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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 (ENDS) AND THE YOUTH EPIDEMIC, MENTHOL, CORRECTIVE STATEMENTS AND CIGARETTE LABELING GRAPHIC HEALTH WARNINGS

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I. INTRODUCTION

Although smoking has plagued the United States for generations, it was not until the past several years that smoking received more serious scrutiny.¹ Yet, the reality is that as far back as the 1960s, tobacco products posed a serious threat to

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1. See generally ROSEANN B. TERMINI, FOOD AND DRUG LAW: FEDERAL REGULATION OF DRUGS, BIOLOGICS, MEDICAL DEVICES, DIETARY SUPPLEMENTS, PERSONAL CARE, VETERINARY AND TOBACCO PRODUCTS 481 (10th ed. 2019). See generally Roseann B. Termini, *The Legal Authority of the United States Food and Drug Administration to Regulate Tobacco: Calling on Congress*, 74 ST. JOHN’S L. REV. 63 (2000).

human health as evidenced by the Surgeon General's report explaining that smoking causes cancer.²

Fast forward to current times, the Centers for Disease Control ("CDC") has determined that over 1,300 people in the United States die each day due to smoking and over sixteen million Americans have a disease attributed to smoking.³ The CDC concluded that in the United States, cigarette smoking is responsible for more than 480,000 deaths annually, and secondhand smoke exposure caused more than 41,000 of these deaths.⁴

These statistics do not just cover the older generations that many associate with smoking. Over the years, the numbers in teen smoking statistics have escalated since the 1990s.⁵ Based on CDC statistics, about 2,000 youth try their initial cigarette by age eighteen, and 200 youth become day-to-day smokers.⁶ This means that using current rates of smoking among youth, 5.6 million Americans younger than eighteen years of age are expected to die prematurely from a smoking-related illness.⁷ This denotes about 1 in every 13 Americans aged seventeen years or younger who are alive today.⁸ The Center for Tobacco Products ("CTP") within the United States Food and Drug Administration ("FDA") regulates tobacco products with a mission of diminishing tobacco related deaths and diseases.⁹ Since its creation, the CTP has maintained a critical mission on educating youth about the dangers of smoking.¹⁰ Yet, teen use of

2. See *The Reports of the Surgeon General: The 1964 Report on Smoking and Health*, U.S. NAT'L LIBR. MED. PROFILES SCIENCE, <https://profiles.nlm.nih.gov/ps/retrieve/Narrative/NN/pnid/608> <https://profiles.nlm.nih.gov/spotlight/nn/feature/smoking> [<https://perma.cc/3V86-KXRY>].

3. *Smoking and Tobacco Use: Diseases and Death*, CTR. FOR DISEASE CONTROL AND PREVENTION, (Feb. 6, 2019), https://www.cdc.gov/tobacco/data_statistics/fact_sheets/fast_facts/index.htm [<https://perma.cc/YL6J-UFF5>].

4. *Id.*

5. See Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. 44,398-99 (Aug. 28, 1996) [hereinafter *Restricting*]. In the 1990's "[a]pproximately three million American adolescents . . . smoke . . . [cigarettes, while] an additional one million adolescent males use smokeless tobacco [products]. Eighty-two percent of adults who . . . smoked . . . their first cigarette [did so] before the age of 18, and more than half . . . became regular smokers by that age."

6. See *The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General*, U.S. DEP'T OF HEALTH & HUMAN SERV., 1, 6 (2014). See also *Smoking and Tobacco Use: Youth and Tobacco Use*, CTR. FOR DISEASE CONTROL & PREVENTION https://www.cdc.gov/tobacco/data_statistics/fact_sheets/youth_data/tobacco_use/index.htm [<https://perma.cc/CE7Y-CP6K>].

7. *Smoking and Tobacco Use: Diseases and Death*, *supra* note 3.

8. See *id.*; *The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General*, *supra* note 6, at 692.

9. *Center for Tobacco Products*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/about-fda/office-medical-products-and-tobacco/center-tobacco-products> [<https://perma.cc/4PRZ-6C3H>].

10. *What CPT Does*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp/what-ctp-does> [<https://perma.cc/H2ZU-T6QP>].

tobacco related products has increased.¹¹

The *Family Smoking Prevention and Tobacco Control Act* (“FSPTCA” or “Tobacco Act”) became law on June 22, 2009.¹² This legislation conferred authority to the FDA to regulate tobacco products.¹³ The FSPTCA amended the Food, Drug, and Cosmetic Act (“FDCA”) and other federal laws by granting FDA regulatory authority over tobacco products.¹⁴ This includes cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco.¹⁵ Yet, the FSPTCA, when enacted, was silent on issues of e-cigarettes and other electronic nicotine delivery systems (“ENDS”) and were eventually “deeming” as part of the FSPTCA.¹⁶

There are a myriad of matters concerning tobacco products regulation. However, this article highlights critical issues important to the public health in the United States. This article provides an overview of tobacco products regulation, including the FSPTCA. Yet, issues persist such as undue delay in reissuing graphic warnings for cigarettes and lengthy legal battles over the language used in court-ordered corrective statements.¹⁷ Further, the FSPTCA was silent on other tobacco products besides traditional cigarettes such as cigars, pipe tobacco, and

11. See generally *Smoking and Tobacco Use: Youth and Tobacco Use*, supra note 6. See also Teresa W. Wang et al., *Tobacco Product Use Among Middle High School Students—United States, 2011–2017*, 67 MORBIDITY & MORTALITY WKLY. REP. (MMWR) 629 (2018), https://www.cdc.gov/mmwr/volumes/67/wr/mm6722a3.htm?s_cid=mm6722a3_w [<https://perma.cc/H9RR-2X4P>].

12. Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, Div. A, Title I, 123 Stat. 1776 (2009) (codified at 21 U.S.C. § 387 *et seq.* (2012)).

13. *Id.*

14. 21 U.S.C. §387a (2018) (“(a) In General—Tobacco products, including modified risk tobacco products for which an order has been issued in accordance with section 911, shall be regulated by the Secretary under this chapter and shall not be subject to the provisions of chapter V”).

15. *Id.* (“(b) Applicability—This chapter shall apply to all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and to any other tobacco products that the Secretary by regulation deems to be subject to this chapter”).

16. See *id.* 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 5, 2016) [hereinafter *Deeming Tobacco Products*].

17. R.J. Reynolds Tobacco Co., et al. v. Food & Drug Admin., 696 F.3d 1205, 1218 (D.C. Cir. 2012). The plaintiff tobacco Companies alleged a violation of their free speech rights under the First Amendment. Preliminary Injunction granted November 7, 2011, which effectively stayed the new graphic warnings from FDA implementation. Subsequently, the district court decided on February 29, 2012, that the government’s rule violated the tobacco companies’ rights to free speech and the FDA filed an appeal. Court of Appeals for the District of Columbia held that the FDA failed to provide substantial evidence that graphic warnings on cigarette advertising would advance the government’s interest in smoking reduction to a material degree.

ENDS including e-cigarettes.¹⁸ To overcome the lack of inclusion in the FSPTCA, deeming regulations were enacted.¹⁹ Despite the deeming regulations, the use of tobacco products, including vaping and e-cigarettes, has escalated.²⁰ Finally, this article discusses the FDA's accomplishments along with further recommendations to stem the rise in youth use of e-delivery products.

II. THE INITIAL RELUCTANCE BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION TO REGULATE TOBACCO PRODUCTS AND EVENTUAL ACQUIESCE

A. Historical Background of Jurisdiction—Therapeutic Claims

Congress passed the *Federal Cigarette Labeling and Advertising Act* in 1965, requiring warning labels on all cigarette packages.²¹ Thereafter, Congress banned cigarette advertising on television and radio.²² The Surgeon General then started issuing more detailed warnings, which prompted the Federal Trade Commission (“FTC”) to refine its labeling criteria to specifically reflect warnings about health consequences.²³ The war on smoking evolved into a full-scale attack—including warnings from the Surgeon General, FTC criteria to ensure warnings contained information on health consequences, and even state enactments of indoor clean air laws, such as Pennsylvania's Clean Indoor Air Act, which concerns smoking

18. *Deeming Tobacco Products*, *supra* note 16, at 28,981.

19. *Id.*

20. Karen A. Cullen et al., *Notes from the Field: Use of Electronic Cigarettes and Any Tobacco Product Among Middle and High School Students*, 67 MORBIDITY & MORTALITY WKLY. REP. (MMWR) 1276 (2018), <https://www.cdc.gov/mmwr/volumes/67/wr/mm6745a5.htm> [<https://perma.cc/VKM4-P2TH>].

21. The Federal Cigarette Labeling and Advertising Act, Pub. Law 89-92, 79 Stat. 282 (1965) (required all cigarette packages to warn, “Caution: Cigarette Smoking May Be Hazardous to Your Health”). Yet Congress did not provide the FDA with the requisite jurisdiction to regulate tobacco products.

22. Public Health Cigarette Smoking Act of 1969, Pub. L. No. 91-222, 84 Stat. 87. President Richard Nixon signed the Public Health Cigarette Smoking Act on April 1, 1970, which banned cigarette ads from airing on television and radio.

23. See John E. Calfee, *Cigarette Advertising, Health Information and Regulation Before 1970*, 1, 2 (F.T.C., Working Paper No. 134, 1985), <https://www.ftc.gov/sites/default/files/documents/reports/cigarette-advertising-health-information-and-regulation-1970/wp134.pdf> [<https://perma.cc/XC5W-L3Y3>] (stating some of these initiatives on cigarette advertising served as models for later FTC litigation and rule-making on advertising in general). Examples are the advertising substantiation doctrine (implicitly applied in the 1955 Cigarette Advertising Guides and the 1960 voluntary ban on tar and nicotine advertising, and later established through litigation) cases involving deception by omission and cases and rules based on the notion of “unfairness,” including ones where the 1964 draft trade rule on cigarette advertising served as the basis for the Commission's later explanation of how it would attack unfair practices.

in public settings and certain workplaces.²⁴

The FDA's assertion of jurisdiction over tobacco products is intriguing. In *United States v. 354 Bulk Cartons*,²⁵ the FDA asserted jurisdiction over cigarettes that promised appetite reduction and subsequent weight loss.²⁶ The district court determined that FDA jurisdiction had been properly asserted where the manufacturer's promises were based upon such weight reduction.²⁷ The manufacturer intended the cigarettes to be used for therapeutic purposes.²⁸ This court held that the intended use articulated by the manufacturer regarding therapeutic use satisfied the requisite intent of a drug under the FDCA as a product intended to affect the structure and function of the human body.²⁹

The FDA also asserted jurisdiction in *United States v. 46 Cartons, Etc.*, when a manufacturer claimed, in advertising leaflets, that cigarettes prevented respiratory infections, circulatory disease, and other physical ailments.³⁰ These advertisements were sufficient to bring the cigarettes under the definition of "drug," which is defined as a product intended to mitigate or prevent disease.³¹

24. See e.g. 35 PA. CONS. STAT. § 637.3 (2019) (regulating smoking in public settings and certain workplaces); LA. REV. STAT. ANN. § 40:1291.11 (2019) (regulating smoking in public workplaces); MO. REV. STAT. § 191.767 (2019) (prohibiting smoking in public places and meetings); NEV. REV. STAT. § 202.2491 (2019) (prohibiting smoking in public elevators, buildings, waiting rooms, stores, hotels, and buses); N.Y. PUB. HEALTH LAW § 1399-o (Consol. 2019) (placing smoking restrictions, includes smoking and vaping, on auditoriums, elevators, gymnasiums, classrooms, and public transportation).

25. *United States v. 354 Bulk Cartons Trim Reducing-Aid Cigarettes*, 178 F. Supp. 847 (D. N.J. 1959).

26. *Id.* at 850 (stating a user can "[s]afely lose up to twenty pounds or double your money back").

27. *Id.* at 851.

28. *Id.*

29. 21 U.S.C. § 321(g)(1) (2018) ("The term "drug" means (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C). A food or dietary supplement for which a claim, subject to sections 343(r)(1)(B) and 343(r)(3) of this title or sections 343(r)(1)(B) and 343(r)(5)(D) of this title, is made in accordance with the requirements of section 343(r) of this title is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 343(r)(6) of this title is not a drug under clause (C) solely because the label or the labeling contains such a statement").

30. *United States v. 46 Cartons, More or Less, Containing Fairfax Cigarettes.*, 113 F. Supp. 336, 337 (D.N.J. 1953).

31. *Id.* at 337-39 ("The term 'drug' means . . . articles intended for use in the diagnosis, cure,

The fact that the FDA only asserted jurisdiction when cigarette manufacturers promised increased health benefits, proved infuriating to Action on Smoking and Health (“ASH”), a citizen’s group.³² ASH filed suit, pushing for the FDA’s active assertion of jurisdiction over all tobacco products.³³ However, the result disfavored ASH because the 1980s litigation resulted in the determination that the FDA lacked general jurisdiction over tobacco products.³⁴ The court found no manifestation of the cigarette manufacturer’s intent “to affect the structure or any function of the body of man.”³⁵ The FDA agreed that it lacked general jurisdiction over tobacco products because ASH had presented no evidence proving this requisite intent.³⁶ The court’s significant point was that even though, at the time, the FDA argued against jurisdiction, this could change in the future.³⁷ Thus, *46 Cartons* should be viewed as indicating the possibility of jurisdiction in the future, rather than as a total bar on FDA jurisdiction indefinitely.³⁸

mitigation, treatment, or prevention of disease in man or other animals”); *see also* 21 U.S.C. § 321(g)(1) (2018) (for the definition of “drug”); 21 U.S.C. § 321 (h) (2018) (“The term “device“ (except when used in paragraph (n) of this section and in sections 331(i), 343(f), 352(c), and 362(c) of this title) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them, (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The term “device” does not include software functions excluded pursuant to section 360j(o) of this title”).

