages initially, and then, sometimes due to changing social pressures, transition to harsher and more concentrated alcoholic beverages).

154. Qasim et al., *supra* note 150, at 2.

155. See, e.g., Press Release, Dick Durbin, U.S. Senator Ill., Durbin to E-Cigarette Industry: Gummy Bear Flavored Liquid Nicotine Helps Adults Quit Smoking? Prove It (July 30, 2018), <https://www.durbin.senate.gov/newsroom/press-releases/durbin-to-e-cigarette-industry-gummy-bear-flavored-liquid-nicotine-helps-adults-quit-smoking-prove-it->. Senator Dick Durbin unveiled bipartisan legislation cracking down on youth-friendly flavorings in highly addictive e-cigarettes. *Id.* The Senator, along with Alaska Republican Senator Lisa Murkowski, are pushing the Stopping Appealing Flavorings in E-Cigarettes for Kids (SAFE Kids) Act to instate tougher restrictions on e-cigarette flavors. *Id.* The SAFE Kids Act would allow tobacco companies one year to prove to the FDA that their e-cigarette flavorings help adults quit smoking cigarettes, do not increase youth initiation of nicotine and tobacco product usage, and do not increase the risk of harm to the user. *Id.* If the company can successfully prove these three criteria, then the flavor can remain on the market. *Id.*

156. *Fast Facts*, CTRS. FOR DISEASE CONTROL & PREVENTION (Feb. 20, 2018), https://www.cdc.gov/tobacco/data_statistics/fact_sheets/fast_facts/index.htm. In the United States, cigarette smoking is responsible for more than 480,000 deaths per year, with more than 41,000 deaths due to secondhand smoke exposure. *Id.* If cigarette smoking persists at this rate among U.S. youth, roughly one in every thirteen Americans age seventeen or younger who are alive today are expected to die prematurely due to a smoking-related disease. See *id.*; U.S. DEP’T OF HEALTH & HUMAN SERVS., THE HEALTH CONSEQUENCES OF SMOKING—50 YEARS OF PROGRESS, A REPORT OF THE SURGEON GENERAL 4 (2014), <https://www.surgeongeneral.gov/library/reports/50-years-of-progress/full-report.pdf> (detailing a message from Kathleen Sebelius). All of the 480,000 estimated tobacco-attributable deaths each year are due to “the machine-made cigarette.” Nitzkin, *supra* note 119, at 6461.

157. WHAT’S THE BOTTOM LINE?, *supra* note 2, at 4.

158. Nitzkin, *supra* note 119, at 6459. *But cf.* Scott R. Weaver et al., *Are Electronic Nicotine Delivery Systems Helping Cigarette Smokers Quit? Evidence from a Prospective Cohort Study of U.S. Adult*

in adolescents often leads to combustible cigarette use.¹⁵⁹ Moreover, because e-cigarettes are newer, scientists and medical professionals are not yet able to determine exactly what the long-term effects might be.¹⁶⁰ As a result, flavored e-cigarette users are inhaling a potentially lethal concoction of chemicals that give the e-liquid its distinctive flavor.¹⁶¹ The data showing that some adolescent users are unaware that the e-cigarette products they are using contain nicotine,¹⁶² the widespread prevalence in schools,¹⁶³ and the reports of youth nicotine addiction¹⁶⁴ suggest that the products could cause harm to individuals and warrants an FDA regulation banning the large majority of these flavored products at this time.

When the FDA banned characterizing-flavored cigarettes in 2009, it did not ban menthol.¹⁶⁵ Early research about e-cigarette flavoring identifies menthol, along with tobacco flavored varieties, as safer than the fruit and

Smokers 2015-2016, PLOS ONE (Jul. 9, 2018), <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0198047> (finding that e-cigarettes did not help adult smokers quit smoking combustible cigarettes).

