Brooklyn Journal of Corporate, Financial & Commercial Law

Volume 16
Issue 1 *SYMPOSIUM A Life Navigating the Securities Markets: A Celebration of Professor Roberta Karmel's Work, Teaching, and Mentorship*

Article 10

12-1-2021

The Means to Ending ENDS: Electronic Nicotine Delivery Systems and America's Youth

Megan C. Feeney

THE MEANS TO ENDING ENDS: ELECTRONIC NICOTINE DELIVERY SYSTEMS AND AMERICA'S YOUTH

ABSTRACT

Electronic Nicotine Delivery Systems (ENDS) have risen in prominence amongst smokers and non-smokers as a way to inhale nicotine since their introduction to the United States in 2006. Often sold in a variety of mouth-watering flavors, ENDS are extremely enticing to both adolescents and adults. Though they are marketed as a safer alternative to combustible cigarettes, these devices have created a growing public health epidemic of nicotine addiction among adolescent users. Ultimately acknowledging the issue in 2020, the Food & Drug Administration (FDA) released guidelines to the nicotine industry and banned the sale of certain flavored ENDS. However, this flavor ban is not as extensive as other state and local laws, as it leaves open loopholes for the industry. Therefore, this paper proposes that the FDA, in its official rulemaking capacity, creates a regulation that prohibits the sale of all flavored ENDS (including menthol flavors) in all forms (including disposable and tank-systems).

INTRODUCTION

Electronic Nicotine Delivery Systems (ENDS) are the beginning of a lifelong nicotine addiction for many naïve and impressionable adolescents. ENDS–more commonly known as e-cigarettes, vapes, or vaporizers–have risen in prominence amongst smokers and non-smokers as a way to inhale nicotine since their introduction to the United States in 2006.[1] In particular, their popularity amongst middle and high school students is concerningly high.[2] These devices, which deliver nicotine by heating a liquid agent and other ingredients "to create an aerosol that the user inhales,"[3] are contributing to a growing public health epidemic of adolescent e-cigarette use.[4] Specifically, millions of young adults are picking up ENDS and developing harmful nicotine addictions due to their appealing, non-tobacco flavors.[5]

1. *Historical Timeline of Electronic Cigarettes*, CONSUMER ADVOCATES FOR SMOKE-FREE ALT. ASS'N (last visited August 22, 2021), http://www.casaa.org/historical-timeline-of-electronic-cigarettes/.

2. *Think E-Cigs Can't Harm Teens Health?*, U.S. FOOD & DRUG ADMIN. (last updated Apr. 30, 2020), https://www.fda.gov/tobacco-products/public-health-education/think-e-cigs-cant-harm-teens-health.

3. *Vaporizers, E-Cigarettes, and other Electronic Nicotine Delivery Systems (ENDS)*, U.S. FOOD & DRUG ADMIN. (last updated Sept. 17, 2020), https://www.fda.gov/tobacco-products/products-ingredients-components/vaporizers-e-cigarettes-and-other-electronic-nicotine-delivery-systems-ends [hereinafter Vaporizers].

4. *Id.*

5. *See* Teresa W. Wang, et al., *E-cigarette Use Among Middle and High School Students — United States, 2020*, CTRS. FOR DISEASE CONTROL & PREVENTION (Sept. 9, 2020), https://www.cdc.gov/mmwr/volumes/69/pdf.

Thousands of flavors, such as mint, cinnamon, and almond, and in categories such as "Fruit, Dessert/Candy, Alcohol/Drinks, Snacks/Meals" have been created and sold over the past decade, [6] exacerbating a nicotine-addiction problem amongst youth throughout the country. These delicious and enticing flavors have contributed to one in five high school students using ENDS as of September 2020[7]—making these e-cigarettes "the most commonly used tobacco product among youth in the United States."[8]

ENDS' prominence and popularity can be explained not only by their mouth-watering appeal but also by marketing directives that aim to help cigarette-smoking adults quit by serving as an alternative to the traditional combustible product.[9] Although using ENDS as a replacement for combustible cigarettes is not approved by the U.S. Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC) has acknowledged that "e-cigarettes may help non-pregnant adult smokers if used as a complete substitute for all combustible cigarettes and other smoked tobacco products."[10] This is attractive to combustible cigarette smokers because it is often advertised as a less harmful alternative both to the smoker and to those around the smoker.[11] Yet, despite ENDS not having any *known* long-term health effects (due to the lack of conclusive data) attributed to their developing stage in the industry,[12] ENDS are composed of *known* harmful substances like nicotine.[13] Further, ENDS possess "potentially harmful substances," like "heavy metals," including "lead, volatile organic compounds, and cancer-causing agents."[14] Additionally, ENDS have been known to "explode and cause serious injury."[15] Thus,

6. Shu-Hong Zhu et al., *Four Hundred and Sixty Brands of E-Cigarettes and Counting: Implications for Product Regulation*, 23 TOBACCO CONTROL 1113, 1114 (2014).

7. *See* Wang, *supra* note 5.

8. *E-Cigarette Use Among Youth and Young Adults: A Report of the Surgeon General*, U.S. DEP'T HEALTH & HUMAN SERVS. (2016), https://www.cdc.gov/tobacco/data_statistics/sgr/ecigarettes/pdfs /2016_sgr _entire _report_508.pdf.

9. MeLisa R. Creamer, PhD, et al, *Tobacco Product Use and Cessation Indicators Among Adults — United States, 2018*, CTRS. FOR DISEASE CONTROL & PREVENTION (Nov. 15, 2019), https://www.cdc.gov/mmwr/volumes/68/wr/mm6845a2.htm?s_cid=mm6845a2_w.

10. CTRS. FOR DISEASE CONTROL & PREVENTION, U.S. DEP'T HEALTH & HUM SERVS., ELECTRONIC CIGARETTES WHAT'S THE BOTTOM LINE?, at 4, https://www.cdc.gov/tobacco/basic_information/e-cigarettes/pdfs/Electronic-Cigarettes-Infographic.pdf [hereinafter BOTTOM LINE].

11. *See* Rachel Davies, *Everything you need to know about switching to vaping*, VAPED BY TOTALLY WICKED (Mar. 12, 2020), https://www.totallywicked-eliquid.co.uk/vaped/everything-you-need-to-know-about-switching-to-vaping/.

12. *See* BOTTOM LINE, *supra* note 10.

13. *Id.*

14. *Id.*

15. Erin Brodwin, *11 key findings from one of the most comprehensive reports ever on the health effects of vaping*, BUS. INSIDER (Jan. 25, 2018, 10:42 AM), https://www.businessinsider.com/national-academies-sciences-report-vaping-e-cig-research-health-effects-2017-1-2018-1; *see*, *e.g.*, Sheila Kaplan, *E-Cigarette Exploded in a Teenager's Mouth, Damaging his Jaw*, N.Y. TIMES (June 19, 2019), https://www.nytimes.com/2019/06/ecigarettes; Ben Kesslen, *Texas man dies after e-cigarette explodes in his face*, NBC NEWS,(Feb. 6, 2019), https://www.nbcnews.com/news/us-

ENDS may be a potentially *less harmful* alternative to traditional, combustible and smokeless tobacco products, but by no means are they *harmless*.

Despite ENDS being a *potential* tool in assisting adult combustible cigarette users to quit, ENDS offer serious harmful effects to youth users.[16] In response, legislatures at both the state[17] and federal levels have enacted rules and regulations limiting—and even banning—flavored ENDS.[18] For example, in August 2020, the governor of California signed SB 793, an unanimously passed Senate bill that bans all flavored tobacco products.[19] This bill, an addendum to the Stop Tobacco Access to Kids Enforcement (STAKE) Act, bans all flavored tobacco products, including menthol-flavored[20] products.[21] This is a similar law to the legislation passed in Massachusetts in June 2020 that ended the sale of all flavored tobacco, including menthol products.[22] There are other states that have enacted similar, but less encompassing laws, therefore both of these laws serve to act as an example to "other states and the entire nation." [23] Specifically, in New York, disposable e-cigarettes are still permitted to be sold;[24] in Maryland, menthol products are still permitted to be sold;[25] and in Rhode Island, tobacco retailers and other adult-only retailers are exempt from the flavor ban.[26]

---

news/man-dies-after-e-cigarette-explodes-his-face; Jacqueline Howard & Tina Burnside, *Florida man dies in e-cigarette explosion, police say*, CNN HEALTH (May 15, 2018), https://www.cnn.com/2018/05/15/health/electronic-cigarette-explosion-death-bn/index.html.

16. Creamer, *supra* note 9.

17. *States and Tribes Stepping in to Protect Communities from the Dangers of E-cigarettes: Actions and Options (2020)*, PUB. HEALTH L. CTR. (last updated Feb. 25, 2020), https://publichealthlawcenter.org/stepping-protect-communities-dangers-e-cigarettes-actions-and-options.

18. Laura Bach, *State & Localities That Have Restricted The Sale of Flavored Tobacco Products*, CAMPAIGN FOR TOBACCO-FREE KIDS (Sept. 18, 2020), https://www.tobaccofreekids.org/assets/factsheets/0398.pdf.