32. *Action on Smoking & Health (ASH) v. Harris*, 655 F.2d 236, 237 (D.C. Cir. 1980). *See also* Termini, *supra* note 1, at 68.

33. *Action on Smoking & Health*, 655 F.2d at 237 (1980) (discussing ASH, along with thirteen other organizations and individuals, filed a citizen petition requesting that the agency assert jurisdiction over all cigarettes that contained nicotine).

34. *Id.* at 239-40, 243 (quoting 21 U.S.C. § 321(g)(1)(C) (1980)) (the agency originally rejected ASH’s request based on this lack of intent; the court agreed and denied the ASH petition). *See id.* at 240 (discussing how the court agreed with this reasoning and denied the ASH petition). *See also id.* at 243.

35. *Id.* at 238.

36. *Id.* at 237.

37. *Id.* at 243.

38. *See generally id.*; Nicotine in Cigarettes and Smokeless Tobacco Is a Drug and These Products Are Nicotine Delivery Devices Under the Federal Food, Drug, and Cosmetic Act: Jurisdictional Determination, 61 Fed. Reg. 44,619 (1996) [hereinafter *Jurisdictional Determination*].

B. The United States Supreme Court in Brown Stymied the 1996 Regulations by Rejecting FDAs Assertion of Jurisdiction, yet this Resulted in the Enactment of the Family Smoking Prevention and Tobacco Control Act

The FDA asserted general jurisdiction over tobacco products only after the majority of health organizations acted in concert to declare nicotine's harmful effects.³⁹ In 2000, the jurisdiction issue was decided by the United States Supreme Court in *FDA v. Brown and Williamson Tobacco Corp.*⁴⁰ Nearly a decade after *Brown*, Congress finally enacted the FSPTCA.⁴¹ Critical to the analysis is that the FSPTCA does not provide the FDA with the authority to ban tobacco products.⁴² However, the overall intent behind FDA regulation is to ensure the safety of the American public.⁴³

Several factors contributed to the impetus of the FSPTCA, such as the rise of youth smoking, deaths associated with smoking, and the Court's decision in *Brown*.⁴⁴ However, in *Brown*, the Court held that the FDA lacked the authority to regulate tobacco products.⁴⁵ The FDA had asserted jurisdiction over tobacco products based on the Food Drug and Cosmetic Act ("FDCA") definitions of "drug" and "device."⁴⁶ Although the district court had agreed with the FDA that the FDA had jurisdiction to regulate tobacco products, in *Coyne Beam, Inc. v. FDA*, the court of appeals in *Brown and Williamson Tobacco Corp. v. FDA* reversed.⁴⁷ The United States Supreme Court affirmed the court of appeals'

39. *Jurisdictional Determination*, *supra* note 38, at 44,634 (several organizations recognized the addictive nature of nicotine in tobacco products. The American Psychiatric Association began the movement in 1980, in which several organizations recognized the addictive nature of nicotine in tobacco products. Since 1981, the U.S. Surgeon General, the World Health Organization, and the American Medical Association, among others, submitted information to the FDA regarding the addictive properties of nicotine).

40. *Food & Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000) (holding that the FDA does not have jurisdiction to regulate tobacco products).

41. *Family Smoking Prevention and Tobacco Control Act*, *supra* note 12.

42. *See also* 21 U.S.C. § 387g ("(3) Limitation On Power Granted To The Food And Drug Administration.—Because of the importance of a decision of the Secretary to issue a regulation— (A) banning all cigarettes, all smokeless tobacco products, all little cigars, all cigars other than little cigars, all pipe tobacco, or all roll-your-own tobacco products; or (B) requiring the reduction of nicotine yields of a tobacco product to zero, the Secretary is prohibited from taking such actions under this chapter").

43. *Termini*, *supra* note 1, at 3, 14.

44. *See generally Restricting*, *supra* note 5; *Action on Smoking & Health*, 655 F.2d at 237 (1980).

45. *Brown & Williamson Tobacco Corp.*, 529 U.S. at 126 (2000) (holding that the FDA does not have jurisdiction to regulate tobacco products).

46. *See 354 Bulk Carton Trim Reducing-Aid Cigarettes*, 178 F. Supp. 847 (1959).

47. *Coyne Beahm, Inc. v. Food & Drug Admin.*, 966 F. Supp., 1374, 1379 (M.D. N.C. 1997), *rev'd sub nom.*, *Brown & Williamson Tobacco Corp. v. Food & Drug Admin.*, 153 F. 3d 155 (4th

decision.⁴⁸ The Court held that the FDA lacked jurisdiction over tobacco products because Congress did not confer such authority to the agency.⁴⁹ The Court denied FDA jurisdiction over tobacco products due to fundamental conflicts and inconsistencies in prior actions by the FDA and prior Congressional inaction.⁵⁰ Despite the strong showing of compatible existing regulatory provisions and evidence of the danger of nicotine addiction, the Court concluded that the FDA lacked jurisdiction over tobacco products.⁵¹

The decision in *Brown* and the national outcry for change spurred the impetus for the eventual passage of the FSPTCA.⁵² Nearly ten years after *Brown*, Congress provided the FDA with explicit legal authority and jurisdiction to regulate tobacco products.⁵³ To that end, on June 22, 2009, Former President Obama signed the FSPTCA.⁵⁴ This historic legislation conferred authority to the FDA to regulate tobacco products.⁵⁵ The FSPTCA amended the FDCA and other federal laws by permitting FDA regulatory authority over the manufacture, marketing, and distribution of tobacco products.⁵⁶ Initially, the FSPTCA included cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco.⁵⁷ Finally, in May 2016, the FDA issued what are identified as “deeming

Cir. 1998) aff’d 529 U.S. 120 (2000).

48. *Coyne Beahm, Inc. v. Food & Drug Admin.*, 966 F. Supp. 1374, 1379 (M.D. N.C. 1997); *Brown & Williamson Tobacco Corp. v. Food & Drug Admin.*, 529 U.S. 120 (2000).

49. *Brown & Williamson Tobacco Corp.*, 529 U.S. at 126 (2000) (holding that the FDA did not have jurisdiction to regulate tobacco products).

50. *Id.* at 152.

51. *Id.* at 161.

52. Former President Clinton announced an initiative to reduce youth smoking which contemplated the FDA’s regulation of tobacco products under the Food Drug and Cosmetic Act. *See* Remarks Announcing the Final Rule to Protect Youth from Tobacco, PUB. PAPERS 1,491-1,493 (Aug. 23, 1996). *See also* David A. Kessler et al., *The Food and Drug Administration’s Regulation of Tobacco Products*, 335 NEW ENG. J. MED. 991-93 (1996) (discussing the FDA’s regulation restricting the sale and distribution of cigarettes and smokeless tobacco to children and adolescents).

53. *Family Smoking Prevention and Tobacco Control Act*, *supra* note 12.

54. *Id.*

55. *Id.* In 2020, President Trump proposed to remove the authority of the FDA to regulate tobacco and instead create a separate federal agency. *See* Jessie Hellmann, *Trump administration proposes removing FDA’s authority over tobacco regulation*, THE HILL (Feb. 10, 2020), <https://thehill.com/policy/healthcare/482345-trump-administration-proposes-removing-fdas-authority-over-tobacco> [<https://perma.cc/8G8M-CQ4W>]

56. *Family Smoking Prevention and Tobacco Control Act*, *supra* note 12.

57. 21 U.S.C. § 321 (2018) (amended by adding at the end the following: ‘(rr)(1) The term ‘tobacco product’ means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product).’ (2) The term ‘tobacco product’ does not mean an article that is a drug under subsection (g)(1), a device under subsection (h), or a combination product described in section 503(g)).”

regulations” to include regulation of e-cigarettes and other ENDS, as well as other covered tobacco products such as cigars and pipe tobacco.⁵⁸ “Covered tobacco product” means any tobacco product deemed subject to the FDCA.⁵⁹

However, as discussed above, years prior to the FSPTCA, when the FDA attempted to regulate tobacco products, it was unsuccessful as illustrated in *Brown*.⁶⁰ The FDA recognized that an outright ban was unrealistic, yet its focus even back in the 1990s was on the prevention of youth nicotine use.⁶¹ In 1996, the FDA subsequently asserted jurisdiction to regulate tobacco products even though it previously had expressly disavowed such authority.⁶² The FDA concluded that nicotine is a “drug” within the meaning of the FDCA and that cigarettes and

58. See *Deeming Tobacco Products*, *supra* note 16, at 29,874 (“Summary ‘The Food and Drug Administration (FDA) is issuing this final rule to deem products meeting the statutory definition of “tobacco product,” except accessories of the newly deemed tobacco products, to be subject to the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). The Tobacco Control Act provides FDA authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco, and any other tobacco products that the Agency by regulation deems to be subject to the law. With this final rule, FDA is extending the Agency’s ‘tobacco product’ authorities in the FD&C Act to all other categories of products that meet the statutory definition of “tobacco product” in the FD&C Act, except accessories of such newly deemed tobacco products. This final rule also prohibits the sale of “covered tobacco products” to individuals under the age of 18 and requires the display of health warnings on cigarette tobacco, roll-your-own tobacco, and covered tobacco product packages and in advertisements. FDA is taking this action to reduce the death and disease from tobacco products. In accordance with the Tobacco Control Act, we consider and intend the extension of our authorities over tobacco products and the various requirements and prohibitions established by this rule to be severable’.”) See also *FDA’s Deeming Regulations for E-Cigarettes, Cigars, and All Other Tobacco Products*, U.S. FOOD & DRUG ADMIN. (June 11, 2019), <https://www.fda.gov/tobaccoproducts/labeling/rulesregulationsguidance/ucm394909.htm#rule> [<https://perma.cc/XN8F-LWRD>].

59. *Family Smoking Prevention and Tobacco Control Act*, *supra* note 12, § 101. (“(a) Definition Of Tobacco Products—Section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended by adding at the end the following: ‘(rr) (1) The term ‘tobacco product’ means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product). ‘(2) The term ‘tobacco product’ does not mean an article that is a drug under subsection (g)(1), a device under subsection (h), or a combination product described in section 503(g)’”).

60. See *Brown and Williamson Tobacco Corp.*, 529 U.S. at 126 (2000) (holding that the FDA lacked jurisdiction and hence could not implement the regulations at issue). See generally *Restricting*, *supra* note 5.

61. *Restricting*, *supra* note 5, at 13,227 (The FDA posed an all-out war on teenage smoking through regulations enacted to curb the sale of tobacco to minors).

62. *Jurisdictional Determination*, *supra* note 38, at 45,216.

smokeless tobacco are “combination products” that deliver nicotine to the body.⁶³ The FDA found that the best way to prevent addiction was to focus on thwarting children and teen’s attempts to smoke at a young age.⁶⁴ Accordingly, the FDA determined that if “the number of children and adolescents who begin tobacco use can be substantially diminished, tobacco-related illness can be correspondingly reduced because data suggests that anyone who does not begin smoking in childhood or adolescence is unlikely ever to begin.”⁶⁵ Besides requiring retailers to verify age of purchasers through photo identification younger than 27, the 1996 regulations prohibited the following: “[s]ale of cigarettes or smokeless tobacco to persons younger than 18; however in 2020 legislation was enacted that raised the minimum age to purchase tobacco to twenty-one; sale of cigarettes in quantities smaller than 20; distribution of free samples; and sales through self-service displays and vending machines except in adult-only locations.”⁶⁶

However, the Court in *Brown* stymied the authority of the FDA to regulate tobacco products.⁶⁷ After the *Brown* decision rejected the 1996 regulations regarding FDA assumption of jurisdiction, the FSPTCA was finally enacted.⁶⁸ The Congressional findings of the FSPTCA are critical to understanding the FDA’s objective of preventing youth from smoking which has remained steadfast over the years.⁶⁹ The findings illustrate how in enacting the FSPTCA, Congress relied on the 1996 regulations that *Brown* struck down due to lack of jurisdiction.⁷⁰ Back in 1996, e-cigarettes were not in the United States marketplace and consequently not on the radar of Congress nor the FDA.⁷¹ Apparently, what occurred in enacting the FSPTCA in 2009 was Congressional reliance on the 1996 regulations as evidenced in the Congressional findings.⁷²

63. *Id.* at 45,217-18.

64. *Restricting*, *supra* note 5, at 44,398-99. The FDA found that 82% of adult smokers had their first cigarette prior to age 18, and over half became regular smokers by 18. The FDA found a similar issue regarding smokeless tobacco.

65. *Id.* at 44,399.

66. *Id.* at 44,616-17, 44,396 (The regulations additionally prohibited outdoor advertising within 1,000 feet of any public playground or school; prohibit the distribution of any promotional items, such as T-shirts or hats, bearing the manufacturer’s brand name; and prohibit a manufacturer from sponsoring any athletic, musical, artistic, or other social or cultural event using its brand name). (21 U.S.C. 387f(d)). Pub. Law 11696 Sec. 603 (2019).

67. *Brown & Williamson Tobacco Corp.*, 529 U.S. at 126 (2000) (holding that the FDA does not have jurisdiction to regulate tobacco products and hence could not implement the 1996 regulations).

68. *Family Smoking Prevention and Tobacco Control Act*, *supra* note 12.

69. *See generally* 21 U.S.C. § 387 note (findings) Former FDA Commissioner Gottlieb has reiterated the stance to prevent youth smoking.

70. *See generally* 21 U.S.C. § 387 (finding 7). *Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000).