159. See generally Janine Wolf, *E-Cigs Breed More Smokers Than They Stop*, BLOOMBERG (Mar. 14, 2018), <https://www.bloomberg.com/news/articles/2018-03-14/e-cigarette-study-says-they-lead-to-more-smokers-than-they-stop> (reporting that vaping has prompted people to use combustible cigarettes rather than quit smoking and estimating that e-cigarettes would eventually lead to roughly 1,510,000 years of life lost).

160. Siegel, *supra* note 119.

161. Rapaport, *supra* note 114. Less complex mixtures of flavoring compounds are likely to be less dangerous, but unfortunately adolescent users are most attracted to the complex blends. Allyson E. Kennedy et al., *E-Cigarette Aerosol Exposure Can Cause Craniofacial Defects in Xenopus Laevis Embryos and Mammalian Neural Crest Cells*, PLOS ONE (Sept. 28, 2017), <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0185729>; see Crow, *supra* note 106 (articulating that of the flavors in the Kennedy study, those with more complexity had the highest correlation with deformity).

162. *A Lot of Youth Think They Aren't Vaping Nicotine, But Is That True?*, TRUTH INITIATIVE (Apr. 12, 2017), <https://truthinitiative.org/news/youth-think-they-arent-vaping-nicotine>.

163. Zernike, *supra* note 89.

164. *Know the Risks*, *supra* note 32, at vii.

165. See Jared Wadley, *Most Youth Use E-Cigarettes for Novelty, Flavors—Not to Quit Smoking*, U. MICH. NEWS (Dec. 16, 2015), <https://news.umich.edu/most-youth-use-e-cigarettes-for-novelty-flavors-not-to-quit-smoking/>. After this ban, the FDA observed a significant reduction in youth cigarette use. *Id.* Implementing this same action with e-cigarettes could deter adolescents from using e-cigarettes, as flavors comprise the primary reason for initiating e-cigarette use among younger users. See, e.g., Qasim et al., *supra* note 150. This course of action does not hinder adult choice by leaving tobacco and menthol e-liquid options for adult smokers who are utilizing the products to quit. See Eric N. Lindblom, *Should FDA Try to Move Smokers to E-Cigarettes and Other Less-Harmful Tobacco Products and, if So, How?*, 73 FOOD & DRUG L.J. 276, 297 (2018) (noting that adult smokers could still buy non-flavored combustible cigarettes and menthol e-cigarettes).

sweet flavors, and complex flavors that mix numerous tastes.¹⁶⁶ Menthol creates a cooling effect which masks the harshness of smoking and eases respiration.¹⁶⁷ Research suggests that the special rule for cigarettes did not achieve its goal because of the ready availability of e-liquids and of menthol cigarettes¹⁶⁸ and that youth smokers are the demographic most likely to use menthol cigarettes.¹⁶⁹ Some lawmakers and proponents of regulation have suggested banning menthol cigarettes to aid smokers in quitting.¹⁷⁰

If the FDA issues a rule restricting the available flavors to only tobacco and menthol and removes the enticing fruity and sweet flavors, which are attractive and alluring to young users, the agency could effectively balance conflicting interests.¹⁷¹ Current combustible cigarette smokers are accustomed to smoking tobacco or menthol flavored cigarettes because there are no flavored cigarettes on the market, so the switch to an e-cigarette can still

166. Crow, *supra* note 106 (finding that unlike the fruity or complex flavors, tobacco and menthol flavored e-cigarettes did not demonstrate harmful effects).

167. Cheryl Platzman Weinstock, *A Menthol Cigarette Ban May Influence Smokers to Quit*, REUTERS (Mar. 8, 2018), <https://www.reuters.com/article/us-health-smoking-menthol/a-menthol-cigarette-ban-may-influence-smokers-to-quit-idUSKCN1GK2L0>.