19. Stanton A. Glantz, *Gov Newsom signs Calif ban on sales of flavored tobacco products*, CTR. TOBACCO CONTROL RSRCH. & EDUC. (Aug. 31, 2020), https://tobacco.ucsf.edu/gov-newsom-signs-calif-ban-sales-flavored-tobacco-products-0.

20. Menthol is a minty-like flavor additive that is often put in tobacco products to reduce the "harshness, bitterness, and astringency" of tobacco. *Menthol and other Flavors in Tobacco Products*, U.S. FOOD & DRUG ADMIN. (Last updated Jan. 3, 2020), https://www.fda.gov/tobacco-products/products-ingredients-components/menthol-and-other-flavors-tobacco-products. It is used in cigarettes, ENDS, cigars, hookah tobacco and smokeless tobacco products, such as dip, chew and snuff and is more likely to be used by younger as opposed to older smokers. *Id.*

21. S.B. 793 (Cal. 2020).

22. Statement of Matthew L. Myers, President, Campaign for Tobacco-Free Kids, *Today Massachusetts Makes History as the First State to End the Sale of All Flavored Tobacco Products, Including Menthol*, CAMPAIGN FOR TOBACCO-FREE KIDS (June 1, 2020), https://www.tobaccofreekids.org/press-releases/massachusetts-flavor-ban.

23. *See id.*

24. *See id.*

25. *Out of Flavor: Updates on Flavor Ban Legislation and Litigation*, PUB. HEALTH L. CTR. (Jul. 29, 2020), https://www.publichealthlawcenter.org//files/Out-of-Flavor-Updates-on-Flavor-Ban-Legislation-and-Litigation.pdf.

26. Bach, *supra* note 18.

Additionally, in January 2020, the FDA passed a similar, but not as extensive flavored ENDS regulation.[27] Pursuant to the FDA's flavor ban,[28] retailers are prohibited from selling cartridge-based ENDS if they contain a flavor.[29] The FDA's flavor ban notably excludes enforcement actions against menthol-flavored and non-cartridge-based ENDS, meaning disposable or tank system products are not banned.[30] The flavor ban comes in the form of "Guidance for the Industry" from the FDA, which means that rather than going through the official rulemaking process, the FDA stated in the Guidance that it will prioritize enforcement resources "with respect to certain illegally marketed ENDS products."[31] Specifically, the FDA "will prioritize enforcement of flavored, cartridge-based ENDS products (other than tobacco- and menthol-flavored products), which are produced primarily by large manufacturers."[32] The FDA highlighted in its Guidance that the "policy should have minimal impact on small manufacturers (*e.g.*, vape shops) that primarily sell non-cartridge based ENDS products, unless they market to youth or fail to take adequate measures to prevent youth access."[33] The FDA defines cartridge-based ENDS as "a type of ENDS product that consists of, includes, or involves a cartridge or pod that holds liquid that is to be aerosolized through product use."[34] This means that other types of ENDS, such as disposable ENDS, and tank or mod systems, which are larger devices that contain a refillable aerosol cartridge named a pod,[35] are exempt from the FDA flavor ban.

This epidemic of adolescent e-cigarette use became even more concerning when the COVID-19 pandemic entered the United States,

27. *FDA finalizes enforcement policy on unauthorized flavored cartridge-based e-cigarettes that appeal to children, including fruit and mint*, U.S. FOOD & DRUG ADMIN. (Jan. 2, 2020), https://www.fda.gov/news-events/press-announcements/fda-finalizes-enforcement-policy-unauthorized-flavored-cartridge-based-e-cigarettes-appeal-children.

28. Although the FDA has denied that this is a "ban" on flavored ENDS, this Note will refer to any restriction on flavored ENDS sale or production as a "flavor ban." U.S. DEP'T HEALTH & HUM SERVS., U.S. FOOD & DRUG ADMIN, CTRS. FOR TOBACCO PRODUCTS, ENFORCEMENT PRIORITIES FOR ELECTRONIC NICOTINE DELIVERY SYSTEMS AND OTHER DEEMED PRODUCTS ON THE MARKET WITHOUT PREMARKET AUTHORIZATION, GUIDANCE FOR INDUSTRY 37 (April 29, 2020), https://www.fda.gov/media/133880/download [hereinafter GUIDANCE].

29. This law was primarily aimed at combatting the popularity of refillable cartridge-based ENDS, such as Juul, amongst adolescents. *See* Laura Bach, *JUUL and Youth: Rising E-Cigarette Popularity*, CAMPAIGN FOR TOBACCO-FREE KIDS (Sept. 21, 2021), https://www.tobaccofreekids.org/assets/factsheets/0394.pdf.

30. Sheila Kaplan, *Teens Find a Big Loophole in the New Flavored Vaping Ban,* N.Y. TIMES (Jan. 31, 2020), https://www.nytimes.com/2020/01/31/health/vaping-flavors-disposable.html.

31. GUIDANCE, *supra* note 28.

32. *Id.* at 18.

33. *Id.*

34. *Id.*

35. *See* VAPORIZERS, *supra* note 3.

signaling many groups to call for more robust rules from the FDA.[36] Most significantly, studies have shown that there is a connection between e-cigarette use and COVID-19 risk that exposes ENDS users to "not just a small increase in risk."[37] According to a study done by the Journal of Adolescent Health, young adults ages thirteen to twenty-four were five times more likely to be diagnosed with COVID-19, and dual-users, those who had used e-cigarettes and combustible cigarettes, were 4.7 times more likely to exhibit symptoms.[38] Additionally, according to a peer-reviewed meta-analysis of nineteen studies done by the UCSF Center for Tobacco Control Research and Education, "smoking was associated with more than a doubling of odds of disease progression in people who had already developed COVID."[39] Although this study has not been confirmed by the FDA or the CDC, both agencies, along with the Surgeon General, have advised the public to "add stop smoking, vaping and avoiding secondhand exposure to their list of important [COVID-19] preventative measures."[40] The COVID-19 pandemic also brought complications to the enforcement capabilities set out by the FDA. Most notably, the FDA had to suspend in-person inspection activities, including as retail compliance checks and vape shop inspections, and has instead resorted to sending out warning letters and focusing on internet monitoring.[41]

The big push for flavor bans has inevitably been followed by pushback from interested parties, such as tobacco retailers and manufacturers, and even smaller vape shops, whose businesses could be impacted by recent flavor ban ordinances.[42] The pushback has come in all shapes and sizes—it has included non-litigious campaigns such as "We Vape, We Vote;"[43] litigious action, such as the R.J. Reynolds' challenges to both Minnesota and California

36. Stanton A. Glantz, *Vaping linked to COVID-19 risk in teens and young adults*, CTR. FOR TOBACCO CONTROL RES. & EDUC. (Aug. 11, 2020), https://tobacco.ucsf.edu/vaping-linked-covid-19-teens-and-young-adults.

37. *Id.*

38. *Id.*

39. Stanton A. Glantz, *Reduce your risk of serious lung disease caused by corona virus by quitting smoking and vaping*, CTR. TOBACCO CONTROL RSRCH. & EDUC. (Aug. 11, 2020), https://tobacco.ucsf.edu/reduce-your-risk-serious-lung-disease-caused-corona-virus-quitting-smoking-and-vaping.

40. *Id.*

41. *FDA Notifies Companies, Including Puff Bar, to Remove Flavored Disposable E-Cigarettes and Youth-Appealing E-Liquids from Market for Not Having Required Authorization*, U.S. FOOD & DRUG ADMIN. (July 20, 2020), https://www.fda.gov/news-events/press-announcements/fda-notifies-companies-including-puff-bar-remove-flavored-disposable-e-cigarettes-and-youth.

42. *See* Thomas Briant, *3 Lawsuits that Challenge Local Flavor Bans,* CSP (Jun. 26, 2020), https://www.cspdailynews.com/tobacco/3-lawsuits-challenge-local-flavor-bans#page=3.

43. Abby Goodnough, et al., *With Partial Flavor Ban, Trump Splits the Difference on Voting,* N.Y. TIMES (Jan. 2, 2020), https://www.nytimes.com/2020/01/02/health/flavor-ban-e-cigarettes.html?searchResultPosition=2.

rules;[44] and legislative lobbying, such as comments submitted to the FDA in response to its Guidance policy.[45] Additionally, since the FDA did not go through the official rulemaking process in accordance with the Administrative Procedures Act (APA)[46] and instead established its power to prohibit flavored e-cigarettes through an already existing rule,[47] many pro-ENDS groups have argued that the FDA's Guidance is improper stating the "FDA is bypassing the requirement[s]" of making an official regulation.[48] Pro-ENDS groups have submitted comments to the FDA, arguing that in order to make a rule such as the one established in the Guidance, the FDA must perform certain necessary analyses, such as the cost-benefit analysis and analysis of the rule's impact on small businesses pursuant to the APA.[49] For retailers and manufacturers, concerns are mounting over sale reductions and companies' abilities to "maintain the value of any brand."[50] Therefore, it is likely that these pro-ENDS groups' challenges to both the FDA's and state-level flavor bans are just beginning and that the ENDS industry will continue to fight these restrictions on their products.

With all these flavor ban challenges, the need for more robust flavor bans from the FDA is more crucial than ever. In order to best combat against the epidemic of adolescent ENDS usage and the risks posed by COVID-19, the FDA should initiate the rulemaking process and ban all flavored tobacco products—including menthol products and non-cartridge-based products—to create uniformity on this issue across all states in the U.S. and to ensure that a flavored ENDS ban will be upheld in court.