71. *See generally Restricting*, *supra* note 5 (providing a comprehensive analysis of nicotine status in the United States, but without commenting on the use of e-cigarettes).

72. *See generally* 21 U.S.C. § 387 note (findings).

All of the Congressional Findings are relevant and significant; however, for purposes of this article, the Congressional findings reveal that Congress focused the 2009 Tobacco Act on prevention of youth tobacco use and specifically found the 1996 regulations comported with First Amendment principles.⁷³

The FSPTCA Congressional findings reveal the focus on the prevention of youth smoking.⁷⁴ These findings are relevant to understand the deeming of other nicotine products and the current momentum to prevent youth from getting hooked on nicotine at such an early, vulnerable age.⁷⁵ Undoubtedly, the FDA's stance, as far back as the 1990s, as well as later legislation, namely the FSPTCA, reaffirms the commitment by the FDA to prevent youth from smoking.⁷⁶ Hence, the FDA's present focus is neither unforeseen nor novel.

III. THE EVOLUTION OF E-CIGARETTES INTO THE UNITED STATES MARKET AND THE OVERLOOKED ELECTRONIC NICOTINE DELIVERY SYSTEMS (ENDS)

The Congressional findings were well-defined in terms of focus, namely, to prevent youth from smoking.⁷⁷ Yet, where do ENDS, such as e-cigarettes, fit in the scheme of FDA regulation? The plausible reason for the omission of ENDS in the 2009 FSPTCA is, that at the time the FSPTCA was enacted back in 2009, e-cigarettes were a relatively new phenomenon in the United States market.⁷⁸ Regrettably, despite the FSPTCA Congressional findings and the 1996 regulations, smoking by youths is on the rise again though with a different nicotine delivery system, namely e-cigarettes.⁷⁹

A historical timeline of an e-cigarette nicotine inhaler details that they were possibly introduced in the United States in the mid-2000s.⁸⁰ Interestingly, the FDA argued that e-cigarettes were drug-device combination products and/or

73. 21 U.S.C. 387f (2018).

74. 21 U.S.C. § 387 note (findings).

75. *Id.* (findings 1, 3, 23, 2)).

76. *Id.* (findings 5, 6).

77. *Id.*

78. U.S. DEP'T OF HEALTH AND HUMAN SERV, E-CIGARETTE USE AMONG YOUTH AND YOUNG ADULTS: A REPORT OF THE SURGEON GENERAL, at i, 9 (2016), https://e-cigarettes.surgeongeneral.gov/documents/2016_SGR_Full_Report_non-508.pdf [<https://perma.cc/BFG8-MNEC>] [hereinafter *Use Among Youth*].

79. *Id.* at vii, 6-7. *See also* Appendix A.

80. *A Historical Timeline of Electronic Cigarettes*, CONSUMER ADVOCATES FOR SMOKE FREE ALTERNATIVES ASS'N, <http://www.casaa.org/historical-timeline-of-electronic-cigarettes/> [<https://perma.cc/J82U-HLAL>]. *See generally* Soterra, Inc. v. Food & Drug Admin., 627 F.3d 891, 893 (D.C. Cir. 2010); *Use Among Youth*, *supra* note 78, at 10; The tariff classification of a nicotine inhaler and parts from China, NY m85579 (2006), <https://rulings.cbp.gov/search?term=m85579&collection=ALL&sortBy=RELEVANCE&pageSize=30&page=1> [<https://perma.cc/87RH-CJBV>]. *See also* Appendix B.

drugs rather than tobacco products.⁸¹ For example, in correspondence to the Electronic Cigarette Association, the FDA deemed e-cigarettes as combination products, subjecting them to Center for Drug Evaluation and Research (“CDER”) as the primary regulator and a new drug application review process (“NDA”).⁸² The FDA stated that despite the legal authority to regulate tobacco products under the 2009 FSPTCA, the e-cigarettes, noted in the warning letters, and similar products fell within the definitions of drugs and devices under the FDCA, with a drug primary mode of action.⁸³ Electronic cigarettes are products designed to deliver nicotine or other substances to a user in the form of a vapor.⁸⁴ “Electronic cigarettes are battery-powered products that allow users to inhale nicotine vapor without fire, smoke, ash, or carbon monoxide.”⁸⁵ Typically, they are composed of a rechargeable, battery-operated, heating element, a replaceable cartridge that may contain nicotine or other chemicals, flavor, and an atomizer that, when heated, converts the cartridge contents into vapor.⁸⁶ The user can then inhale this vapor.⁸⁷ These products are manufactured to appear similar to cigarettes, cigars, and pipes.⁸⁸ They are sometimes also created to appear like ordinary items, like pens or USB memory sticks.⁸⁹ Electronic cigarette marketers touted different flavors such as chocolate and mint, yet hopefully FDA will use enforcement authority in this regard.⁹⁰

81. *Soterra*, 627 F.3d at 894-95 (2010).

82. Letter from Janet Woodcock, Dir., Ctr. for Drug Evaluation & Res., to Matt Salmon, President, Electronic Cigarette Ass’n, (Sept. 10 2010), <https://www.femaflavor.org/sites/default/files/Electronic%20Cigarette%20Association%20-%20Letter%20to%20Industry.pdf> [https://perma.cc/NZD4-99EP]. (The Electronic Cigarette Association is now defunct).

83. *Soterra*, 627 F.3d at 894-95 (2010) (Rehearing *en banc* denied Jan. 24, 2011); Letter from Janet Woodcock, *supra* note 82; 21 U.S.C. § 321(g), (h), (p) (2018). *See generally*, *Combination Products: Therapeutic and Diagnostic Products that Combine Drugs, Devices, and/or Biological Products*, U.S. FOOD AND DRUG ADMIN., <http://www.fda.gov/CombinationProducts/default.htm> [https://perma.cc/C4Z9-3R7Q].

84. *Vaporizers, E-Cigarettes, and other Electronic Nicotine Delivery Systems (ENDS)*, U.S. FOOD AND DRUG ADMIN. <https://www.fda.gov/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm456610.htm> [https://perma.cc/V5MG-RUL9] [hereinafter *ENDS*]. *See also* *Soterra*, 627 F.3d at 893 (2010).

85. *Soterra*, 627 F.3d at 893 (2010).

86. *Id.*; *Vaporizers, E-Cigarettes, and other Electronic Nicotine Delivery Systems (ENDS)*, *supra* note 84.

87. *Vaporizers, E-Cigarettes, and other Electronic Nicotine Delivery Systems (ENDS)*, *supra* note 84.

88. *Id.*

89. *Id.*

90. *Id.* *See also* *PATH Study Findings Give Insight into Flavored Tobacco, Health Effects of E-Cigarettes, and Adult Use of Cigars and Hookah*, U.S. FOOD & DRUG ADMIN. (June 19, 2019), <https://www.fda.gov/tobacco-products/ctp-newsroom/path-study-findings-give-insight-flavored-tobacco-health-effects-e-cigarettes-and-adult-use-cigars> [https://perma.cc/H6NM-6MSG]. *See* U.S. FOOD & DRUG ADMIN., ENFORCEMENT PRIORITIES FOR ELECTRONIC NICOTINE DELIVERY SYSTEM

The Surgeon General's Report enumerated the health consequences of electronic cigarettes:

1. "Nicotine exposure during adolescence can cause addiction and can harm the developing adolescent brain."⁹¹
2. "Nicotine can cross the placenta and has known effects on fetal and postnatal development. Therefore, nicotine delivered by e-cigarettes during pregnancy can result in multiple adverse consequences, including sudden infant death syndrome, and could result in altered corpus callosum, deficits in auditory processing, and obesity."⁹²
3. "E-cigarettes can expose users to several chemicals, including nicotine, carbonyl compounds, and volatile organic compounds, known to have adverse health effects. The health effects and potentially harmful doses of heated and aerosolized constituents of e-cigarette liquids, including solvents, flavorants, and toxicants, are not completely understood."⁹³
4. "E-cigarette aerosol is not harmless "water vapor," although it generally contains fewer toxicants than combustible tobacco products."⁹⁴
5. "Ingestion of e-cigarette liquids containing nicotine can cause acute toxicity and possibly death if the contents of refill cartridges or bottles containing nicotine are consumed."⁹⁵

A. Product Classification Settled by the Smoking Everywhere, Inc. Decision

The decision in *Smoking Everywhere, Inc.*, paved the path for product classification of e-cigarettes.⁹⁶ In *Smoking Everywhere, Inc.*, the district court found that electronic cigarettes were tobacco products under FSPTCA.⁹⁷ On appeal, the question before the *Soterra* court was "whether Congress has authorized the Food and Drug Administration ("FDA") to regulate e-cigarettes under the drug/device provisions of the Federal Food, Drug, and Cosmetic Act

(ENDS) AND OTHER DEEMED PRODUCTS ON THE MARKET WITHOUT PREMARKET AUTHORIZATION (2020), <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-priorities-electronic-nicotine-delivery-system-ends-and-other-deemed-products-market> [<https://perma.cc/4GRT-5Z23>]. See also *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> [<https://perma.cc/4KL3-N6D8>].

91. *Use Among Youth*, supra note 78, at 5.

92. *Id.* at 7.

93. *Id.*

94. *Id.*

95. *Id.*

96. See generally *Smoking Everywhere, Inc. v. United States Food and Drug Admin.*, 680 F. Supp. 2d 62 (D.D.C. 2010).

97. *Id.* at 73.

(“FDCA”), 21 U.S.C. § 351 et seq., or under the Family Smoking Prevention and Tobacco Control Act of 2009” (the “Tobacco Act” or FSPTCA).⁹⁸ In *Soterra*, the court grappled with the issue of “whether *Brown & Williamson*’s reading of the FDA’s authority under the drug/device provisions of the FDCA applies only to tobacco products for which Congress has passed specific regulatory statutes or whether it extends to all tobacco products as customarily marketed.”⁹⁹ The Court of Appeals affirmed the district court’s decision.¹⁰⁰ The court in *Soterra* held that e-cigarettes and other products made or derived from tobacco can be regulated as “tobacco products” under the FSPTCA and are not drugs/devices unless they are marketed for therapeutic purposes.¹⁰¹ The court’s reasoning was based on the intended use set forth by the manufacturer.¹⁰² The company stated that NJOY is marketed as a “pleasure product” and not for therapeutic purposes.¹⁰³ Therefore, the FDA lacked authority under FDCA’s drug/device provisions to regulate tobacco products customarily marketed without claims of therapeutic effect.¹⁰⁴ The FDA has the authority to regulate tobacco products customarily marketed without claims of therapeutic benefit under the FSPTCA.¹⁰⁵ This means that a company would not have to submit an application under the parameters for human drug approval and the parameters for medical devices. This distinction is critical as both the drug approval processes and medical device approval processes are at best lengthy processes.¹⁰⁶ The *Soterra* decision effectively permitted *Soterra* to market and distribute e-cigarettes under the brand name NJOY for pleasure purposes under the FSPTCA.¹⁰⁷

B. Evolution of the Deeming Rule—Covered Tobacco Products Regulation

Overall, the FDA’s concern over electronic or e-cigarettes has stemmed from safety issues as well as marketing and promotion to youth.¹⁰⁸ For example, in 2009, the FDA notified healthcare professionals and patients that a laboratory analysis of electronic cigarettes found that they contain carcinogens and toxic

98. *Soterra*, 627 F.3d at 892 (2010).

99. *Id.* at 895.

100. *Id.* at 899. (Pending appeal, Smoking Everywhere voluntarily withdrew its complaint against FDA. *Id.* at 893. See *Smoking Everywhere, Inc. v. Food & Drug Admin.*, No. 10-5032, 2010 WL 3260117 (D.C. Cir. Aug. 13, 2010)).

101. *Id.* at 895.

102. *Id.* at 897-98.

103. *Id.* at 893.

104. *Id.* 891.

105. *Id.* at 900.

106. See generally 21 U.S.C. §§ 355, 360e (2018); see also *Learn About Drug and Device Approvals*, U.S. FOOD & DRUG ADMIN (June 18, 2019), <https://www.fda.gov/patients/learn-about-drug-and-device-approvals> [<https://perma.cc/22V5-2NC9>]

107. *Smoking Everywhere, Inc.*, 680 F. Supp. 2d at 73 (2010).

108. See generally *Food & Drug Admin v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000).

chemicals such as diethylene glycol, an ingredient used in antifreeze.¹⁰⁹ Further, the FDA issued warning letters in 2010 to certain manufacturers of electronic cigarettes for violations of the FSPTCA due to unsubstantiated claims and poor manufacturing practices, such as varying amounts of nicotine or cartridges with nicotine, yet labeled without nicotine. Warning letters were sent to: Gamucci America (Smokey Bayou, Inc.); E-Cig Technology, Inc.; E-CigaretteDirect, LLC; Johnson Creek Enterprises, LLC; and Ruyan America, Inc.¹¹⁰

Finally, six years after the warning letters were issued, the FDA issued a deeming final rule which includes e-cigarettes and other ENDS within the FDA's authority to regulate under the FSPTCA.¹¹¹ Yet, despite the relatively recent marketplace entry, youth are using these products at an alarming rate.¹¹²

C. Youth Epidemic and FDA Initiatives

A theme throughout the conundrum of tobacco products regulation is the focus on prevention of youth smoking of traditional tobacco products and e-cigarettes and other ENDS. This was evident for years as illustrated by the 1996 regulations that were challenged in *FDA v. Williamson*.¹¹³ Several years elapsed before Congress finally gave the FDA jurisdiction to regulate tobacco by enacting the FSPTCA and, included in the Congressional findings, notice of the constitutionality of the 1996 regulations as well as the concern of youth smoking.¹¹⁴ Echoing a similar concern regarding youth smoking and e-cigarettes,

109. U.S. FOOD & DRUG ADMIN. CONSUMER HEALTH INFO., FDA WARNS OF HEALTH RISKS POSED BY E-CIGARETTES, <http://alaskaquitline.com/wp/wp-content/uploads/2016/06/FDA-ConsumerUpdates-E-cig.pdf> [<https://perma.cc/KQ49-WDFU>]. See also CNN, *FDA and health experts warn against use of e-cigarettes*, CNN (July 22, 2009), <http://www.cnn.com/2009/HEALTH/07/22/ecigarettes.fda/index.html> [<https://perma.cc/9RUC-3RZB>].