168. See Charles J. Courtemanche et al., *Influence of Flavored Cigarette Ban on Adolescent Tobacco Use*, 52 AM. J. PREVENTATIVE MED. e139, e141, e144–45 (2018); Andrea C. Villanti et al., *Changes in the Prevalence and Correlates of Menthol Cigarette Use in the USA, 2004–2014*, 25 TOBACCO CONTROL ii14 (2016), https://tobaccocontrol.bmj.com/content/tobaccocontrol/25/Suppl_2/ii14.full.pdf (finding that youth e-cigarette users are disproportionately more likely to choose menthol cigarettes over non-menthol cigarettes).

169. Villanti et al., *supra* note 168, at ii14, ii16, ii19. Menthol cigarette smoking increased from 2004 to 2014 and data showed that younger smokers are most likely to smoke menthol cigarettes. *Id.* While African-Americans are still the most likely demographic to smoke menthol cigarettes, menthol cigarettes are now more prevalent across the board in all demographics as research showed an increase in white, Asian, and Hispanic smokers since 2010. *Id.* at ii16.

170. Weinstock, *supra* note 167. Ontario banned menthol in cigarettes and observed an influx of smokers wanting to quit. However, menthol cigarettes made up only 5% of Ontario's tobacco market before the ban, in comparison to the 26% statistic in the United States. Although, in light of the recent ban in San Francisco, researchers should now be able to observe whether a menthol cigarette ban would benefit smokers in the United States.

171. Clive Bates, *E-Cigarettes, Vaping, and Public Health*, CONSUMER ADVOCS. FOR SMOKE FREE ALTERNATIVES ASS'N, (Feb. 2015), <http://www.casaa.org/e-cigarettes-vaping-and-public-health/> (“The optimum regulatory regime would strike a subtle balance between protecting users, non-users, bystanders and limiting the risks of harmful unintended consequences.”). Three percent of adults are using e-cigarettes while twelve percent of kids are using them, and e-cigarette use causes eighty-one times more new smokers than quitters. Laura Bach, *Electronic Cigarettes and Youth*, CAMPAIGN FOR TOBACCO-FREE KIDS 1, 2 (June 8, 2018), <https://www.tobaccofreekids.org/assets/factsheets/0382.pdf>. Additionally, among adolescents who use e-cigarettes, 81% reported that their first tobacco product was flavored. *Id.*

provide the same sensory experience and dose of nicotine. Since tobacco and menthol are not enticing characterizing flavors, youth users are less likely to be tempted to use them, and therefore less likely to make an eventual switch to combustible cigarettes.¹⁷² For adult smokers who switch to e-cigarettes, tobacco flavors are often preferred when e-cigarette use begins and users gradually transition to the sweet and fruity flavors.¹⁷³ Further, the use of tobacco-flavored e-cigarettes is more common among dual users of e-cigarettes and combustible cigarettes than among exclusive e-cigarette users,¹⁷⁴ suggesting that smokers are using tobacco e-liquids to simulate smoking a combustible cigarette, and that most tobacco-flavored e-liquid users are using the products to quit smoking.¹⁷⁵

While JUUL's November action to remove their fruity flavors from retail stores¹⁷⁶ was a step in the right direction,¹⁷⁷ FDA intervention is still necessary to ensure that these products do not return to shelves. Users can still purchase all of the flavored pods online at JUUL's website, which has added age-verification measures,¹⁷⁸ but as long as JUUL continues to sell these products,

172. See *The Appeal of E-Cigarette Flavors*, TOBACCO CTRS. OF REG. SCI. (Apr. 13, 2017), <https://sph.uth.edu/research/centers/dell/news/story.htm?id=appeal-of-e-cig-flavors>.