This Note highlights the risks associated with adolescent ENDS usage, discusses the authority of the federal government to create regulations on tobacco products, identifies the challenges to current laws, and proposes new, more vigorous legislation for flavored ENDS in order to combat these issues. Part I of this Note contemplates the legal history of government regulation of tobacco products and discusses the FDA's regulatory power as it pertains to ENDS. Part II of this Note highlights the key players in the fight for and against flavor bans and briefly identifies the strategies and motivations on both sides. Part III discusses the current regulatory environment such as the

44. Jack Queen, *Tobacco Cos. Strike Out in Challenge To City Flavor Ban*, LAW 360 (Sept. 2, 2020), https://plus.lexis.com/document/.

45. GUIDANCE, *supra* note 28.

46. The APA is a law that governs the general procedures for various types of rulemaking and applies to all agencies, including the FDA. TODD GARVEY, A BRIEF OVERVIEW OF RULEMAKING AND JUDICIAL REVIEW CONG. RSCH. SERV., R41546, (Mar. 27, 2017), https://fas.org/sgp/crs/misc/R41546.pdf. The APA provides for procedures regarding formal rulemaking, as well as informal rulemaking, also known as notice-and-comment. *Id.*

47. GUIDANCE, *supra* note 28.

48. *See id.* at 33.

49. *Id.*

50. *Tobacco Industry, Health Groups Meeting with OMB On FDA Flavor Ban*, Law 360 Legal News (Nov. 6, 2019), https://plus.lexis.com/document/?pdmfid=1530671&crid=136b478c-fb63-440d-afb6-%3A5XFB-SCW1-.

California flavor ban, other state and local bans and proposed menthol bans. It also highlights the industry's strong showing of opposition to all these bans, discusses the current federal regulations on flavored ENDS and highlight the current framework's weaknesses. Lastly, Part IV of this Note proposes an expansion of FDA regulations on flavored ENDS in order to combat the current ENDS epidemic amongst adolescents, the growing concern with its association of negative impacts by COVID-19 and to ensure sustainability of flavored ENDS restrictions.

I: THE FDA'S REGULATORY POWER OF TOBACCO PRODUCTS AND ENDS

A. RULEMAKING POWER THROUGH THE ADMINISTRATIVE PROCEDURES ACT

The FDA has the authority to make rules under the APA.[51] Typically, this results in the FDA engaging in a more common, informal form of rulemaking, known as the notice-and-comment rulemaking procedure.[52] Through this process, the FDA, in an effort to encourage participation and feedback from the public,[53] provides the public "with adequate notice of a proposed rule" and provides "interested persons with a meaningful opportunity to comment on the proposed rule" through written submissions.[54] Then, considering the public's feedback, and any relevant scientific or empirical evidence, either terminates the rulemaking process or issues a final rule.[55] Once the FDA issues a final rule, it will acknowledge the comments that were submitted during the comment period and the final rule will be published in *The Federal Register*, with a codified version of the rule published in the *Code of Federal Regulations* under Title 21.[56]

B. THE FDA'S EARLY, FAILED ATTEMPTS AT REGULATING TOBACCO

In 1995, after decades of refusing to regulate tobacco products, the FDA proposed legislation that would give it the power to regulate tobacco products under its power to regulate "drugs" pursuant to the Food, Drug & Cosmetics Act (FDCA).[57] The FDA determined that since nicotine is a drug, and since combustible cigarettes and smokeless tobacco products deliver that drug to

51. *See* Administrative Procedure Act, 5 U.S.C. § 553 (2012).
52. GARVEY, *supra* note 46.
53. *Id.*
54. *Id.*
55. U.S. FOOD & DRUG ADMIN., FDA RULES & REGULATIONS (2018), https://www.fda.gov/regulatoryinformation/rulesregulations/htm.
56. *Id.*
57. William Tilburg, et al., *FDA Regulation of Electronic Nicotine Delivery Systems and the "Deeming" Rule: What's Left for the States*?, 20 J. HEALTH CARE L. & POL'Y 27, 48 (2017).

the body, that it had authority to create regulations that would prevent tobacco use through the "drug-device" provision within the FDCA.[58] Five years later, in *FDA v. Brown & Williamson Corp.*, the Supreme Court of the United States rejected this determination and held that the FDA did not have the authority to regulate tobacco under the FDCA.[59] The Supreme Court reasoned that to interpret the term "drug" in this way is "clearly contrary to congressional intent"[60] and thus concluded that Congress meant to "exclude tobacco products from the FDA's jurisdiction."[61]

Ten years after *Brown & Williamson Corp.*, in *Smoking Everywhere, Inc.,* the FDA was back in court defending its regulation of tobacco products when it attempted to restrict the sale of e-cigarettes through barring shipments of those products from China [62] The FDA determined that it had the power to restrict the import of e-cigarettes because they were an "unapproved drug-device combination under the [FDCA]"[63] and defended its action by distinguishing the decision in *Brown Williamson Corp.* by arguing it did not apply to e-cigarettes.[64] The plaintiff e-cigarette companies, in *Smoking Everywhere, Inc.*, argued that e-cigarettes are the "functional equivalent" to cigarettes and, therefore, the decision in *Brown Williamson Corp.* applied.[65] The D.C. District Court sided with the e-cigarette companies, granting a huge win for the ENDS industry as it held that the FDA could not regulate e-cigarettes under the drug device provision in the FDCA.[66] Affirming this decision in 2009, less than a year after *Smoking Everywhere, Inc.* in *Sottera, Inc. v. FDA*, the U.S. Court of Appeals for the D.C. Circuit held that under the drug-device provision of the FDCA, the FDA only had jurisdiction to regulate tobacco products which claimed therapeutic effect.[67]

C. THE FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT (TCA)

The FDA's failed attempts at regulating traditional tobacco products and ENDS would be remedied in 2009 and 2016, respectively, when the TCA[68]

58. Matti Rose Vagnoni, *The Vapes of Wrath: Why the FDA should ban fruity and sweet flavored e-liquids to preclude adolescent use of e-cigarettes*, 71 ADMIN. L. REV. 277, 284 (2019).
59. FDA v. Brown & Williamson Corp., 529 U.S. 120, 156 (2000).
60. *Id.* at 130.
61. *Id.* at 143.
62. *See* Smoking Everywhere, Inc. v. United States FDA, 680 F. Supp. 2d 62 (D.C. Cir. 2010).
63. *Id.* at 63.
64. *Id.* at 67.
65. *Id.* at 66.
66. *See id.* at 71.
67. Sottera, Inc. v. FDA, 627 F.3d. 891, 898–99 (D.C. Cir. 2010).
68. *See* Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111–31, § 3(4) (2009).

and the Deeming Rule [69] were enacted under the Obama Administration. In 2009, when Congress passed the TCA, it granted the FDA the power "to regulate the manufacture, marketing, and distribution of cigarettes, cigarette tobacco, roll-your-own (RYO) tobacco, and smokeless tobacco products to protect the public health and to reduce tobacco use by minors."[70] In addition to this authority, the TCA gave the FDA the "authority to issue regulations deeming other products that meet the statutory definition of a tobacco product to be subject" to Chapter IX of the FDCA.[71] Thus, although the TCA was silent on the FDA's regulatory power over ENDS, this law gave the FDA the ability to deem this product a "tobacco product" in the future. [72]

D. THE DEEMING RULE AND PRE-MARKET REVIEW

In 2016, the FDA issued the Deeming Rule that deemed "all products that meet the statutory definition of a tobacco product," with the exclusion of those products' accessories, as "subject to [the] FDA's tobacco product authority."[73] The Deeming Rule extended the umbrella of regulatory power to all ENDS products.[74] By enacting the Deeming Rule, the FDA made ENDS subject to the pre-market authorization requirements in Section 910 in Chapter IX of the FDCA.[75] Section 910 imposes pre-market requirements for "new tobacco products," which are products that were "not commercially marketed in the United States as of February 15, 2007."[76] In doing a review of a product, the FDA conducts science-based testing to determine if it is "appropriate for the protection of public health with respect to the risks and benefits to the population as a whole."[77] The Deeming Rule noted that it would delay the enforcement of failure to meet this requirement during the submission and application processes for pre-market review, but noted that this delay did not apply to any products that were not already on the market as of August 8, 2016.[78] "Industry experts claim premarket approval would be

69. 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, 974 (May 10, 2016).

70. GUIDANCE, *supra* note 28.

71. *Id.*

72. Rosanne B. Termini, *A Look Back at the Evolution of the Family Smoking Prevention and Tobacco Control Act and the Present-Day Impact on 'Overlooked and Belated Issues' — Electronic Nicotine Delivery Systems and the Youth Epidemic, Menthol, Graphic Warnings and Corrective Statements,*17 IND. HEALTH L. REV. 107, 109 (2020).