110. See WebMD, *FDA Warns Five Companies Over E-Cigarette Claims*, CBS NEWS (September 10, 2010), <https://www.cbsnews.com/news/fda-warns-five-companies-over-e-cigarette-claims/> [<https://perma.cc/E4WR-VRFT>]. These warning letters are archived at: [https://www.archive-it.org/collections/7993?q=Gamucci+America+%28Smokey+ Bayou%2C+ Inc.%29&show=ArchivedPages&hitsPerDupe=0&go=Search+the+Archive](https://www.archive-it.org/collections/7993?q=Gamucci+America+%28Smokey+Bayou%2C+Inc.%29&show=ArchivedPages&hitsPerDupe=0&go=Search+the+Archive) [<https://perma.cc/D42B-AHWF>].

111. *Deeming Tobacco Products*, *supra* note 16, at 28,937.

112. *Use Among Youth*, *supra* note 78; Cullen et al., *supra* note 20. As mentioned, e-cigarettes are a relatively novel phenomenon in the United States. A historical timeline of an e-cigarette nicotine inhaler details that they were first introduced in the United States in the mid-2000s. See *A Historical Timeline of Electronic Cigarettes*, *supra* note 80. See also The tariff classification of a nicotine inhaler and parts from China, *supra* note 80. See also Appendix B.

113. *Brown & Williamson Tobacco Corp. v. Food & Drug Admin.*, 529 U.S. 120 (2000). (holding that FDA lacked jurisdiction yet upholding the 1996 regulations). The congressional findings in the 2009 FDPTCA specifically address the Constitutionality of the 1996 regulations. 21 U.S.C. §. 387 note (finding 30).

114. 21 U.S.C. § 387 note (findings 30-32) (relying on and incorporating the 1996 regs).

youth who use e-cigarettes are using them frequently, and addiction is an issue.¹¹⁵ Further, the flavors are attractive to youth.¹¹⁶ Perhaps e-cigarettes would not appeal to youth if unflavored.¹¹⁷ This issue is fraught with the potential for dire consequences and is quite complex. For example, unlike how cigarettes are the prime delivery device for tobacco, e-cigarettes present an entirely different pattern in terms of delivery devices.¹¹⁸ This latest phenomenon concerns the proliferation of flavored e-cigarettes with names that appeal to youth and, arguably, “cookie box” names and flavors are meant for youth rather than adults.¹¹⁹ Despite the FSPTCA and deeming regulations, the reality is that marketing to youth has occurred most recently with ENDS products.¹²⁰ Marketing to youth poses a concern about the impact on our youth, who possibly could

115. Bonnie Halpern-Felsher, Karma McKelvey, Mike Baiocchi, *Adolescents' and Young Adults' Use and Perceptions of Pod-Based Electronic Cigarettes*, 1 JAMA NETWORK OPEN E183535 (2018), <http://doi.org/10.1001/jamanetworkopen.2018.3535> [<https://perma.cc/9RC8-MHP2>]. According to the authors, “electronic cigarettes (e-cigarettes) are the most commonly used tobacco product among adolescents and young adults. Further, pod-based e-cigarette devices could subject both adolescents and young adults at increased risk for polytobacco use and nicotine dependence.” The authors refer to the JUUL® company website, “each JUUL pod is designed to contain approximately 0.7 mL with 5% nicotine by weight at time of manufacture which is approximately equivalent to 1 pack of cigarettes or 200 puffs.” *Id.* (citing information that can now be found at: *How much nicotine is in a JUULpod?*, JUUL, <https://support.juul.com/hc/en-us/articles/360026223453-How-much-nicotine-is-in-a-JUULpod-> [<https://perma.cc/GTP3-MYUC>]). See also *Teens Using Vaping Devices in Record Numbers*, NAT'L INST. ON DRUG ABUSE (Dec. 17, 2018), <https://www.drugabuse.gov/news-events/news-releases/2018/12/teens-using-vaping-devices-in-record-numbers> [<https://perma.cc/ZXK7-AYMV>]. The increased vaping rates between 2017-2018 comport with the CDC/FDA government-funded National Youth Tobacco Survey. See *Youth Tobacco Use: Results from the National Youth Tobacco Survey*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/TobaccoProducts/PublicHealthEducation/ProtectingKidsfromTobacco/ucm405173.htm> [<https://perma.cc/6DCD-ULZ5>]. See also Richard Miech, *Adolescent Vaping and Nicotine Use in 2017–2018 — U.S. National Estimates*, 380 NEW ENG. J. MED. 192 (2019). Dr. Miech, notes “the one-year increases in the prevalence of nicotine vaping translate into almost 1.3 million additional adolescents who vaped in 2018 in comparison to 2017.” Vaping among youth in 2019 increased to 5.4 million. See *Smoking and Tobacco Use: Youth and Tobacco Use*, *supra* note 6.

116. Halpern-Felsher, McKelvey & Baiocchi, *supra* note 115, at 9. Youth are attracted to the fruit and mint flavors.

117. See *id.*

118. *Id.*

119. See e.g., *Durbin To E-Cigarette Industry: Gummy Bear-Flavored Liquid Nicotine Helps Adults Quit Smoking? Prove It*, DICK DURBIN UNITED STATES SENATOR ILLINOIS (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-> [<https://perma.cc/7H53-5LZ5>].

120. See Alisa A. Padon, Erin K. Maloney & Joseph N. Cappella, *Youth-Targeted E-cigarette Marketing in the US*, 3 TOBACCO REG. SCI. 95 (2017).

experience health consequences during their teen years and as adults.¹²¹

D. A Matter of Ethics and Perceived Curtailment Yet Use by Youth Soars

Interestingly, some Silicon Valley investors swiftly decided not to fund JUUL Labs Inc. (“JUUL®”), in part for ethical reasons; however, they did fund cannabis companies, perhaps due to stated health benefits of medical marijuana.¹²² JUUL® has revamped its website and marketing strategy to focus on smoking cessation and the Chief Executive Officer of JUUL® stepped down and was replaced by a former executive from the Altria Group, Inc., which owns approximately \$13 billion stakes in JUUL®.¹²³ A question remains: is this too little too late? Nevertheless, possibly due to voluntary compliance and/or FDA action, companies that market to youth might consider otherwise.¹²⁴ The Altria tobacco conglomerate discontinued the sale of several flavored e-cigarettes, such as Strawberry Brulee, Apple Cider, and Hazelnut Cream, and at the end of 2018, Altria invested \$12.8 billion to acquire a 35 percent stake in JUUL®.¹²⁵

121. Mark Sampson, *Researchers Explore Health Effects of E-Cigarettes*, U.S. DEP’T OF HEALTH AND HUMAN RES. (Nov. 6, 2018), <https://www.hhs.gov/blog/2018/11/6/researchers-explore-health-effects-of-ecigarettes.html> [<https://perma.cc/GNA4-XFEM>]. See also Isaac Ghinai et al., *Characteristics of Persons Who Report Using Only Nicotine-Containing Products Among Interviewed Patients with E-cigarette, or Vaping, Product Use–Associated Lung Injury — Illinois, August–December 2019*, 69 MORBIDITY & MORTALITY WKLY. REP. (MMWR) 84, 88 (2020), https://www.cdc.gov/mmwr/volumes/69/wr/mm6903e1.htm?s_cid=mm6903e1_w [<https://perma.cc/QM8Q-95NG>].

122. See Erin Griffith, *Silicon Valley Investors Shunned JUUL, but Back Other Nicotine Start-Ups*, N.Y. TIMES (Oct. 8, 2018), <https://www.nytimes.com/2018/10/07/technology/silicon-valley-investors-juul-nicotine-start-ups.html> [<https://perma.cc/2GHG-9ARK>] (revealing though that some investors might not have invested due to the market share not being large enough for profits. Cannabis start-ups have raised \$1.1 billion).

123. *Id.* See also *JUUL® Newsprint Advertisement*, PHILA. INQUIRER, Sept. 27, 2018, at A7. See also *JUUL® Newsprint Advertisement: Warning to Parents*, PHILA. INQUIRER, Oct. 14, 2018 at A12. See Aimee Pichee, *JUUL CEO shakeup includes halt on advertising in U.S.*, MONEYWATCH (Sept. 25, 2019, at 7:27PM), <https://www.cbsnews.com/news/juul-ceo-kevin-burns-steps-down-replaced-by-altria-executive/> [<https://perma.cc/BKX3-EQYD>]. See also Timothy Annett, *JUUL Labs CEO to Step Down After Vaping Backlash*, BLOOMBERG (Sept. 25, 2019, at 7:45AM), <https://www.bloomberg.com/news/articles/2019-09-25/juul-labs-ceo-to-step-down-amid-growing-vaping-backlash> [<https://perma.cc/KD9B-46S5>].

124. See e.g., Jennifer Maloney, *Altria Will Pull Its E-Cigarette Pods From the Market*, WALL ST. J. (Oct. 25, 2018), <https://www.wsj.com/articles/altria-will-pull-its-e-cigarette-pods-from-the-market-1540471369> [<https://perma.cc/D584-GM2M>]. Altria CEO Howard Willard wrote a letter to FDA regarding this initiative. See Letter from Howard A Willard III, CEO, Altria, to Scott Gottlieb, former U.S. Food & Drug Admin. Comm’r (Oct. 25, 2018), <https://perma.cc/GED8-43KV>.

125. Griffith, *supra* note 122. The \$12.8 billion investment in JUUL® declined in value to

Originally Altria planned to continue marketing for JUUL® but decided otherwise¹²⁶ Yet, by way of illustration, when Altria decided to discontinue Altria's Green Smoke and Mark Ten brands, they represented a minor portion of the e-cigarette market.¹²⁷ By contrast, JUUL®, who sells online, in retail vape stores, and convenience stores (including those with gas stations), represents a much larger market share of over 70 percent.¹²⁸

The increased use of ENDS by youth has escalated and has hooked teenagers.¹²⁹ The FDA and the CDC data from the 2018 National Youth Tobacco Survey indicate a significant increase in the use of ENDS by youth.¹³⁰ For example, from 2017 to 2018, there was a 78 percent increase in e-cigarette use among high school students and a 48 percent increase among middle school students.¹³¹ The total number of youth, including middle school and high school students, that use e-cigarettes increased from 3.6 million in 2018 to 5.4 million in 2019.¹³² Suffice it to state, the FDA mandate is that of public health and specifically to prevent youth tobacco addiction.¹³³ The FDA's Comprehensive Plan for Tobacco and Nicotine Regulation, issued in 2017 and affirmed in 2018, focuses on youth tobacco and nicotine prevention.¹³⁴ The Youth Prevention Plan's purpose is threefold: "preventing youth access to tobacco products;

\$4.1 billion as of Dec. 31, 2019. Jennifer Maloney, *Altria Takes \$4.1 Billion Charge on JUUL Investment*, (January 30, 2020) <https://www.wsj.com/articles/altria-takes-4-1-billion-writedown-on-juul-investment-11580386578> [<https://perma.cc/43G7-638K>]

126. Maloney, *supra* note 125. See also *infra* note 127.

127. Maloney, *supra* note 124. According to Maloney, Altria represented 5.6% of the United States' e-cigarette market excluding online sales for the four weeks. *Altria Reports 2019 Fourth-Quarter and Full-Year Results; Provides 2020 Full-Year Earnings Guidance; Revises 2020 - 2022 Adjusted Diluted EPS Growth Objective; Revises Terms of JUUL Transaction*, ALTRIA GROUP, INC. <http://investor.altria.com/file/Index?KeyFile=402520678> [<https://perma.cc/HQ94-5MQB>].

128. Maloney, *supra* note 124. According to Maloney, JUUL® represents a 74.5% share of the United States market.

129. Jan Hoffman, *One Drag on a JUUL® Hooked a Teenager for Years*, N.Y. TIMES (Nov. 16, 2018), <https://www.nytimes.com/2018/11/16/health/vaping-juul-teens-addiction-nicotine.html> [<https://perma.cc/3W59-XCFZ>].

130. Cullen et al., *supra* note 20.

131. *Id.*

132. *Smoking and Tobacco Use: Youth and Tobacco Use*, *supra* note 6. See also *Statement from FDA Commissioner Scott Gottlieb, M.D., on new data determining rising youth use of tobacco products and the agency's ongoing actions to confront the epidemic of youth e-cigarette use*, U.S. FOOD & DRUG ADMIN. (Feb. 11, 2019), <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-new-data-demonstrating-rising-youth-use-tobacco> [<https://perma.cc/WP29-NPE2>]. <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm631112.htm>

133. *FDA's Comprehensive Plan for Tobacco and Nicotine Regulation*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/tobacco-products/ctp-newsroom/fdas-comprehensive-plan-tobacco-and-nicotine-regulation> [<https://perma.cc/WL7Y-AR29>].