This study reported that sweet flavors were likely enticing adolescents to try e-cigarettes. *Id.* Survey results found that the percentages of youth and young adult current e-cigarette users whose first e-cigarette was flavored were 98.6% and 95.2% respectively. *Id.* Data also revealed that restricting sweet flavors could reduce youth use, as 77.8% of youth and 73.5% of young adult users would not use e-cigarettes if sweet flavors were not available. *Id.*; see also M.B. Harrell et al., *Flavored Tobacco Product Use Among Youth and Young Adults: What if Flavors Didn't Exist?*, TOBACCO REG. SCI. 1, 5 (April 2017), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5536860/pdf/nihms882409.pdf> (indicating that “eliminating characterizing flavors in tobacco products during the manufacturing process . . . could substantially reduce the prevalence of tobacco use among youth and young adults for many types of tobacco products,” including e-cigarettes).

173. Harrell et al., *Flavored E-Cigarette Use*, *supra* note 70, at 34 (stating that sweet flavors become “more relevant” as e-cigarette use continues).

174. *Id.* at 36.

175. *Id.* at 38 (predicting that tobacco and menthol flavored e-cigarettes could be the most relevant to and helpful for adult cigarette smokers using e-cigarettes to quit smoking).

176. See *supra* notes 73–76 and accompanying text.

177. But see *JUUL Fails to Remove All of Youth's Favorite Flavors From Stores*, TRUTH INITIATIVE (Nov. 15, 2018), <https://truthinitiative.org/news/juul-fails-remove-all-youths-favorite-flavors-stores> (criticizing JUUL's decision to keep selling its cool mint flavored JUULpods in stores because the brand's flavor is different than traditional menthol cigarettes, as users have described it as “lighter” and “sweeter”); Nitasha Tiku, *JUUL Exhales After Dodging Full Ban on Flavored E-Cigs*, WIRED (Nov. 15, 2018), <https://www.wired.com/story/juul-dodging-ban-flavored-e-cigs/> (noting that mint is one of the most popular JUUL-pod flavors for 18 to 21 year-old users, and that “mint is not menthol . . . [a] roll of Life Savers comes in mint—it's a candy flavor”).

178. *Id.*

underage users will still get their hands on them.¹⁷⁹ Merely requiring brick and mortar retailers to invest in age-verification technology without providing any actual guidance or specific qualifications offers a loophole for retailers to continue selling flavored e-cigarettes.¹⁸⁰

The FDA has the opportunity to prevent history from repeating itself.¹⁸¹ With cigarette smoking at an all-time low,¹⁸² it is vital that the agency takes all precautions to ensure that this generation of youth and young adults is not exposed to another product that facilitates nicotine addiction. Tobacco is not a sweet or enticing flavor and unlike some of the other flavors on the market—like unicorn milk,¹⁸³ thug juice,¹⁸⁴ or stardust¹⁸⁵—it does not have a beguiling flavor title. Even though tobacco flavored varieties are not as popular as the fruity and sweet flavors among all e-cigarette users, adult preference for tobacco-flavored e-liquid is over triple that of youth.¹⁸⁶ Additionally, the additives in tobacco and menthol e-liquids present less risk than

179. Amanda Mull, *Juul's a Business and They're Behaving Like a Business*, ATLANTIC (Nov. 30, 2018), <https://www.theatlantic.com/health/archive/2018/11/juul-atonement-tour-addicted-teens/577072/> (“[T]eens primarily buy vape products from classmates, which means it would take only one kid who had figured out how to game the system (or secured help from an older sibling or friend) at any particular school to continue to distribute pods to dozens, if not hundreds, of classmates.”); Horace Holmes, *7 On Your Side Goes Undercover to Find Out How Easy It Is For Teens to Get JUULs*, WJLA (Nov. 8, 2018), <https://wjla.com/features/7-on-your-side/teens-buy-juuls-e-cigarettes-fda-investigation> (detailing how simple it is for teenagers to walk into convenience stores and purchase JUULs, sometimes in mass quantities).

180. See Erin Brodwin, *Regulators Will Ban Menthol Cigarettes and Chip Away at Flavored E-Cigs to Combat Teen Vaping—But Experts Say Their Plans Fall Short*, BUS. INSIDER (Nov. 18, 2018), <https://www.businessinsider.com/fda-government-bans-menthol-cigarettes-chips-away-flavored-e-cigs-juul-2018-11>.