73. GUIDANCE, *supra* note 28.

74. *Id.*

75. *Id.*

76. *Id.*

77. *Id.*

78. *Id.*

catastrophic for the ENDS market"[79] since the approval process is so costly.[80]

E. CHALLENGES TO ENDS BEING "DEEMED" TOBACCO

With the Deeming Rule in effect, the ENDS industry attempted to push back on the regulatory power of the FDA in this regard, but with little success. Specifically, pro-ENDS groups brought lawsuits against the FDA claiming both that it exceeded its statutory power, and that the existence of this power is unconstitutional. For example, in *Nicopure Labs, LLC v. FDA,* Nicopure, a manufacturer of e-cigarettes, brought an action against the FDA claiming that the FDA exceeded its statutory authority under the FDCA and TCA.[81] Nicopure claimed that the deeming decision was "arbitrary and capricious and should be set aside under the [APA]."[82] The D.C. District Court held that the FDA acted within its statutory authority, given the broad power granted to it by Congress under the TCA.[83] Additionally, it held that because the rule was reasonable and supported by the record, that it was not arbitrary and capricious.[84] Moreover, in *Big Time Vapes, Inc. v. FDA*, Big Time Vapes, a small-business manufacturer and retailer of ENDS, challenged Congress' delegation of the authority to the FDA to deem what products should be governed by the TCA.[85] Big Time Vapes claimed that this delegation was unconstitutional, and asked the court to enjoin the FDA from exercising its authority to regulate ENDS products.[86] The Fifth Circuit held this suit was properly dismissed by the district court in part because the deeming authority was "plainly limited" by Congress and it "restricted the [Secretary of Health and Human Services'] discretion by making many of the key regulatory decisions itself.[87]

II: THE STAKES

A. OPPONENTS OF FLAVOR BANS

Opponents of the current ENDS flavor bans, namely big tobacco companies and small retail vape shops, have argued that these bans are harmful not only to them, but to society for public health and economic reasons.[88] Specifically, opponents to these ENDS regulations have said that

79. Tillburg, *supra* note 57, at 62.
80. *Id.* at 61–62.
81. Nicopure Labs, LLC v. FDA, 266 F. Supp. 3d 360, 366 (D.D.C. 2017).
82. *Id.* at 366.
83. *Id.* at 367–68.
84. *Id.*
85. Big Time Vapes, Inc. v. FDA, 963 F.3d 436, 440 (5th Cir. 2020).
86. *Id.*
87. *Id.* at 445.
88. *See* Guy Bentley, *The Trump Administration's Ban of Flavored Vaping Cartridges Is Bad for Public Health*, REASON FOUND. (Jan. 2, 2020), https://reason.org/commentary/the-trump-

flavor bans will put small business vape shops into bankruptcy,[89] that the ENDS flavor restrictions will cost states billions of dollars in tax revenue,[90] and that adults, using ENDS as a way to stop smoking combustible cigarettes, will be left with fewer, less effective options to quit.[91] Opponents claim that "a total vape flavor ban would shut down more than 14,000 small businesses and put at least 166,000 people out of work, while denying millions of Americans access to the tools they used to quit smoking."[92] Additionally, convenience store owners in San Francisco and Sacramento claimed they had seen a 35% decrease in revenue due to flavor bans.[93] These owners surmised that when a consumer cannot get flavored ENDS at one store, they will travel further to get their gas and other convenient-store items at a store that *does* sell flavored ENDS.[94]

ENDS regulation opponents also suggest that with nineteen million ENDS users in the United States, the demand will not go away; instead an ENDS black market, with no oversight, will inevitably form.[95] ENDS regulation opponents also claim that by taking away flavored ENDS, adult smokers will turn back to combustible cigarettes or to the black market.[96] Big tobacco companies have claimed that ENDS can help adult smokers quit and can be "part of the 'public health solution.'"[97] By perpetuating this wholesome image of ENDS, the industry "continues to innovate to rebrand its public image and maintain its bottom line."[98] But big tobacco's stake in the outcome of these flavor bans is about more than public image since "despite declines in cigarettes sales," big tobacco "continues to maintain its

administrations-ban-of-flavored-vaping-cartridges-is-bad-for-public-health/; *see also* Jacob James Rich, *How California's Flavored Tobacco Ban Will Hurt Communities and Budgets*, REASON FOUNDATION (Nov. 18, 2020), https://reason.org/commentary/how-californias-flavored-tobacco-ban-will-hurt-communities-and-budgets/.

89. Amanda Hoover, *Vape shops said a flavor ban would end them. Coronavirus has only made things worse.*, NJ.COM (Apr. 7, 2020), https://www.nj.com/healthfit/2020/04/vape-shops-said-a-flavor-ban-would-end-them-coronavirus-has-only-made-things-worse.html#:~:text=Gov.,period%20before%20going%20into%20effect.

90. *See also* Hannah Prokop, *California Flavored Tobacco Sales Ban Would Devastate Small Retailers, Opponents Say*, CSP (Jul. 30, 2020), https://www.cspdailynews.com/tobacco/california-flavored-tobacco-sales-ban-would-devastate-small-retailers-opponents-say; *see also* Hoover, *supra* note 89.

91. Guy Bentley, *A Vaping Ban Would Be Bad Policy and Bad Politic*s, REASON FOUND. (Dec. 3, 2019), https://reason.org/commentary/vaping-ban-bad-policy-bad-politics/.

92. *Id.*

93. Prokop, *supra* note 90.

94. *Id.*

95. Bentley, *supra* note 91.

96. Hoover, *supra* note 89.

97. *Spinning a new tobacco industry: How Big Tobacco is trying to sell a do-gooder image and what Americans think about it*, TRUTH INITIATIVE (Dec. 20, 2019), https://truthinitiative.org/research-resources/tobacco-industry-marketing/spinning-new-tobacco-industry-how-big-tobacco-trying.

98. *Id.*

upward trajectory in profit, generating $18.4 billion in 2016."[99] Why? "In 2018 alone, the top twenty-five e-cigarette manufacturers brought in more than $2.5 billion in sales" with "96% of these sales" derived from "brands owned in whole or part by [b]ig [t]obacco."[100] Thus, big tobacco and ENDS are one in the same. These companies have spent millions of dollars in anti-flavor ban campaigns in recent years.[101]

B. PROPONENTS OF FLAVOR BANS

Proponents of flavor bans qualify opponents' arguments as deceptive and "a clear attempt to . . . increase the industry's revenue by continuing to addict our kids as long as they possibly can."[102] Flavor ban advocates say that since "4 out of 5 youth smokers will become adult smokers," and "since half of all adult smokers will die from smoking, tobacco companies need a constant stream of new recruits to stay profitable."[103] Proponents of flavor bans push back on the idea that flavors should be allowed to remain on the market for adults, since young children and adolescents are also exposed to "toxins such as heavy metals, ultrafine particulates, and nicotine through [adult use,] second-hand exposure" since "80% of parents who vape do so in homes and cars."[104] Flavor ban advocates' primary argument for initiating these bans is to "save lives" and prevent adolescents from "the lasting damages of the use and exposure to tobacco products."[105]

Flavor ban advocates, like their opponents, also have economic reasons behind as their motivation. Namely, these advocates point to data from the CDC that says "smoking-related illnesses in the United States costs more than $300 billion each year" both in direct costs and loss in productivity.[106] And to the vape shop owners who claim these flavor ban laws should only be directed towards kids and not adults, advocates are skeptical that they would even abide by those rules saying that "more kids who purchase e-cigarettes today purchase them from vape shops [as] they have the worst track record

99. *Id.*

100. *Id.*

101. *Gov. Newsom Lt. Gov. Kounalakis to California: Beware Big Tobacco's lies and deception to overturn landmark law to protect kids*, CALIFORNIA MED. ASS'N (Oct. 8, 2020), https://www.cmadocs.org/newsroom/Gov-Newsom-Lt-Gov-Kounalakis-California-Beware-Big-Tobacco-lies-deception-overturn-landmark-law-protect-kids.

102. *Id.*

103. *Banning Menthol and Flavored Tobacco,* TOBACCO STOPS WITH ME (last visited Oct. 25, 2020), https://stopswithme.com/not-ok/flavored-tobacco-ban/.

104. CALIFORNIA MED. ASS'N, *supra* note 101.

105. *Id.*

106. *Economic Trends in Tobacco Economic Costs Associated With Smoking*, CTR. FOR DISEASE CONTROL (last updated May 18, 2020), https://www.cdc.gov/tobacco/data_statistics/fact_sheets/economics/econ/index.htm.

for selling to underage youth."[107] Additionally, advocates point to a recent study that showed that the TCA's restriction of the sale of certain flavored combustible cigarettes in 2009, was effective.[108] Specifically, the predicted probability of youth traditional, combustible cigarette smoking was reduced by 43% in comparison to the model predicted probability in the absence of the ban.[109] The positive effects of this ban have clearly been stifled by the growing flavored ENDS epidemic. However, the beneficial results of the flavored cigarette ban provide strong evidence for how effective an ENDS flavor ban could be.