134. *Id.*

curbing marketing of tobacco products aimed at youth; and educating teens about the dangers of using any tobacco product, including e-cigarettes, as well as educating retailers about their key role in protecting youth.”¹³⁵

Enforcement has increased. By way of illustration, the FDA issued over 1,300 warning letters to tobacco retailers for selling tobacco products, such as e-cigarettes, e-liquids, and cigars to minors and since 2010, the FDA issued approximately 1,800 violations against the Walgreen company for selling e-cigarette products to minors.¹³⁶ Further, the FDA has increased inspection of e-cigarette manufacturers and seized documents.¹³⁷ In 2018, former FDA Commissioner Gottlieb issued statements about the epidemic regarding the use of e-cigarettes by youth, and the agency issued a Youth Tobacco Prevention Plan including that of enforcement.¹³⁸ The FDA and FTC have joint coordination concerning the promotion of e-cigarettes that resemble candy, cookies, and juice boxes.¹³⁹ Further, a hearing was held in late 2018 to discuss efforts to eliminate youth e-cigarette use, focusing on the potential role of drug therapies to support

135. *FDA’s Youth Tobacco Prevention Plan*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/tobacco-products/youth-and-tobacco/fdas-youth-tobacco-prevention-plan> [<https://perma.cc/PL4P-9YAW>].

136. *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*, U.S. FOOD & DRUG ADMIN. (Sept. 11, 2018), <https://www.fda.gov/news-events/press-announcements/fda-takes-new-steps-address-epidemic-youth-e-cigarette-use-including-historic-action-against-more> [<https://perma.cc/YY5T-EQYD>]; *FTC, FDA Take Action Against Companies Marketing E-liquids That Resemble Children’s Juice Boxes, Candies, and Cookies*, FED. TRADE COMM’N (May 1, 2019), <https://www.ftc.gov/news-events/press-releases/2018/05/ftc-fda-take-action-against-companies-marketing-e-liquids> [<https://perma.cc/A78F-3ABQ>]. *Statement from FDA Commissioner Scott Gottlieb, M.D., on new steps to address epidemic of youth e-cigarette use*, U.S. FOOD & DRUG ADMIN. (Sept. 11, 2018), <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-new-steps-address-epidemic-youth-e-cigarette-use> [<https://perma.cc/TAX7-WELR>]; see, e. g., Letter from Scott Gottlieb, M.D., Commissioner, U.S. Food & Drug Admin, to Richard Ashworth, President of Operations, Walgreen Co. (Mar. 4, 2019), <https://www.fda.gov/media/122587/download> [<https://perma.cc/M63K-4J87>].

137. Jennifer Maloney, *FDA Conducted Surprise Inspection of JUUL’s Headquarters*, WALL STREET J. (Oct. 2, 2018), <https://www.wsj.com/articles/fda-conducted-surprise-inspection-of-juul-headquarters-1538496393> [<https://perma.cc/WZJ8-2M73>] (addressing the seizure of documents from JUUL® Labs). See also Jan Hoffman, *F.D.A. Seizes Documents From JUUL Headquarters*, N.Y. TIMES (Oct. 2, 2018) (addressing the seizure of documents from JUUL® Labs as well).

138. *Statement from FDA Commissioner Scott Gottlieb, M.D., on new steps to address epidemic of youth e-cigarette use*, *supra* note 136; *FDA’s Youth Tobacco Prevention Plan*, *supra* note 135.

139. *FDA, FTC take action against companies misleading kids with e-liquids that resemble children’s juice boxes, candies and cookies*, U.S. FOOD & DRUG ADMIN. (Apr. 30, 2018), <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm605507.htm> [<https://perma.cc/Q2B7-466W>].

cessation and the issues impacting the development of such therapies.¹⁴⁰ Former FDA Commissioner Gottlieb announced implementation procedures to restrict youth access to flavored products (except mint, menthol and tobacco flavors), both at retail establishments and online and Acting FDA Commissioner Ned Sharpless has reinforced this stance and a guidance document was issued shortly after FDA Commissioner Hahn was confirmed.¹⁴¹ States such as New York have attempted to ban flavored e-cigarettes, yet the ban was appealed and a stay was granted.¹⁴² As of February 2020, the Centers for Disease Control and Prevention (“CDC”) reported over 2,800 lung injury cases from 50 states and two United States territories, as well as several deaths, which additionally raises the issue of the impact of a comprised immune system and the coronavirus pandemic.¹⁴³

140. Eliminating Youth Electronic Cigarette and Other Tobacco Product Use: The Role for Drug Therapies; Public Hearing; Request for Comments, 83 Fed. Reg. 55,318 (Nov. 5, 2018).

141. *FDA’s Youth Tobacco Prevention Plan*, *supra* note 135; *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, 2018), <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-proposed-new-steps-protect-youth-preventing-access> [<https://perma.cc/6KHP-9WGP>]. *FDA, FTC take action against companies misleading kids with e-liquids that resemble children’s juice boxes, candies and cookies*, *supra* note 139; *Statement from FDA Commissioner Scott Gottlieb, M.D., on new steps to address epidemic of youth e-cigarette use*, *supra* note 136. *See also* Sheila Kaplan, *Purveyors of Juice-Box Style, Nicotine-Filled E-Liquids Quit Selling the Products* N.Y. TIMES (Aug. 23, 2018), <https://www.nytimes.com/2018/08/23/health/e-cigarettes-marketing.html> [<https://perma.cc/TXX8-B8XV>]. *See also* Jennifer Maloney & Tom McGinty, *FDA Seeks Ban on Menthol Cigarettes*, WALL STREET J. (Nov. 15, 2018, 1:18PM), <https://www.wsj.com/articles/big-tobacco-warns-it-may-fight-fda-over-a-menthol-ban-1542277800> [<https://perma.cc/VE5Q-L6V7>]. *See also* Ned Sharpless, *How FDA is Regulating E-Cigarettes*, U.S. Food & Drug Admin. (Sept. 9, 2019), <https://www.fda.gov/news-events/fda-voices-perspectives-fda-leadership-and-experts/how-fda-regulating-e-cigarettes> [<https://perma.cc/X227-334D>]. OFFICE OF COMPLIANCE AND ENFORCEMENT, OFFICE OF HEALTH COMMUNICATION AND EDUCATION, OFFICE OF REGULATIONS, & OFFICE OF SCIENCE IN THE CENTER FOR TOBACCO PRODUCTS, GUIDANCE FOR INDUSTRY, ENFORCEMENT PRIORITIES FOR ELECTRONIC NICOTINE DELIVERY SYSTEMS (ENDS) AND OTHER DEEMED PRODUCTS ON THE MARKET WITHOUT PREMARKET AUTHORIZATION (2020), <https://www.fda.gov/media/133880/download> [<https://perma.cc/7KUV-GFMB>].

142. *Vapor Technology Association v Cuomo*, No. 906514-19, 2020 NY Slip Op 20012 (N.Y. App. Div. Jan. 8, 2020). *See also* Jesse McKinley & Christina Goldbaum, *N.Y. approves emergency ban on flavored e-cigarettes* (Sept. 18, 2019), N.Y. TIMES <https://www.nytimes.com/2019/09/15/nyregion/vaping-ban-ny.html> [<https://perma.cc/FZ33-5S5D>].

143. *See Outbreak of Lung Injury Associated with the Use of E-Cigarette, or Vaping, Products*, CTRS. FOR DISEASE CONTROL & PREVENTION (Oct. 3, 2019), https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html#what-we-know [<https://perma.cc/3RTY-N94A>]. Around this same time period, President Trump pronounced a ban on flavored on e-cigarettes including mint and menthol. Sheila Kaplan, *Trump Administration Plans to Ban Flavored E-Cigarettes*, N.Y. TIMES (Sept. 19, 2019), <https://www.nytimes.com/2019/09/11/health/trump-vaping.html> [<https://perma.cc/2K8A-TU27>]. Subsequently, the FDA issued a

Walmart stopped selling fruit-flavored e-cigarettes and raised the age to purchase tobacco products to twenty-one, which was prior to the legislation raising the minimum age to twenty-one to purchase tobacco and prior to the FDA issued guidance document concerning flavored products.¹⁴⁴ Interestingly, JUUL®, who insists it did not market to teens, has pledged to restrict youth vaping, yet lobbyists in fifty states have vigorously objected to the proposed ban of flavors in e-cigarette pods popular with teenagers.¹⁴⁵ JUUL®, the largest e-cigarette merchant, has focused on stricter online age verification, suspension of most flavors, and promotion to adults rather than to youth.¹⁴⁶

Further, the FDA is concerned about menthol in cigarettes; however, suffice it to say that lengthy court challenges will follow if menthol is banned.¹⁴⁷ The

Guidance Policy directed toward refillable e-cigarette cartridges. *See also* Sheila Kaplan and Matt Richtel, *The Mysterious Vaping Illness That's 'Becoming an Epidemic'*, N.Y. TIMES (Aug. 31, 2019), <https://www.nytimes.com/2019/08/31/health/vaping-marijuana-ecigarettes-sickness.html> [<https://perma.cc/5E9C-2WLL>].

144. Further Consolidated Appropriations Act, Pub. L. No 116-94, Sec. 603, <https://www.congress.gov/bill/116th-congress/house-bill/1865/text>. This Act was signed into law on December 20, 2019, amended section 906(d) of the Federal Food, Drug, and Cosmetic Act to increase the federal minimum age to purchase tobacco products from 18 to 21, and added a provision that it is unlawful for any retailer to sell a tobacco product to any person younger than 21 years of age. *See also* Sarah Nassauer, *Walmart to Stop Selling All E-Cigarettes*, WALL STREET J. (Mar. 5, 2020), <https://www.wsj.com/articles/walmart-to-stop-selling-all-e-cigarettes-11569003925> [<https://perma.cc/8K94-KUFC>]. *See* Jennifer Maloney, *JUUL Debates Pushing Back on E-Cigarette Ban*, WALL STREET J. (Sept. 12, 2019, at 10:01PM), <https://www.wsj.com/articles/juul-debates-pushing-back-on-e-cigarette-ban-11568327978> [<https://perma.cc/X7PJ-44LT>]. Julie Creswell & Sheila Kaplan, *A Ban on Flavored E-Cigarettes Would Sharply Cut Sales* N.Y. TIMES (Sept. 13, 2019), <https://www.nytimes.com/2019/09/12/health/vaping-juul.html> [<https://perma.cc/MC83-7YQG>]. Sheila Kaplan, *In Washington, JUUL Vows to Curb Youth Vaping. Its Lobbying in States Runs Counter to That Pledge.*, N.Y. TIMES (April 28, 2019), <https://www.nytimes.com/2019/04/28/health/juul-lobbying-states-ecigarettes.html> [<https://perma.cc/98GL-STRW>]

145. *See* Nassauer, *supra* note 144; Creswell & Kaplan *supra* note 144; Kaplan, *supra* note 144. Yet see: Sheila Kaplan, *JUUL Bought Ads Appearing on Cartoon Network and Other Youth Sites, Suit Claims*, N.Y. TIMES, (Feb. 12, 2020), <https://www.nytimes.com/2020/02/12/health/juul-vaping-lawsuit.html> [<https://perma.cc/53LF-ELHC>]. *See also* *Attorney General's Office Lawsuit Against JUUL*, MASS.GOV, <https://www.mass.gov/lists/attorney-generals-office-lawsuit-against-juul> [<https://perma.cc/XEM4-Z6B5>].

146. *See* Sheila Kaplan & Jan Hoffman, *F.D.A. Seeks Restrictions on Teens' Access to Flavored E-Cigarettes and a Ban on Menthol Cigarettes*, N.Y. TIMES (Nov 15, 2018), <https://www.nytimes.com/2018/11/15/health/ecigarettes-fda-flavors-ban.html> [<https://perma.cc/77H6-47YS>]. *See also* 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-ecigarettes-vaping-teenagers.html> [<https://perma.cc/ZL4R-TDQ3>]

147. Regulation of Flavors in Tobacco Products, 83 Fed. Reg. 122,94 (Mar. 21, 2018) (data regarding use of menthol cigarettes and non-cigarette tobacco products among youth indicate

European Union's ban on menthol cigarettes will commence in mid-2020,¹⁴⁸ and interestingly, San Francisco has already prohibited the sale of menthol cigarettes.¹⁴⁹ Canada has imposed a ban on menthol cigarettes as well.¹⁵⁰ Truly, this is a global issue. Further, regarding menthol, e-cigarettes, and other ENDS, the evidence is far from convincing that menthol cigarettes, as well as e-cigarettes, are not harmful.¹⁵¹

IV. ILLUSTRATIONS OF DELAY AND HARM TO THE PUBLIC IN CONTRAVENTION OF THE ENUMERATED CONGRESSIONAL FINDINGS OF THE TOBACCO CONTROL ACT

Tobacco use remains a leading cause of both premature, yet preventable, death in the United States according to the FDA and the CDC.¹⁵² There are several specific areas where delay has been prevalent.¹⁵³ First Amendment concerns and the cost of human life, due to the deleterious effects of nicotine addiction, are apparently at a crossroad as illustrated by the marked delay in reissuing graphic warnings and the delay in issuing corrective statements discussed below.¹⁵⁴ The question to examine is the cost of human life to the addictive effects of nicotine.

A. FDA's Legal Authority to Issue Graphic and Warning Statements

More than thirty years have passed since warnings were issued on cigarette

widespread appeal of flavored tobacco products). Maloney & McGinty, *supra* note 141 (detailing that according to a representative for RJR Reynolds, who manufactures the Newport brand, a legal battle will probably ensue).