181. Press Release, April Statement from FDA Commissioner Scott Gottlieb, *supra* note 65 (cautioning that e-cigarette use could be hooking another generation of kids on nicotine).

182. See Mike Stobbe, *Smoking Reaching All-Time Low with U.S. Adults, Government Reports Show*, USA TODAY (June 19, 2018), <https://www.usatoday.com/story/news/nation/2018/06/18/smoking-united-states-cigarette-sales/713002002/> (reporting that cigarette smoking among high school students is down to 9%).

183. *Unicorn Milk by Cutwood E-Liquids*, ELIQUID.COM, <https://www.eliquid.com/products/cuttwood-unicorn-milk> (last visited Jan. 6, 2019) (“[A] blend of four different cream flavors, mixed with all natural strawberry extract.”).

184. *Thug Juice*, THE VAPE MALL, <https://thevapemall.com/thug-juice/> (last visited Jan. 6, 2019) (“[A] blend of berries and melon, with a cool menthol finish.”).

185. *VAPE WILD: Stardust*, ELECTRIC TOBACCONIST, <https://www.electrictobacconist.com/vape-wild-stardust-30ml-vape-juice-p1458> (last visited Jan. 6, 2019) (“[A] fresh summery flavor . . . melon tartness combines with the crunch of sweet cucumbers in an unexpected treat”).

186. Harrell et al., *Flavored E-Cigarette Use*, *supra* note 70, at 37. Use of tobacco flavored e-cigarettes was significantly more common among older adults nationwide (47.5%) compared to young adults nationwide (21%), young adult college students (4.8%), and youth

other more complex flavors.¹⁸⁷ The FDA should use its regulatory authority to ban the sale of all flavored e-cigarettes, except for the tobacco and menthol varieties. Because the FDA did not ban menthol flavored combustible cigarettes in 2009 with other characterizing flavors,¹⁸⁸ smokers who are addicted to menthol cigarettes would not be deprived of the opportunity to benefit from menthol flavored e-cigarettes as a cessation tool. Additionally, as combustible cigarette smokers are accustomed to the tobacco flavor, continuing to allow the sale of tobacco flavored e-liquids balances the competing considerations of combustible cigarette smokers using e-cigarettes to quit, and the concern about the overwhelming prevalence of vaping among adolescents and young adults.

CONCLUSION

Now is an ideal time for the FDA to intervene and utilize its regulatory power. Individual cities that have banned flavors are taking the next logical step to prevent adolescent use and addiction to e-cigarettes.¹⁸⁹ The FDA has the authority under the TCA to make a rule banning sweet and alluring flavors, and the Deeming Rule further bolsters its regulatory authority. The explosion of e-cigarette popularity in just the last five years indicates how problematic early adolescent use of these products will inevitably be in the future. While there is no concrete evidence definitively proving that e-cigarettes are successful smoking cessation tools, or that they are unsafe for consumption, the evidence that is currently available is sufficient for the FDA to ban fruity and sweet e-liquids. Without intervention, the FDA will have failed to fulfill its obligation to prevent youth access to nicotine and tobacco products.¹⁹⁰

(1.4%). *Id.* Fruity flavors dominated across all studies as the usual flavor of choice. *Id.*

187. Crow, *supra* note 106; Kennedy et al., *supra* note 161.

188. See *Menthol and Other Flavors in Tobacco Products*, FOOD & DRUG ADMIN. (July 20, 2018), <http://www.fda.gov/tobaccoproducts/labeling/productingredientscomponents/ucm2019416.htm>.

189. Hoffman, *supra* note 144.

190. See Rubinstein et al., *supra* note 5; Press Release, April Statement from FDA Commissioner Scott Gottlieb, *supra* note 65 (affirming the FDA's duty to "end the tragic cycle of successive generations of nicotine and tobacco addiction").