The main goal of these flavor bans is to reduce adolescent exposure to nicotine and to prevent the health risks associated with tobacco use, since tobacco use is the number one preventable cause of death in the United States[110] and since the connection between flavored ENDS and adolescent addiction is clear. Nicotine is proven to be "highly addictive," "toxic to developing fetuses" and "can harm adolescent brain development which continues into the early to mid-20s;"[111] ENDS aerosols also can contain "cancer-causing chemicals and tiny particles that reach deep into the lungs."[112] Additionally, research showed that in 2020 "85% of high school students and 74% of middle school students who used tobacco products in the past 30 days" reported that they had used a flavor tobacco product.[113] Also, over 80% of adolescent users that tried e-cigarettes for the first time said that their first use was with a flavored product.[114] Even more problematic, the tobacco industry's claim that ENDS are a healthier alternative to combustible cigarettes is still relatively unreliable given ENDS have only been on the market since 2004.[115] The World Health Organization (WHO) has even pointed out that some e-cigarette brands contain "the same

107. Marisa Fernandez, *FDA Issues Ban On Fruit and Mint-Flavored Vape Cartridges,* AXIOS (Jan. 2, 2020), https://www.axios.com/fda-ban-flavored-vaping-cartridges-f58680ae-7ad2-4e2c-85a1-eac1d1f0104a.html.

108. *See* Matthew Rossheim, et al., *Cigarette Use Before and After the 2009 Flavored Cigarette Ban*, 67 J. ADOLESCENT HEALTH 432 (Sept. 1, 2020), https://www.jahonline.org/article/S1054-%2820%2930335-9/abstract.

109. Jamie Long, *California is Second State to Prohibit Flavored Tobacco Product Sales*, PUB. HEALTH L. CTR. (Aug. 28, 2020), https://www.publichealthlawcenter.org/blogs/2020-08-28/california-second-state-prohibit-flavored-tobacco-product-sales.

110. *See* Maddie Hayness, *California's STAKE Act (Stop Tobacco Access to Kids Enforcement)*, FOUNDS. OF LAW & SOC'Y (Dec. 18, 2020), https://foundationsoflawandsociety.wordpress.com/2018/12/07/california-stake-act-stop-tobacco-access-to-kids-enforcement/.

111. Bottom Line, *supra* note 10.

112. *Id.*

113. *Youth and Tobacco Use*, CTR. FOR DISEASE CONTROL (last updated Sept. 9, 2020), https://www.cdc.gov/tobacco/data_statistics/fact_sheets/youth_data/tobacco_use/index.htm.

114. *Is Vaping Better Than Smoking?,* AMERICAN HEART ASS'N (last reviewed Oct. 30, 2018), https://www.heart.org/en/healthy-living/healthy-lifestyle/quit-smoking-tobacco/is-vaping-safer-than-smoking.

115. Alyssa Sheets, *Paternalism as a Justification for Federally Regulating Advertising E-Cigarettes to Children*, 12 WASH. U. JURIS. REV. 321, 326 (2020).

amounts of carcinogenic ingredients that are found in conventional cigarettes," including formaldehyde,[116] and the American Heart Association has identified that some e-cigarettes deliver more nicotine that combustible cigarettes.[117] Thus, despite there being some short-term economic costs to those selling the product, the overall benefits of combatting this epidemic as soon as possible outweighs any negative side effects of the flavor bans.

III: CURRENT ENDS FLAVOR RESTRICTIONS

A. CALIFORNIA FLAVOR BAN

The California flavor ban, in addition to the Massachusetts flavor ban, is one of the most comprehensive flavor bans to date, as it bans flavored tobacco in all tobacco products, including ENDS across the spectrum, like disposable vape pens, pods and tank-based systems.[118] It defines "flavored tobacco product" as "any product that has a characterizing flavor, which is defined to cover any distinguishable taste or aroma other than that of tobacco, explicitly listing mint and menthol flavors as examples."[119] The ban states that any violation of the law, by a tobacco retailer or its agents, is punishable by $250 per violation.[120]

In response to the law, big tobacco companies have succeeded in forcing a referendum, which postpones the law's effect date, which was scheduled for January 1, 2021.[121] On the same day the bill was passed, three individuals with ties to big tobacco companies filed the necessary paperwork to start collecting signatures to get the referendum added to the ballot in November of 2022.[122] To get the referendum on the ballot, these petitioners needed to submit "623,212 signatures" or "5 percent of the votes cast for all candidates for Governor in 2018" by November 30, 2020.[123] The petition received over a million signatures, which means the law will be ineffective until at least

116. *Id.*

117. AMERICAN HEART ASS'N, *supra* note 114.

118. Elizabeth Aguiera, *Goodbye 'banana smash' cigarillos: Governor quickly signs bill to ban flavored tobacco*, CAL MATTERS (Aug. 28, 2020), https://calmatters.org/health/2020/08/california-flavored-tobacco-ban/.

119. *California's Flavored Tobacco Ban (SB793)*, PUB. HEALTH L. CTR. 1 (Sept. 2020), https://www.publichealthlawcenter.org/sites/default/files/resources/CA-Flavor-Tobacco-Ban-SB793.pdf.

120. S.B. 793, 2000, Reg Sess. (Ca. 2000).

121. *Tobacco industry funded referendum postpones California flavor ban*, COUNTERTOBACCO.ORG (Dec. 11, 2020), https://countertobacco.org/tobacco-industry-funded-referendum-postpones-california-flavor-ban/.

122. Stanton A. Glantz, *Tobacco Companies to Force a Referendum on California State Flavor Tobacco Product Ban*, CTR. FOR TOBACCO CONTROL RSRCH. & EDUC. (Sept. 7, 2020), https://tobacco.ucsf.edu/tobacco-companies-force-referendum-california-state-flavored-tobacco-product-ban.

123. Jamie Long, *What the Referendum on California's Flavored Tobacco Sales Means*, PUB. HEALTH L. CTR. (Sept. 18, 2020), https://publichealthlawcenter.org/blogs/2020-09-04/what-referendum-californias-flavored-tobacco-sales-ban-means.

November 2022.[124] In California alone, the tobacco industry is projected to make $1.1 billion before November 2022 and to hook approximately 37,000 more high school aged adolescents on ENDS, costing the state $800 million in healthcare costs.[125] If the voters defeat the law on the ballot in November 2022, then SB-793 will no longer be law.[126]

The referendum push came on the heels of one big tobacco company's, R.J. Reynolds, suit challenging a Los Angeles County flavor ban.[127] The suit was thrown out by a federal judge, who ruled that "federal law gives states and localities the power to ban the sale of tobacco products."[128] R.J. Reynolds, petitioning with American Snuff Co. and Santa Fe Natural Tobacco Co., claimed in their suit that the TCA preempted LA's ordinance and that the ordinance "undermines the [TCA's] ability to set national standards to control the manufacture of tobacco products."[129] The federal judge pointed out that that the ordinance is protected by the preservation clause, which "allows states and localities to prohibit the sale of tobacco products even if those sales bans are stricter than federal law."[130] R.J. Reynolds has since filed an appeal to the 9th Circuit, requesting a preliminary injunction against Los Angeles from enforcing its ban.[131] Should SB-793 get defeated by the California citizen's vote, local counties, such as LA will still be able to maintain their flavor ban ordinances,[132] unless the 9th Circuit overrules the lower court's ruling.

B. OTHER STATE AND LOCAL FLAVOR BANS

Nine states—Massachusetts, Michigan, Montana, Maryland, Rhode Island, New Jersey, New York, Utah, and California—have temporarily or permanently banned at least flavored e-cigarettes.[133] Other states, like Maine, have only enacted flavor bans on flavored cigars.[134] Of these states, Maryland and Utah exempt menthol flavors and Utah allows flavored e-cigarettes to be sold in specialty shops.[135] Many big cities, including Chicago, Minneapolis, and Philadelphia, have also banned flavored e-cigarettes; this is in addition

124. COUNTERTOBACCO.ORG, *supra* note 121.
125. CALIFORNIA MED. ASS'N, *supra* note 101.
126. Long, *Referendum on California*, *supra* note 123.
127. *R.J. Reynolds Tobacco Company et al v. County of Los Angeles et al. (2020),* PUB. HEALTH L. CTR. (last updated Sept. 30, 2020), https://www.publichealthlawcenter.org/content/rj-reynolds-tobacco-company-et-al-v-county-los-angeles-et-al-2020.
128. Laura Berg, *LA Vape Flavor Ban Survives Tobacco Industry Challenge*, LAW 360 (Aug. 10, 2020), https://www.law360.com/articles/1299923/la-vape-flavor-ban-survives-tobacco-industry-challenge.
129. *Id.*
130. *Id.*
131. PUB. HEALTH L. CTR., R.J. Reynolds, *supra* note 127.
132. Long, *Referendum on California*, *supra* note 123.
133. *See* PUB. HEALTH L. CTR., *Out of Flavor*, *supra* note 25.
134. *Id.*
135. *Id.*

to the over 270 local bans in nine states across the country.[136] These city and locality ordinances vary in how robust they are. For example, some of these ordinances, such as the St. Louis Park, Minnesota ordinance, are as strong as the California and Massachusetts laws and ban all flavors, including menthol-flavors and with little exceptions as to whom it applies.[137] Whereas other ordinances, such as the Providence, Rhode Island ordinance, have long lists of exemptions.[138]

Most of these ordinances have been challenged with litigation by plaintiffs that vary from big tobacco companies[139] to small, independent convenience stores.[140] In Edina, Minnesota, for example, tobacco giants R.J. Reynolds and American Snuff Company, LLC teamed up with two independent retailers to challenge the City of Edina's extensive flavor ban.[141] In the complaint, the plaintiffs assert that the TCA "expressly denie[s] states and local units of government the ability to promulgate standards that are different from or in addition to federal tobacco product standards"[142] and "preempts the ordinance because the City of Edina's ban stands as an obstacle to the purposes of federal law."[143] These claims, along with notions of unconstitutional vagueness and violation of substantive due process rights,[144] are amongst the most cited arguments put forth by these flavor ban challengers.