148. Directive 2014/40, of the European Parliament and of the Council of 3 April 2014 on the Approximation of the Laws, Regulations and Administrative Provisions of the Member States Concerning the Manufacture, Presentation and Sale of Tobacco and Related Products and Repealing Directive 2001/37/EC, 2014 O.J. (L 127). *See also* Corinne Gretler, *Europe's Menthol Ban Has Tobacco Firms Thinking Outside the Pack* (Feb. 5, 2020), <https://www.bloomberg.com/news/articles/2020-02-05/eu-menthol-ban-tobacco-firms-offer-alternatives-to-cigarettes> [<https://perma.cc/474P-FTPH>] (author details that Imperial Brands Plc commenced selling cardboard (peppermint aroma) strips that can be inserted into a cigarette pack or pouch of rolling tobacco).

149. San Francisco, Cal. Ordinance 140-17 (June 20, 2017). *See also* Sheila Kaplan, *U. S. F.D.A. Plans to Seek a Ban on Menthol Cigarettes*, N.Y. TIMES, (Nov. 9, 2018), <https://www.nytimes.com/2018/11/09/health/fda-menthol-cigarettes-ban.html> [<https://perma.cc/XNZ6-7U6Z>].

150. Order Amending the Schedule to the Tobacco Act (Menthol), SOR/2017-45 (Can.).

151. *See* Kaplan, *supra* note 144; Maloney & McGinty, *supra* note 141. *See also* Sheila Kaplan, *Flashy Science Hub and Vaping Parties Fail to Win Friends at W.H.O. Tobacco Talks*, N.Y. TIMES (Oct. 8, 2018), <https://www.nytimes.com/2018/10/07/health/tobacco-e-cigarettes-treaty.html> [<https://perma.cc/PZ7R-3NPJ>].

152. *Smoking and Tobacco Use: Diseases and Death*, *supra* note 3.

153. Padon, Maloney & Cappella, *supra* note 120.

154. *Id.*

packaging and advertisements.¹⁵⁵ To that end, the FSPTCA mandated that the FDA develop regulations pertaining to warning statements and images to appear on cigarette packages and in cigarette advertisements.¹⁵⁶ Despite the issuance of the nine cigarette health warnings for all cigarette packaging and advertisements, legal challenges prevailed.¹⁵⁷ Scheduled to commence in September 2012, this issue became legally contentious due to the R. J. Reynolds' quest for an injunction, which the court granted and which led to the FDA's withdrawal of the proposed graphic warnings.¹⁵⁸ Yet, in *Discount Tobacco City & Lottery, Inc.*, the court held that curbing juvenile tobacco use is a substantial government interest that is directly advanced by the FSPTCA's provisions.¹⁵⁹

Further, *Discount Tobacco* held that graphic and textual warnings on cigarettes and smokeless tobacco products were reasonably related to the

155. LAURA BACH, TOBACCO HEALTH WARNINGS: EVIDENCE OF EFFECTIVENESS, <https://www.tobaccofreekids.org/assets/factsheets/0325.pdf> [<https://perma.cc/75MQ-RGG2>].

156. *Id.*

157. R.J. Reynolds Tobacco Co. et al. v. Food & Drug Administration, 696 F.3d 1205 (D. C. Cir. 2012). (On Dec. 5, 2012, the Court denied the government's petition for panel rehearing and rehearing *en banc*. R.J. Reynolds Tobacco Co. v. Food & Drug Admin., No. 11-5332, 2012 U.S. App. LEXIS 24978 (D.C. Cir. Dec. 5, 2012); R.J. Reynolds Tobacco Co. v. Food & Drug Admin., No. 11-5332, 2012 U.S. App. LEXIS 24976 (D.C. Cir. Dec. 5, 2012)). The plaintiff tobacco Companies alleged violation of their free speech rights under the First Amendment. *See* R.J. Reynolds Tobacco Co. et al. v. Food & Drug Admin., 845 F. Supp. 2d 266 (D.D.C. 2012). Preliminary Injunction granted November 7, 2011, which effectively stayed the new graphic warnings from FDA implementation. R.J. Reynolds Tobacco Co. et al. v. Food & Drug Admin., 823 F. Supp. 2d 36 (D.D.C. 2011). Subsequently, the district court decided on February 29, 2012, that the government's rule violated the tobacco companies' rights to free speech and the FDA filed an appeal. Reynolds Tobacco Co. et al. v. Food & Drug Admin., 845 F. Supp. 2d 266 (D.D.C. 2012). (Court of Appeals for the District of Columbia held that FDA failed to provide substantial evidence that graphic warnings on cigarette advertising would advance the government's interest in smoking reduction to a material degree R.J. Reynolds Tobacco Co. et al. v. Food & Drug Admin., 696 F.3d 1205 (D.C. Cir. 2012)).

158. R.J. Reynolds Tobacco Co. et al. v. Food & Drug Admin., 823 F. Supp. 2d 36 (D.D.C. 2011). *See also* Required Warnings for Cigarette Packages and Advertisements 76 Fed. Reg. 36,627 (June 22, 2011); *See* Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Review; Experimental Study of Graphic Cigarette Warning Labels 77 Fed. Reg. 72,355 (Dec. 5, 2012); Am. Acad. of Pediatrics, et al. v. U. S. Food & Drug Administration, 330 F. Supp. 3d 657 (D. Mass. 2018); *Deeming Tobacco Products*, *supra* note 16, at 29,032. American Meat Institute v. United States Dept. of Agriculture, 760 F.3d 18 (D.C. Cir. 2014) *rev'd R. J. Reynolds* on other grounds. The Deeming Rule uses the term that the *R. J. Reynolds* decision was "overtaken" by the *American Meat Institute* decision. *Deeming Tobacco Products*, *supra* note 16, at 28,989.

159. *Discount Tobacco City & Lottery, Inc.* 674 F.3d 509, 562 (2012). The United States Supreme Court denied cert., (Case re-captioned). *Am. Snuff Co., LLC v. United States* 569 U.S. 946 (2013).

government's interest in preventing consumer deception and deemed them constitutional.¹⁶⁰ The objectives of the warnings were to communicate the dangers of smoking and to decrease the number of people who smoke.¹⁶¹ The FDA selected the final nine cigarette health warnings based on their ability to effectively communicate smoking health risks to the public.¹⁶² In creating the statements, the FDA reviewed relevant scientific literature, more than 1,000 public comments, and results from its 18,000-person study.¹⁶³ FDA does have the legal authority to issue warnings.¹⁶⁴ The Tobacco Control Act provided the FDA with the authority to regulate the labeling and advertising of cigarettes and, most importantly, directed that the FDA issue color graphic warnings on cigarette packaging.¹⁶⁵ The statute provides as follows: “[n]ot later than 24 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary shall issue regulations that require color graphics depicting the negative health consequences of smoking to accompany the label statements specified in subsection (a)(1).”¹⁶⁶

Further, the deeming regulation issued in 2016 clarified that the FDA still retains the legal authority to require warnings under the FSPTCA.¹⁶⁷ In 2018, the court ordered the FDA to issue long overdue revamped warnings on an expedited schedule since several years elapsed and FDA did reissue textual warning and graphic images in 2020.¹⁶⁸ Hopefully, the reissued graphic warnings will pass Constitutional muster without further delay, however a lawsuit by R.J. Reynolds and other tobacco companies was filed in the federal District Court Eastern District Texas regarding the reissued graphic warnings.¹⁶⁹

160. *Discount Tobacco City & Lottery, Inc.* 674 F.3d at 564 (2012).

161. *Id.*

162. *R.J. Reynolds Tobacco Co.*, 696 F.3d at 1209 (2012).

163. *Id.*

164. 15 U.S.C. § 1333 (2018).

165. *Id.*

166. *Id.*

167. *Deeming Tobacco Products*, *supra* note 16, at 29,026.

168. *See Tobacco Products; Required Warnings for Cigarette Packages and Advertisements* 85 Fed. Reg. 15638 (March 18, 2020) (to be codified 21 CFR 1141). *See also Tobacco Products; Required Warnings for Cigarette Packages and Advertisements* 84 Fed. Reg. 42754 (Aug. 16, 2019). *See also* U.S. FOOD & DRUG ADMIN., REQUIRED CIGARETTE HEALTH WARNINGS, 2020, <https://www.fda.gov/media/136157/download> [<https://perma.cc/2SRB-LYHD>]. *See* Lawsuit instituted by R.J. Reynolds and other tobacco companies concerning the issuance of the graphic warnings, Compl., *R.J. Reynolds Tobacco Company et al. v. U.S. Food and Drug Administration et al.*, No 6:20-cv-00176 (Dist. Ct. E. D. Tex., Tyler Div.). *See also Am. Acad. of Pediatrics*, 330 F. Supp. 3d. at 667 (2018). *See also* Appendix C.

169. *See id.* (stating that the FDA was ordered to submit to the court an expedited schedule); *Am. Acad. of Pediatrics v. United States FDA*, 2019 WL 1047149 (D. Mass. Mar. 5, 2019) (stating the Proposed Rule be submitted for publication in the Federal Register by August 15, 2019, and the Final Rule submitted for Publication in the Federal Register by March 15, 2020). *Tobacco Products; Required Warnings for Cigarette Packages and Advertisements*, 84 Fed. Reg. 42754 (Aug. 16,

B. Manifest Delay in the Issuance of Corrective Statements

Another illustration of patent delay was the issuance of corrective statements in *United States v. Philip Morris USA, Inc.*, where the court ordered cigarette companies to issue corrective statements.¹⁷⁰ Undoubtedly, the wording of the corrective statements was significant; however, a ten-year delay is excessive. Again, the issue is that of public health and the right-to-know. In a protracted court case, corrective statements were ordered,¹⁷¹ yet delay ensued, and the case against cigarette manufacturers and other tobacco entities spanned several years. In 2006, the district court determined that for years, decades, in fact, cigarette manufacturers were in violation under RICO.¹⁷² Further, the district court determined that for decades, the cigarette manufacturers had conspired to deny the health effects of smoking in violation of RICO and ordered the cigarettes manufacturers to publish “corrective statements” to appear in newspapers, on television, on cigarette packages, and on websites specific to the health effects of smoking.¹⁷³ The parties quarreled over the wording of these statements for a decade.¹⁷⁴ Eventually, the corrective statements were published in 2018.¹⁷⁵

2019). <https://www.federalregister.gov/documents/2019/08/16/2019-17481/tobacco-products-required-warnings-for-cigarette-packages-and-advertisements> [<https://perma.cc/8BYZ-2DFD>]. Compl., *R.J. Reynolds Tobacco Company et al. v. U.S. Food and Drug Administration et al.*, No. 6:20-cv-00176 (Dist. Ct. E. D. Tex., Tyler Div.).

170. *United States v. Philip Morris USA Inc.*, 855 F.3d 321, 328-28 (D.C. Cir. 2017).

171. *Id.*

172. *See generally* *United States v. Philip Morris USA, Inc.*, 449 F. Supp. 2d 1 (D.D.C. 2006). *See also* *Philip Morris USA Inc.*, 855 F.3d. at 323 (“In 2006, the district court found that Appellant cigarette manufacturers had for decades conspired to deny the health effects of smoking in violation of RICO . . . the court ordered Appellants to disseminate “corrective statements” relating to the health effects of smoking in newspapers, on television, on cigarette packages, and on websites. For more than a decade since, the parties have battled over the precise language of these statements. Appellants claim the most recent language proposed by the government is conduct-focused and is backward-looking beyond the scope of RICO and . . . violates the First Amendment.”) (citations omitted). The term RICO is commonly used to denote the Racketeer Influenced and Corrupt Organizations Act. *RICO Charges*, DEP’T OF JUST., <https://www.justice.gov/jm/criminal-resource-manual-109-rico-charges> [<https://perma.cc/5T6W-C7EA>].

173. *See generally* *Philip Morris USA, Inc.*, 449 F. Supp. 2d 1 (2006).

174. *Philip Morris USA Inc.*, 855 F.3d. at 323 (2006).

175. Second Superseding Order Implementing the Corrective Statements Remedy for Newspapers and Television, *United States v. Philip Morris*, No. 99-CV-2496 (D.D.C. Oct. 5, 2017), https://ecf.dcd.uscourts.gov/cgi-bin/show_public_doc?1999cv2496-6227 [<https://perma.cc/K8YK-WFUL>]. *Corrective Statements: Ads and Social Media*, CAMPAIGN FOR TOBACCO-FREE KIDS, <https://www.tobaccofreekids.org/media/2017/corrective-statements> [<https://perma.cc/Q5YT-AR5V>]; *Text of Court-Ordered Corrective Statements: United States v. Philip Morris USA Inc.*, CAMPAIGN FOR TOBACCO-FREE KIDS, https://www.tobaccofreekids.org/assets/content/what_we_do/

V. VIABLE RECOMMENDATIONS TO PROTECT THE PUBLIC HEALTH

Although the FDA is restricted at times to a reactionary role in regulating tobacco products, the agency does have methods to regulate such as warning letters, Civil Money Penalty (CMP) complaints, No-Tobacco-Sale Order (NTSO) complaints, seizures, injunctions, and criminal prosecution.¹⁷⁶ The question remains as to the lengthy timeframe involved in such measures. As illustrated by the graphic warnings proceedings, several years elapsed and still, the reissued warnings are questionable in terms of potential challenges by stakeholders such as tobacco conglomerates.¹⁷⁷ Undoubtedly, the tobacco industry could again hamper FDA efforts and public protection with protracted court battles. Further, lobbying has played a significant role in the tobacco products regulation.¹⁷⁸ Today, the power of the tobacco industry's lobbying campaigns continues to be a major obstacle in preventing the implementation of increased regulation.¹⁷⁹ While most major industries have lobbying efforts, the tobacco industry stands out from the rest, spending a colossal amount of money annually.¹⁸⁰

Admittedly, there is no perfect solution to these delays. Understandably, advocacy on behalf of the client is critical. Yet the extensive delay involved in finally issuing the corrective statements appears well beyond that of zealous advocacy. The FDA's delay in reissuing graphic warning statements was equally as troubling. Perhaps the FDA's reluctance to reissue new warnings was due in part to another perceived looming First Amendment challenge. Finally, the FSPTCA and deeming regulations that include e-cigarettes and other ENDS have

industry_watch/doj/corrective_statements/2017_10_corrective_statements.pdf [https://perma.cc/P6G2-VQ65].