Although many of these challenges have had little success, judges have sided with challengers and enjoined some of these laws. For example, Philadelphia's ban on the sale of flavored tobacco was enjoined by a federal district court, when the court found that the plaintiff met their burden of demonstrating a likelihood of success on the merits of their claim that the law was preempted by Pennsylvania state laws.[145] Additionally, in May 2020, "a three-judge panel of the Michigan Court of Appeals upheld a Court of Claims preliminary injunction against Gov. Gretchen Whitmer's [ENDS flavor

136. Long, *California is Second State to Prohibit Flavored Tobacco*, *supra* note 109.

137. PUB. HEALTH L. CTR., *Out of Flavor*, *supra* note 25.

138. *Id.* Some of these exceptions include: retailers that derive more than 80% of revenue from sale of tobacco products, adult-only tobacco stores or establishments, smoking bar establishments, or retailers not within 500 feet of a school. *Id.*

139. As of July 2020, from JUUL Labs, Inc. alone, there were 758 lawsuits across the United States. *E-Cigarette Lawsuits*, DRUGWATCH (last modified Oct. 6, 2020), https://www.drug watch.com/e-cigarettes/lawsuits/.

140. *See* PUB. HEALTH L. CTR., *Out of Flavor*, *supra* note 25.

141. Complaint at 1, R.J. Reynolds Tobacco Company, et.al, v. City of Edina, et al. No. 0:20-cv-01402 (D. Minn. June 27, 2020).

142. *Id.* at 4.

143. *Id.* at 5.

144. *See* PUB. HEALTH L. CTR., *Out of Flavor*, *supra* note 25.

145. Agustin Rodriguez, *Federal Court Enjoins City of Philadelphia Ban on Flavored Tobacco Products,* TOBACCO L. BLOG (last visited Nov. 21, 2020), https://www.tobaccolawblog.com/2020/11/federal-court-enjoins-city-of-philadelphia-ban-on-flavored-tobacco-products/#more-4007.

ban]"[146] finding that the law was a "government overreach" and that the vape shop plaintiffs showed a likelihood of prevailing on the merits of their contention that the [law] is procedurally invalid."[147] Although these cases will likely be appealed, "they "[show] the vulnerability of local ordinances."[148]

C. PROPOSED MENTHOL-RELATED BANS

When the FDA excluded menthol from its flavored-cigarette ban in 2009, it left open an avenue for non-smokers to initiate smoking and for smokers to avoid cessation.[149] Menthol has a cooling, mitigating effect on the harshness of tobacco products, making it easier for a non-smoker to begin smoking and making it more difficult for any smoker to quit.[150] Additionally, it has been demonstrated that the tobacco industry has used menthol popularity to prey on certain segments of the U.S., particularly African American youth and the broader community—approximately 86% of current African American smokers use menthol cigarettes.[151] Over the past eleven years, there have been calls by various groups, including the Black Lives Matter movement, to ban menthol-flavored cigarettes and other tobacco products.[152] These groups have sued the FDA, proposed legislation and most recently, the Campaign for Tobacco-Free Kids, the American Dental Association, and sixty other organizations have asked the FDA to join over twenty jurisdictions in the United States[153] and prohibit the use of menthol-flavor in *all* tobacco products.[154]

D. FDA FLAVORED ENDS INDUSTRY GUIDANCE

The FDA flavor ban, although a valid attempt by the Trump Administration to "protect [American] children" and to "protect the

146. Robin Erb, *Michigan appeals court sides with vape shop, against flavored vaping ban*, BRIDGE MICHIGAN (May 21, 2020), https://www.bridgemi.com/michigan-health-watch/michigan-appeals-court-sides-vape-shop-against-flavored-vaping-ban.

147. David Eggert, *Court: Injunction Blocking Michigan E-cigarette Bans Stands*, AP NEWS (May 22, 2020), https://apnews.com/article/a1cfeb2d69501b318098faaf8bd2f22a.

148. Rodriguez, *supra* note 145.

149. *ADA, others ask FDA to ban menthol-flavored tobacco products*, TOBACCO FREE CO. (Dec. 14, 2020), https://www.tobaccofreeco.org/product/ada-and-others-ask-fda-to-ban-menthol-flavored-tobacco-products/.

150. U.S. FOOD & DRUG ADMIN., *supra* note 20.

151. *Id.*

152. Tiffany Kary, *Lawsuit Aims to Ban Menthols, Big Tobacco's Bait for Black Smokers*, BLOOMBERG BUSINESSWEEK (Oct. 13, 2020), https://www.bloomberg.com/news/features/2020-10-13/lawsuit-aims-to-ban-menthols-big-tobacco-bait-for-black-smokers.

153. Christopher J. Cadham, et al., *The actual and anticipated effects of a menthol cigarettes ban: a scoping review*, 20 BMC PUB. HEALTH 1055 (2020).

154. *See e.g.* Kary, *supra* note 152; Matthew Daly, *House approves bill to ban the sale of flavored e-cigarettes*, ABC NEWS (Feb. 28, 2020), https://abcnews.go.com/Health/wireStory/house-approves-bill-ban-sale-flavored-cigarettes-69286647; TOBACCO FREE CO., *supra* note 149.

industry,"[155] is not without its weaknesses. First, it was not enacted through the official rulemaking process which creates opportunity for potential challenges to the ban on the claim that the Guidance exceeded the FDA's authorized powers. Second, the ban's lack of extensivity as it pertains to menthol-flavored products and non-cartridge-based products is counter-productive to the overall goal of ending adolescent ENDS usage.

The FDA flavor ban comes not in the form of an official rule to be registered with the *Federal Register*, but in the form of Guidance which "contains nonbinding recommendations."[156] The Guidance was issued to advise the industry on how it intends to "prioritize [the] enforcement resources with regard to the marketing of certain deemed tobacco products that do not have premarket authorization."[157] In other words, since ENDS are "new" tobacco products under the Deeming Rule, all "deemed new tobacco products that remain on the market without marketing authorization are marketed unlawfully in contravention of the [TCA];"[158] premarket authorization is a long and expensive process in which the FDA reviews the health and safety of the product.[159] This Guidance thus advises large ENDS manufacturers that the "FDA intends to prioritize enforcement for lack of marketing authorization against any flavored cartridge-based ENDS product (other than a tobacco- or menthol-flavored ENDS product) that is offered for sale in the United States without regard to whether or when premarket application for such product has been submitted" under Section 910 of the FDCA.[160] Therefore, it is just redirecting its enforcement powers from a different section, rather than creating a new regulation directed at flavored ENDS products.

The Guidance makes exceptions for small manufacturers and vape shop retailers, stating it will still allow for ENDS to be reviewed and potentially approved for legal marketing and sale.[161] In the pre-market application, applicants must submit "scientific studies assessing [the] public health factors, as well as showing whether there are harmful health effects for individuals from vaping."[162] Due to ENDS relatively new entry to the market, applicants are at an advantage here since the harmful health effects are not

155. Jamie Gumbrecht & Kevin Liptak, *Trump administration plans to ban most flavored e-cigarette cartridges, but not menthol*, CNN (last updated Jan. 1, 2020), https://www.cnn.com/2019/12/31/health/e-cigarette-flavor-ban-fda-trump-bn/index.html.

156. GUIDANCE, *supra* note 28.

157. *Id* at 2.

158. *Id* at 2, n.2.

159. *See* Tilburg, *supra* note 57.

160. GUIDANCE, *supra* note 28.

161. Alexandra Kelley, *The vaping 'flavor ban' goes into effect today. Here's what it does*, THE HILL (Feb. 6, 2020), https://thehill.com/changing-america/well-being/prevention-cures/481853-the-vaping-flavor-ban-goes-into-effect-today.

162. Andrew Siddons, *FDA to Review Huge Applications from vaping companies*, ROLL CALL (Sept. 10, 2020), https://www.rollcall.com/2020/09/10/fda-to-review-huge-applications-from-vaping-companies/.

well documented. Additionally, applicants are likely to cite the benefits of combustible cigarette smoking cessation over the past decade that they will attribute to ENDS. This means that products "targeted under the enforcement" by the FDA "could ultimately be approved and re-enter the market."[163] While applications are pending, so long as these non-large ENDS manufacturers are not marketing their products to young adults, their products will remain on the shelves and remain unprioritized by the FDA for enforcement.

In addition to failing to include menthol-flavored products, the FDA fails to incorporate any products other than cartridge-based ENDS into the enforcement policy.[164] Cartridge-based ENDS, although among one of the most popular products with the youth since they are refillable, small and easily concealable devices,[165] are not the only enticing ENDS products on the market. Namely, disposable products, such as Puff Bars,[166] are just as appealing to adolescents, and remain available in flavored form, due to the Guidance's footnoted exception of disposable ENDS.[167] Not only will these flavored products, such as pink lemonade, blueberry ice and tropical mango, remain on the market, but they are also typically a cheaper alternative to cartridge-based ENDS, such as Juul, and thus could be even more appealing to young adults.[168] Tank systems are also exempt according to the definition of "cartridge-based ENDS."[169] These products "require the flavored liquids be added to devices that then convert them into an inhalable aerosol"[170] are often sold at vape shops, which the FDA has said it would not be seeking enforcement against. This is problematic since vape shops have a poor track record when it comes to selling to underage youths.[171]

163. Goodnough, *supra* note 43.

164. GUIDANCE, *supra* note 28, at 19.

165. Azim Chowdhury & LieAnn Van-Tull, *FDA's New Enforcement Priority Guidance for E-Cigarettes Focuses on Flavored Cartridge-Based Devices as well as Companies and Products that FDA Views as Targeting Youth*, KELLER & HECKMAN LLC (Jan. 14, 2020), https://www.thecontinuumofrisk.com/2020/01/fdas-new-enforcement-priority-guidance-for-e-cigarettes-focuses-on-flavored-cartridge-based-devices-as-well-as-companies-and-products-that-fda-views-as-targeting-youth/#page=1.

166. In July 2020, the FDA issued warning letters to Puff Bar and nine other companies, advising them to remove their "flavored disposable e-cigarettes" off the market because they do not have premarket authorization. *FDA Notifies Companies, Including Puff Bar, to Remove Flavored Disposable E-Cigarettes and Youth-Appealing E-Liquids from Market for Not Having Required Authorization*, U.S. FOOD & DRUG ADMIN. (July 7, 2020), https://www.fda.gov/news-events/press-announcements/fda-notifies-companies-including-puff-bar-remove-flavored-disposable-e-cigarettes-and-youth. The FDA, however, did not issue an addendum to the Guidance or move to use its enforcement priorities against the ten warned companies. *Id.*

167. GUIDANCE, *supra* note 28, at 9.

168. Matthew Perrone, *FDA crackdown on vaping flavors has blind spot: disposables*, ABC NEWS (Feb. 6, 2020), https://abcnews.go.com/Health/wireStory/fda-crackdown-vaping-flavors-blind-spot-disposables-68803315.

169. GUIDANCE, *supra* note 28, at 9.

170. Goodnough, *supra* note 43.

171. Fernandez, *supra* note 107.

It is likely that the FDA did not seek to create a rule under the official rulemaking process due to the backlash it would get from the tobacco industry and the time it would take to carry out the process. The non-binding and temporary nature of the Guidance, however, is weak as it does not offer a long-term solution to this already existing adolescent ENDS usage issue.

IV: THE NEED FOR A MORE ROBUST FLAVOR BAN

The FDA should incorporate certain necessary changes to its current, temporary enforcement priorities listed in the Guidance and should enact an extensive flavored ENDS regulation in an effort to: (i) create a permanent solution to the current adolescent ENDS usage epidemic; (ii) combat the negative effects associated with ENDS usage and COVID-19; (iii) address the public health crisis associated with menthol; and (iv) establish uniformity of laws across the US as it pertains to ENDS.

It is necessary that during the permanent solution rulemaking process, the FDA incorporates menthol-flavored products and non-cartridge-based products into its current Guidance. Next, the FDA should use its regulatory authority to codify a flavored ENDS regulation, ensuring that three significant concepts are included in the final regulation. First, the FDA should create a regulation that prohibits the use of any flavored ingredients, other than tobacco-flavor, including menthol flavors, in the production of any ENDS products. Second, the FDA should ensure this regulation applies to all ENDS products, including "vapes, vaporizers, vape pens, hookah pens, electronic cigarettes (e-cigarettes or e-cigs), and e-pipes."[172] Third, the new regulation should not have any exceptions for small manufacturers or retailers. Lastly, if the ENDS product is not manufactured within the United States and thus is not produced in accordance with this proposed regulation, the FDA should restrict the sale of those products unless the products comply with the proposed regulation standards.

A. RULEMAKING AUTHORITY: A PERMANENT SOLUTION

The TCA gives the FDA the power to implement product standards, including ingredient standards, for tobacco products in order to protect the public's health.[173] Since the current Guidance is neither binding nor permanent, the FDA should use this regulatory authority to create a product standard banning all flavored ingredients other than tobacco-flavors in all ENDS products to create a permanent solution to this epidemic. By creating an official regulation through its rulemaking authority, the FDA would subdue concerns that it is exceeding its power by circumventing the

172. VAPORIZERS, *supra* note 3.

173. *Family Smoking Prevention and Tobacco Control Act – An Overview,* U.S. FOOD & DRUG ADMIN. (last updated June 3, 2020), https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/family-smoking-prevention-and-tobacco-control-act-overview.

necessary processes for permanent and binding regulations. Specifically, the FDA should follow necessary procedures established by the APA. This means the FDA should issue a Notice of Proposed Rulemaking, conduct required cost-benefit analyses, and provide for a more extensive notice and comment period for stakeholders to provide public comments.[174] Hosting an additional notice and comment period on the proposed regulations would provide clarity on what suppliers and retailers must do in order to meet compliance standards[175] and allow those parties to prepare for the regulatory scheme in order to create stability within the market.

Enacting a regulation will also relieve states and localities from needing to defend their flavor banning ordinances in court. State and local governments, although they do have the authority to make laws regarding ENDS sales and distributions, do not have product standard authority—meaning states do not have authority to make ingredient regulations. Thus, having a federal baseline flavor ban will create uniformity and stability, and it would not prevent state and local governments from creating restrictions even bolder than what the FDA enacts.[176]

B. THE NEED FOR MORE ROBUST REGULATIONS

Former Health and Human Services Secretary Alex M. Azar II stated "by prioritizing enforcement against the products that are most widely used by children" the FDA Guidance "seeks to strike the right public health balance by maintaining e-cigarettes as a potential off-ramp for adults using combustible tobacco while ensuring these products don't provide an on-ramp to nicotine addiction for our youth."[177] The issue with this measure, however, is that youths are not deterred from picking up ENDS products simply because they are menthol-flavored. Instead, youths are switching to the menthol-flavored ENDS, which is not surprising given that menthol is similar to mint-flavor in that it "cools and numbs the throat and reduces the harshness of tobacco smoke."[178] Federal data shows that menthol, despite accounting for about one-tenth of e-cigarette sales in 2019, now accounts for more than 52% of total e-cigarette sales, effectively taking the place of mint-flavored

174. When the FDA wants additional input from the public before issuing a rule, it issues Advance Notice of Proposed Rulemaking (ANPRM). Vagnoni, *supra* note 58. In March 2018, the FDA issued ANPRM regarding the regulation of flavors in e-cigarettes in order to obtain additional information about flavored-tobacco usage amongst adolescent users. Vagnoni, *supra* note 58.

175. GUIDANCE, *supra* note 28, at 33.

176. The TCA preserves state and local governments' rights "to regulate sales and other consumer-related aspects of the industry." U.S. Smokeless Tobacco Mfg. Co. v. City of New York, 708 F.3d 428, 434 (1st Cir. 2013). Since the statutory language of the TCA preserved broad authority for the states, flavor bans are not preempted by the TCA.

177. Goodnough, *supra* note 43.

178. *U.S. State and Local Issues Ending the Sale of Flavored Tobacco Product,* CAMPAIGN FOR TOBACCO-FREE KIDS (last updated Sept. 1, 2020), https://www.tobaccofreekids.org/what-we-do/us/flavored-tobacco-products.

ENDS.[179] Since adolescent ENDS users are likely to switch to menthol, defeating the purpose of the flavor ban, it is necessary to include menthol in the FDA product ingredient restrictions.

For similar reasons, disposable and non-cartridge-based ENDS, including tank systems, should also be incorporated into the flavor-ban restricted products. Disposable ENDS' use increased 1000% from 2019 to 2020, according to federal data, with 72.6% of those disposable sales being for flavored products.[180] Adolescents are not disincentivized from using disposable products because they too, like cartridge-based ENDS, are typically small and easily concealable and they are often a cheaper alternative to cartridge-based ENDS.[181] Additionally, tank systems, despite typically being sold at adult vape shops, should also be included in this regulation since vape shops are the worst offenders when it comes to selling to adolescents.[182] By having loopholes that allow for products like disposable and open-tank systems on the market, any progress that has been made by the curbing of flavored cartridge-based ENDS use, risks being "significantly slowed" or even "reversed."[183]

Although some stakeholders claim that non-cartridge based and menthol-flavored ENDS are necessary for adult combustible cigarette cessation success, the maintenance of tobacco-flavored ENDS on the market should satisfy their concerns for several reasons. Most importantly, "current combustible cigarette smokers are accustomed to smoking tobacco" because flavored combustible cigarettes are not on the market, "so the switch to a [tobacco-flavored e-cigarette] can still provide the same sensory experience and dose of nicotine" needed to have success in the cessation process.[184] In fact, most adult users begin with tobacco-flavored ENDS and then switch to flavored ENDS later on.[185] Therefore, flavored ENDS in the form of menthol-flavors or non-cartridge-based systems, may help an adult smoker to quit combustible cigarette smoking, but could also prolong tobacco use in the long term. Additionally, e-cigarettes cause eighty-one times more new smokers than quitters, so keeping an enticing and harmful product on the market for the 3% of adult ENDS users cannot be justified.[186] Lastly, tobacco-flavor

179. *New federal data: Flavored e-cigarettes continue to drive youth vaping epidemic, with disposable use up 1,000% among high schoolers*, TRUTH INITIATIVE (Sept. 15, 2020), https://truthinitiative.org/research-resources/emerging-tobacco-products/new-federal-data-flavored-e-cigarettes-continue-drive.