176. *Compliance, Enforcement & Training*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/tobaccoproducts/guidancecomplianceregulatoryinformation/default.htm> [https://perma.cc/ZQ2V-8DQH].

177. *See Am. Acad. of Pediatrics* 330 F. Supp. 3d at 662 (2018). Tobacco Products; Required Warnings for Cigarette Packages and *Advertisements*, 84 Fed. Reg. 42754 (Aug. 16, 2019). <https://www.federalregister.gov/documents/2019/08/16/2019-17481/tobacco-products-required-warnings-for-cigarette-packages-and-advertisements> [https://perma.cc/8BYZ-2DFD]. *See also supra* note 168.

178. ASH, *Denial, deceit and delay — tobacco industry lobbying tactics*, MEDIUM (May 2, 2017), https://medium.com/@ASH_LDN/denial-deceit-and-delay-tobacco-industry-lobbying-tactics-c5aee7ff4bbc [https://perma.cc/43E8-ZQQU].

179. *See e. g.*, Eric Lipton, *A Lobbyist Wrote the Bill. Will the Tobacco Industry Win Its E-Cigarette Fight?*, N.Y. TIMES (Sept. 2, 2016), <https://www.nytimes.com/2016/09/03/us/politics/e-cigarettes-vaping-cigars-fda-altria.html> [https://perma.cc/3EV3-YAMT]; Tobacco War Lobbying Documents, N.Y. TIMES (Sept. 2, 2016), <https://www.nytimes.com/interactive/2016/08/26/us/politics/document-tobacco-lobbying-documents.html> [https://perma.cc/Q3K8-337E] (hosting documents illustrating efforts to thwart deeming rule).

180. *Id. See also Tobacco*, OPENSECRETS, <https://www.opensecrets.org/industries/indus.php?ind=A02> [https://perma.cc/C3PV-247N].

taken the forefront in the “tobacco war.”¹⁸¹ Just as it is incumbent for the FDA to take concrete action as it has recently done with the epidemic of youth e-cigarette use and other ENDS products, the tobacco industry needs to step up as well. The reality is that the FDA clearly does not have the legal authority to ban tobacco, yet the FDA has the legal authority to regulate it.¹⁸² Traditional rulemaking will only delay, for example, any menthol ban and delay any prohibition of youth use of e-cigarettes and other END systems. Perhaps the FDA, the CDC, and other relevant federal agencies and industry stakeholders, should aim to resolve issues through informal rulemaking.

*A. Lessons from Other FDA Centers—Guidance Documents
and Declaratory Orders*

1. Guidance Documents

The FDA could issue a series of guidance documents with the recognition that guidance documents are not legally binding, and in fact did so in 2020.¹⁸³ An

181. Notably in 2018, former FDA Commissioner Scott Gottlieb, M. D. announced policies aimed toward curbing youth smoking. *See, e.g.,* Scott Gottlieb & Mitch Zeller, *Advancing Tobacco Regulation to Protect Children and Families: Updates and New Initiatives from the FDA on the Anniversary of the Tobacco Control Act and FDA’s Comprehensive Plan for Nicotine*, U.S. FOOD & DRUG ADMIN. (Aug. 2, 2018), <https://www.fda.gov/NewsEvents/Newsroom/FDAVoices/ucm619118.htm> [<https://perma.cc/5J8W-UTNG>].

182. *See* 21 U.S.C. § 387g (2018) (“(3) LIMITATION ON POWER GRANTED TO THE FOOD AND DRUG ADMINISTRATION.—Because of the importance of a decision of the Secretary to issue a regulation—(A) banning all cigarettes, all smokeless tobacco products, all little cigars, all cigars other than little cigars, all pipe tobacco, or all roll-your-own tobacco products; or (B) requiring the reduction of nicotine yields of a tobacco product to zero, the Secretary is prohibited from taking such actions under this Act”).

183. *See generally* *Guidances*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/forindustry/fdabasicsforindustry/ucm234622.htm> [<https://perma.cc/5ZWL-6ME3>]. *See* U.S. FOOD & DRUG ADMIN, ENFORCEMENT PRIORITIES FOR ELECTRONIC NICOTINE DELIVERY SYSTEMS AND OTHER DEEMED PRODUCTS ON THE MARKET WITHOUT PREMARKET AUTHORIZATION; GUIDANCE FOR INDUSTRY (2020), <https://www.fda.gov/media/133880/download> [<https://perma.cc/UG8G-86R7>]. The *Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization* guidance prohibiting most flavors (including mint) except menthol and tobacco in cartridge-based e-cigarettes; however, the ban is inapplicable to tank vaping systems. According to the guidance policy the definition of ENDS in the guidance document does not include disposable products; *See also* Executive Order 13891 84 Fed. Reg. 55,235 (Oct. 9, 2019). It is titled: *Promoting the Rule of Law Through Improved Agency Guidance Documents* and was issued in 2019. The overall purpose is that of uniformity similar to the discussion below and focuses on increased accountability in terms of a 30-day minimum notice and comment period prior to issuing the guidance as well as providing notice to the public of the issuance of the guidance document.

example of stakeholder and FDA collaboration that could transcend to tobacco products regulation is that of the agency's Center of Veterinary Medicine which handles antimicrobial resistance and residues.¹⁸⁴ The FDA is responsible for ensuring that animal drugs and medicated feeds are not only safe and effective for animals but also that food products from treated animals are safe for humans to consume.¹⁸⁵ Over the years, the FDA responded to concerns about antimicrobial resistance and drug residues.¹⁸⁶ The National Antimicrobial Resistance Monitoring System ("NARMS") coordinated with the United States Department of Agriculture and the CDC.¹⁸⁷ The FDA issued several guidance documents throughout the years.¹⁸⁸ Although the FDA actively tackled the issue of antimicrobial resistance since 1996, it was not until late 2013 when the FDA issued Guidance for Industry (GFI) #213 that outlined more proactive steps.¹⁸⁹ The guidance detailed a phase-out of antimicrobial drugs in animals used for food

184. See generally *FDA Releases Annual Summary Report on Antimicrobials Sold or Distributed in 2017 for Use in Food-Producing Animals Showing Declines for Past Two Years*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm628504.htm> [<https://perma.cc/R7BU-GPEW>]. See also *Antimicrobial Resistance*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/default.htm> [<https://perma.cc/5LGM-DMRE>].

185. *FDA Fifth Biannual Progress Report on Judicious Use of Antimicrobials in Food-producing Animals*, U.S. FOOD & DRUG ADMIN., <https://wayback.archive-it.org/7993/20190208023234/https://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm509403.htm> (archived copy Feb. 8, 2019). Besides the FDA, the Center for Disease Control is involved with safety issues concerning food-producing animals. See, e.g., *Antibiotic Resistance, Food, and Food-Producing Animals*, CTNS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/features/antibiotic-resistance-food/index.html> [<https://perma.cc/87PR-6HU7>].

186. *Antimicrobial Resistance*, *supra* note 184.

187. *The National Antimicrobial Resistance Monitoring System*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/animalveterinary/safetyhealth/antimicrobialresistance/nationalantimicrobialResistanceMonitoringSystem/default.htm> [<https://perma.cc/DNR6-FCRP>].

188. See generally U.S. FOOD & DRUG ADMIN, FINAL GUIDANCE FOR INDUSTRY STUDIES TO EVALUATE THE SAFETY OF RESIDUES OF VETERINARY DRUGS IN HUMAN FOOD: GENERAL APPROACH TO ESTABLISH A MICROBIOLOGICAL ADI VICH GL-36 AND A GUIDANCE TITLED: FINAL GUIDANCE FOR INDUSTRY STUDIES TO EVALUATE THE SAFETY OF RESIDUES OF VETERINARY DRUGS IN HUMAN FOOD: GENERAL APPROACH TO TESTING VICH GL33 (2009), <https://www.fda.gov/media/75205/download> [<https://perma.cc/D3EL-L4ZM>]. This final guidance replaced a 2006 guidance and outlined a testing approach to assure human food safety following the consumption of food products derived from animals treated with veterinary drugs. The guidance combines developmental toxicity testing proposals of the European Union, Japan, and the United States for the safety of veterinary drug residues in human food.

189. U.S. FOOD & DRUG ADMIN., NEW ANIMAL DRUGS AND NEW ANIMAL DRUG COMBINATION PRODUCTS ADMINISTERED IN OR ON MEDICATED FEED OR DRINKING WATER OF FOOD-PRODUCING ANIMALS: RECOMMENDATIONS FOR DRUG SPONSORS FOR VOLUNTARILY ALIGNING PRODUCT USE CONDITIONS WITH GFI #209 (2013), <https://www.fda.gov/media/83488/download> [<https://perma.cc/7Z9G-34VU>].

production.¹⁹⁰ According to the FDA, the agency issued voluntary guidance promoting the judicious use of antibiotics in food animal production as preferable due to resource limitations; that is, according to the FDA, the agency would use fewer resources compared to withdrawing the animal drugs on an individual basis.¹⁹¹ In so doing, the FDA used a collaborative methodology involving stakeholders such as animal pharmaceutical companies.¹⁹²

2. *Declarative Order Under the Administrative Procedures Act*

Perhaps the FDA should consider utilizing section 554(e) of the Administrative Procedures Act (APA) and issue a declarative order regarding menthol and any further action regarding e-cigarettes.¹⁹³ For example, the FDA issued a milestone determination in 2015, stating that partially hydrogenated oils (PHOs) are not “generally recognized as safe (GRAS) for use in any food.”¹⁹⁴ A “declaratory order”, which has the “force and effect” of a rule, was issued pursuant to 5 U.S.C. 554(e) of the APA.¹⁹⁵ There was a phase-out program regarding the use of these oils in the food supply and removal from the United States food supply.¹⁹⁶ The Federal Register notice concerning hydrogenated fat

190. *Id.*

191. Interestingly, the FDA had denied petitions to ban medically important antibiotics used in animals. However, the District Court in *Natural Resources Defense Council, Inc. v. United States FDA* ordered the FDA to reconsider the denied petitions. 872 F. Supp. 2d 318, 342 (S.D.N.Y. 2012). The Court of Appeals reversed the District Court’s determination that the FDA was required by “21 U.S.C. § 360b(e)(1) to proceed with hearings to determine whether to withdraw approval for the use of penicillin and tetracyclines in animal feed and that the FDA’s decision denying two citizen petitions urging it to hold such hearings was arbitrary or capricious within the meaning of 5 U.S.C. § 706(2).” *NRDC, Inc. v. United States FDA*, 760 F.3d 151, 153 (2nd Cir. 2014). Specifically, the Court of Appeals concluded that the “decision whether to institute or terminate a hearing process that may lead to a finding requiring withdrawal of approval for an animal drug is a discretionary determination left to the prudent choice of the FDA.” *Id.* at 175. The Appeals Court agreed with the FDA’s determination that its “preferred program of voluntary compliance offers greater prospect for immediate and significant reductions in animal antibiotic use than the pursuit of a potentially contentious withdrawal hearing.” *Id.* Further, the Court of Appeals opined that they could not conclude that it is “arbitrary or capricious” for the FDA to follow policies intended to reduce the use of animal feed containing antibiotics through various phases “short of withdrawing approval for the use of antibiotics in feed via a protracted administrative process and likely litigation.” *Id.*

192. *See generally* TERMINI, *supra* note 1.

193. *See generally* 5 U.S.C. § 554(e) (2018).

194. Final Determination Regarding Partially Hydrogenated Oils, 80 Fed. Reg. 34,650 (June 17, 2015). PHOs are the primary dietary source of artificial *trans* fat in processed foods.

195. 5 U.S.C. 554(e) (2018).

196. Final Determination Regarding Partially Hydrogenated Oils, 83 Fed. Reg. 23,358 (May 21, 2018).

was published on November 8, 2013.¹⁹⁷ The FDA received 6,000 comments and 4,500 letters in response to the November 2013 notice about the FDA tentative determination regarding GRAS elimination.¹⁹⁸ The FDA found “that there is no longer a consensus among qualified experts that partially hydrogenated oils (PHOs), which are the primary dietary source of industrially-produced trans fatty acids (IP-TFA) are generally recognized as safe (GRAS) for any use in human food.”¹⁹⁹ The FDA order specific to the PHO ban means that food manufacturers would no longer be permitted to sell PHOs, either directly or as ingredients in another food product, without prior FDA approval for use as a food additive.²⁰⁰ The order permitted a three-year phase-out period for reformulation and product relabeling, with compliance required by June 18, 2018, and in some situations by January 1, 2020.²⁰¹ Could the same, in terms of a declaratory order under the APA, be accomplished for a menthol ban and curtailing the e-cigarette epidemic by youth?

VI: FINAL INSIGHT FOR THE READER

The question remains—at what cost to human life? The FDA, the CDC, industry stakeholders, health care, and consumer interest stakeholders need to solve these critical issues in the most expedient manner. In so doing, this imparts designing realistic solutions to curb, for instance, the discernable upsurge of youth e-cigarette use. Continued delay tactics harm the health of the United States population and most significantly, our youth.

197. Tentative Determination Regarding Partially Hydrogenated Oils; Request for Comments and for Scientific Data and Information, 78 Fed. Reg. 67,169 (Nov. 8, 2013). The comment period was extended until March 8, 2014. Tentative Determination Regarding Partially Hydrogenated Oils; Request for Comments and for Scientific Data and Information; Extension of Comment Period 78 Fed. Reg. 79,701 (Dec. 31, 2013).