180. *Id.*

181. Perrone, *supra* note 168.

182. Fernandez, *supra* note 107.

183. TRUTH INITIATIVE, *supra* note 179.

184. Vagnoni, *supra* note 58.

185. *See* M.B. Harrell et al., *Flavored E-Cigarette Use: Characterizing Youth, Young Adult, and Adult Users*,
5 PREVENTATIVE MED. REP. 33, 34 (2016).

186. Laura Bach, *Electronic Cigarettes and Youth*, CAMPAIGN FOR TOBACCO-FREE KIDS 1, 2 (June 8, 2018), https://www.tobaccofreekids.org/assets/factsheets/0382.pdf.

being the only ENDS flavor on the market is likely to decrease usage among adolescents since "adult preference for tobacco-flavored ENDS is over triple that of youth."[187]

It is also necessary for this regulation *not* to have exceptions for vape shops, adult smoke shops, and other retailers, due to the circumvention tactics we have already seen by these parties with current flavor bans. For example, if the regulation made exceptions for vape or smoke shops, then convenience stores, such as the entrepreneurial Holiday Station store in Duluth, Minnesota, can merely build smoke shops within their stores to meet compliance standards.[188] Additionally, these extensive measures are necessary because if the FDA were not to take as strong a stance, and instead "[m]erely require[ed] brick and mortar retailers to invest in age-verification technology without providing any actual guidance or specific qualifications, " the FDA would allow for "a loophole for retailers to continue selling flavored e-cigarettes."[189] Lastly, any non-large manufacturers must be included in these regulations, so that the FDA can ensure that these products are completely removed from the market.

Additionally, the economic arguments that stakeholders pose in opposition to ENDS flavor bans are weak when juxtaposed to the health of America's youth and when compared to similar legislation concerning combustible cigarettes. First, the TCA gave the FDA "the authority to regulate the manufacture, marketing, and distribution of combustible cigarettes, combustible cigarette tobacco, roll-your-own (RYO) tobacco, and smokeless tobacco products to protect the public health and to reduce tobacco use by minors"[190] and so for the FDA to not use its power to stop this growing epidemic due to the fear of loss in tax revenue, would be irresponsible. Second, "almost 40 percent of high school users are using an e-cigarette on 20 or more days out of the month and almost a quarter of them use e-cigarettes every day, indicating a strong dependence on nicotine among youth."[191] This dependence is problematic for a variety of reasons. Namely, "[e]xposure to nicotine during adolescence, which researchers describe as 'an age of explosive development of both emotional and cognitive sides of the mind,' increases the risk of developing memory and attention impairment, as well as a variety of mental and behavioral problems—major depressive

187. Vagnoni, *supra* note 58, at 304.

188. Brady Slater, *Duluth businesses circumvent flavored tobacco ban*, DULUTH NEWS TRIBUNE (Mar. 19, 2020), https://www.duluthnewstribune.com/news/government-and-politics/4587043-duluth-businesses-circumvent-flavored-tobacco-ban.

189. Vagnoni, *supra* note 58, at 304.

190. GUIDANCE, *supra* note 28, at 3.

191. *Youth Tobacco Use: Results from the National Youth Tobacco Survey,* U.S. FOOD & DRUG ADMIN. (last updated Nov. 19, 2020), https://www.fda.gov/tobacco-products/youth-and-tobacco/youth-tobacco-use-results-national-youth-tobacco-survey#1.

disorder, agoraphobia, and panic disorder [included]."[192] These problems, in addition to the potential for "mysterious vaping-related illness"[193] or death, are enough of a moral reason, let alone an economic reason, to use every effort not only to stop this epidemic, but to reduce the amount of adolescent nicotine usage. Lastly, the FDA banned flavored, combustible cigarettes, with the exclusion of menthol-favored cigarettes in 2009.[194] The FDA characterized this ban as "an important first step for responsible tobacco regulation to protect the American public, particularly children, from the dangers of combustible cigarettes—the product most responsible for tobacco-related death and disease in the United States."[195] Since the FDA has already used its power to ban flavored-cigarettes, it should do the same for all ENDS products. Additionally, since the FDA is considering now banning menthol-flavored cigarettes,[196] it is important it does the same for ENDS products. Due to the popularity of tobacco products today,[197] it is possible that flavored restrictions will not economically harm the tobacco industry as much as it claims since the sales for tobacco-flavored products will likely continue.

Lastly, due to the global COVID-19 pandemic effects on ENDS users, extensive regulations are more important than ever to protect America's youth. Opponents of flavor bans may argue that these ENDS/COVID-19 concerns are unwarranted because the FDA approved vaccines are "highly effective at preventing severe illness and death from COVID-19."[198] However, "scientists still don't know how long vaccine-induced protection will last," and they do not know "whether inoculations can block actual infection, or only prevent the onset of disease."[199]Even more worrisome is the low rates of fully vaccinated young people: as of July 2021, only 25 percent of young adults ages 12–15 were vaccinated and about 37% of 16–

192. Jenni Avins, *How to make sense of the vaping crisis*, QUARTZ (Oct. 4, 2019), https://qz.com/1720450/will-flavor-bans-really-help-the-vaping-crisis/.

193. *Id.*

194. U.S. FOOD & DRUG ADMIN., supra note 20.

195. *Id.*

196. *Statement from FDA Commissioner Scott Gottlieb, M.D., on proposed new steps to protect youth by preventing access to flavored tobacco products and banning menthol in cigarettes*, U.S. FOOD & DRUG ADMIN. (Nov. 15, 2020), https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-proposed-new-steps-protect-youth-preventing-access.

197. *See 50.6 Million U.S. Adults Currently Use Tobacco Products,* CTRS. FOR DISEASE CONTROL & PREVENTION (Nov 19, 2020), https://www.cdc.gov/media/releases/2020/p1119-millions-use-tobacco.html.

198. Kathy Katella, *5 Things Everyone Should Know About the Coronavirus Outbreak*, YALE MED. (Dec. 18, 2020), https://www.yalemedicine.org/news/2019-novel-coronavirus.

199. Marlene Cimons*, Reports of two promising Covid-19 vaccines don't mean we 'magically,' quickly return to normal,* WASH. POST (Nov. 21, 2020), https://www.washingtonpost.com/health/covid-vaccine-masks-normal-life/2020/11/20/b4ed16c8-2922-11eb-9b14-ad872157ebc9_story

17 year olds were fully vaccinated.[200] Additionally, scientists have concluded that COVID-19 is "here to stay," like the common flu, even after the vaccine has been administered to the entire population.[201] Therefore, concerns for America's youth and the studied impacts COVID-19 has on ENDS users, is a long-term focus and should not be dismissed merely because of the promise of vaccinations.

CONCLUSION

It is clear from the patchwork of hundreds of local and state bans that the FDA must act now to protect American youth from the damaging effects of nicotine usage. If the FDA does not act within the full power granted to it by the TCA, further strengthened by the Deeming Rule, state and local bans remain vulnerable and the ENDS industry will continue to hook hundreds of thousands of adolescents with exempt non-cartridge-based and menthol-flavored products. The explosion in popularity of flavored ENDS over the past decade, along with the immediate shift to disposable and menthol-flavored products by youths in the past year, demonstrates the need for more robust regulations that do not leave exploitable loopholes. Any costs associated with a full flavor ban are outweighed by the benefits of combatting the damaging effects of this public health crisis growing amongst the American youth that are being exacerbated by the COVID-19 pandemic. If the FDA fails to take the necessary steps to create an official rule that bans the production of flavored ENDS products, excluding tobacco-flavored products, it will fail to protect any successes established by the ban of flavored combustible cigarettes. More importantly, it will fail to protect the health of America's youth from lifelong nicotine addictions. A blanket FDA flavor ban is the only justified means to end the ENDS epidemic amongst America's youth.

Megan C. Feeney[*]

200. Cecelia Smith-Schoenwalder, *CDC Data: Coronavirus Vaccine Coverage Lowest Among 12-15-Year-Olds,* U.S. NEWS (July 14, 2021), https://www.usnews.com/news/health-news/articles/2021-07-14/cdc-data-coronavirus-vaccine-coverage-lowest-among-12-15-year-olds.

201. Megan Scudellari, *How the pandemic might play out in 2021 and beyond*, NATURE.COM (Aug. 5, 2020), https://www.nature.com/articles/d41586-020-02278-5.

* B.A., The University of North Carolina at Chapel Hill, 2014; J.D., Brooklyn Law School, 2021. I'd like to thank the Brooklyn Journal of Corporate, Financial & Commercial Law editorial board for their consistent patience and thoughtful review. And most importantly, I'd like to thank my loving mother, brilliant father, inspiring older brother and wildly creative older sister, who guide me, push me to be the best version of myself, and never stop believing in me.