198. Final Determination Regarding Partially Hydrogenated Oils, 80 Fed. Reg. 34,650, 34,651 (June 17, 2015).

199. *Id.* at 34,650.

200. *Id.* at 34,652-53.

201. Tentative Determination Regarding Partially Hydrogenated Oils; Request for Comments and for Scientific Data and Information, 78 Fed. Reg. 67,169 (Nov. 8, 2013).

APPENDIX A: DIVERSITY OF E-CIGARETTE PRODUCTS²⁰²

Figure 1.1

E-cigarettes include a diverse group of devices that allow users to inhale an aerosol, which typically contains nicotine, flavorings, and other additives. E-cigarettes vary widely in design and appearance, but generally operate in a similar manner and are composed of similar components (Figure 1.1). A key challenge for surveillance of the products and understanding their patterns of use is the diverse and nonstandard nomenclature for the devices (Alexander et al. 2016). These devices are referred to, by the companies themselves, and by consumers, as “e-cigarettes,” “e-cigs,” “cigalikes,” “e-hookahs,” “mods,” “vape pens,” “vapes,” and “tank systems.” In this report, the term “e-cigarette” is used to represent all of the various products in this rapidly diversifying product category. The terms may differ by geographic region or simply by the prevailing preferences among young users. For example, some refer to all cigarette-shaped products as “e-cigarettes” or as “cigalikes,” and some may refer to the pen-style e-cigarettes as “hookah pens” or “vape pens” (Richtel 2014; Lempert et al. 2016).



Source: Photo by Mandie Mills, CDC at 3.

202. U.S. DEP’T OF HEALTH AND HUMAN SERV, E-CIGARETTE USE AMONG YOUTH AND YOUNG ADULTS: A REPORT OF THE SURGEON GENERAL 3 (2016), https://e-cigarettes.surgeongeneral.gov/documents/2016_SGR_Full_Report_non-508.pdf [<https://perma.cc/BFG8-MNEC>]

APPENDIX B: THE TARIFF CLASSIFICATION OF A NICOTINE INHALER AND PARTS FROM CHINA²⁰³

NY M85579

August 22, 2006

CLA-2-85:RR:NC:N1:112 M85579

CATEGORY: Classification

TARIFF NO.: 8543.89.9795; 3824.90.2800

Mark Weiss
Weiss & Moy, P.C.
4204 N. Brown Avenue
Scottsdale, AZ 85251-3914

RE: The tariff classification of a nicotine inhaler and parts from China

Dear Mr. Weiss,

In your letter dated July 20, 2006, you requested a tariff classification ruling.

The items concerned are the Ruyan Electronic Cigarette and the Ruyan Electronic Cigarette cartridge. The Cigarette is a spherical, metal tube with a plastic mouthpiece tip on the end which measures approximately 5 ½" in length. Inside the tube are a sensor, electronic atomizer, integrated circuits and a lithiumion battery. The spherical cartridge is attached to a plastic mouthpiece tip and contains nicotine and propylene glycol.

The purpose of the Ruyan Electronic Cigarette is to act as a nicotine inhaler that has atomized smoke being forced out of the plastic mouthpiece tip.

You state that the these items will be marketed in five, different packages:

1. Electronic cigarette with two rechargeable 3.7-volt batteries
2. Electronic cigarette with two rechargeable 3.7-volt batteries and five cartridges
3. Five cartridges, ten cartridges and twenty cartridges

The applicable classification subheading for the Ruyan Electronic Cigarette with batteries and the Ruyan Electronic Cigarette with batteries and cartridges will be

203. The tariff classification of a nicotine inhaler and parts from China, NY m85579 (2006), <https://rulings.cbp.gov/search?term=m85579&collection=ALL&sortBy=RELEVANCE&pageSize=30&page=1> [<https://perma.cc/87RH-CJBV>].

8543.89.9795, Harmonized Tariff Schedule of the United States (HTSUS), which provides for “Electrical . . . apparatus, having individual functions, not specified or included elsewhere . . . : Other . . . apparatus: Other: Other: Other: Other: Other”. The rate of duty will be 2.6%.

The applicable classification subheading for the packages of five Cartridges, ten Cartridges and twenty Cartridges will be 3824.90.2800, Harmonized Tariff Schedule of the United States (HTSUS), which provides for “. . . preparations of the chemical or allied industries . . . , not elsewhere specified or included: Other: Other: Mixtures containing 5 percent or more by weight of one or more aromatic or modified aromatic substances: Other”. The rate of duty will be 6.5%.

Duty rates are provided for your convenience and are subject to change. The text of the most recent HTS and the accompanying duty rates are provided on World Wide Web at <http://www.usitc.gov/tata/hts/>.

This ruling is being issued under the provisions of Part 177 of the Customs Regulations (19 C.F.R. 177).

A copy of the ruling or the control number indicated above should be provided with the entry documents filed at the time this merchandise is imported. If you have any questions regarding the Ruyan Electronic Cigarette, contact National Import Specialist Richard Laman at 646-733-3017. If you have any questions regarding the Ruyan Electronic Cigarette cartridge, contact National Import Specialist Richard Dunkel at 646-733-3032.

APPENDIX C: REQUIRED HEALTH WARNINGS²⁰⁴

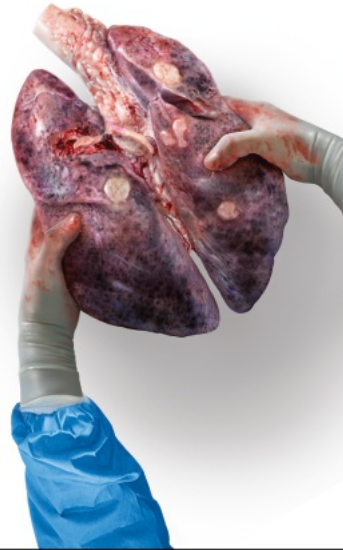
The Family Smoking Prevention and Tobacco Control Act (TCA) granted FDA important new authority to regulate the manufacture, marketing, and distribution of tobacco products. The TCA also amended Section 4 of the Federal Cigarette Labeling and Advertising Act (FCLAA), directing FDA to issue regulations requiring color graphics depicting the negative health consequences of smoking to accompany new textual warning statements. The TCA amends the FCLAA to require each cigarette package and advertisement to bear one of the new required warnings.

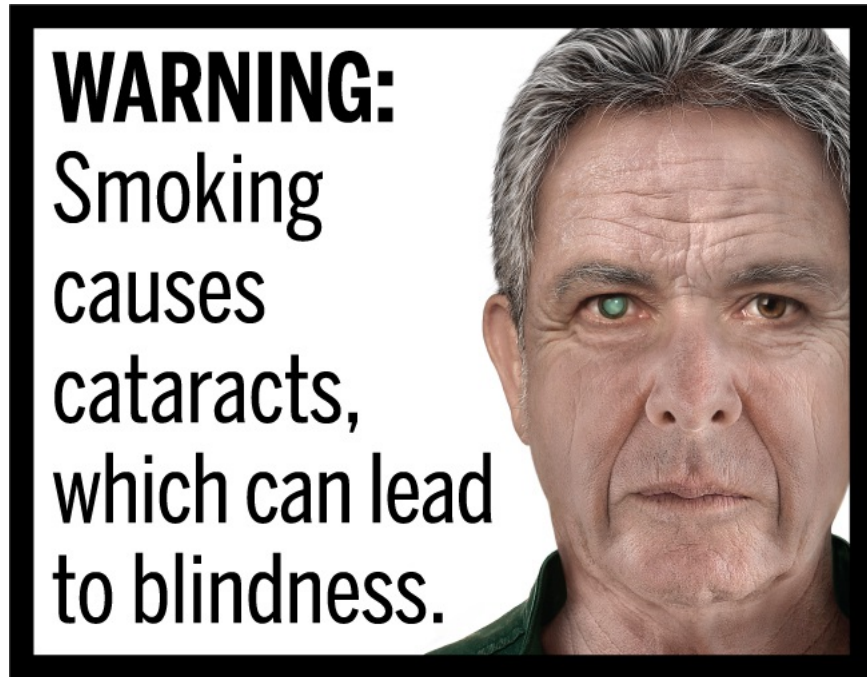
In March 2020, FDA finalized the “Required Warnings for Cigarette Packages and Advertisements” rule, establishing 11 new cigarette health warnings, consisting of textual warning statements accompanied by color graphics, in the form of concordant photorealistic images, depicting the negative health consequences of cigarette smoking. These new required warnings depict some of the lesser-known, but serious health risks of smoking.

204. CIGARETTE LABELING AND HEALTH WARNING REQUIREMENTS, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/tobacco-products/labeling-and-warning-statements-tobacco-products/cigarette-labeling-and-health-warning-requirements> [https://perma.cc/3NRF-HRK5]. See also U.S. FOOD & DRUG ADMIN., REQUIRED CIGARETTE HEALTH WARNINGS, 2020, <https://www.fda.gov/media/136157/download> [https://perma.cc/2SRB-LYHD]. See also lawsuit instituted by R.J. Reynolds and other tobacco companies concerning the issuance of the graphic warnings, Compl., *R.J. Reynolds Tobacco Company et al. v. U.S. Food and Drug Administration et al.*, No 6:20-cv-00176 (Dist. Ct. E. D. Tex., Tyler Div.).



WARNING:
Tobacco
smoke causes
fatal lung
disease in
nonsmokers.





WARNING:
Smoking reduces blood
flow, which can cause
erectile dysfunction.





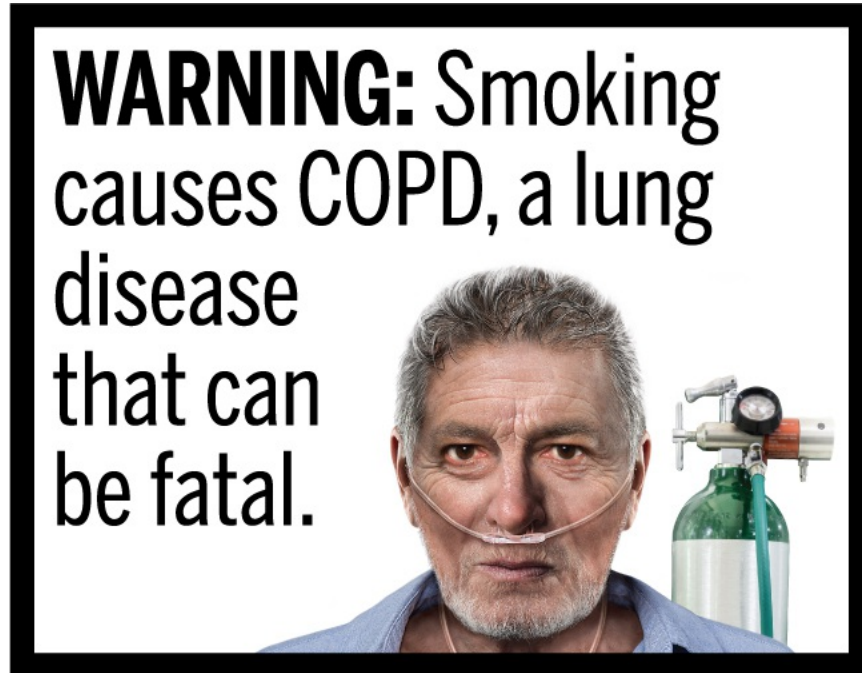
WARNING:

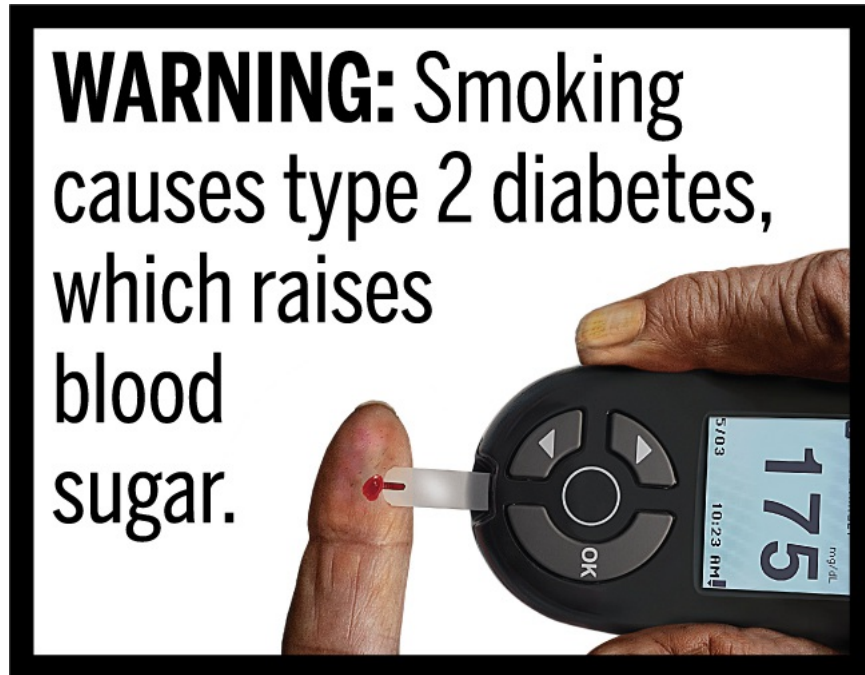
Smoking
causes bladder
cancer, which
can lead to
bloody urine.





WARNING: Smoking
reduces blood flow
to the limbs, which can
require amputation.







WARNING: Smoking
during pregnancy
stunts fetal growth.

WARNING:
Smoking can
cause heart
disease and
strokes by
clogging
arteries.

