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# ARE VAPE PENS THE NEW CIGARETTE? THE FDA'S IMPENDING QUEST TO REGULATE THE E-CIGARETTE AND ITS EFFECT ON SOCIETY'S YOUTH

ADDISON J. MORGAN\*

## INTRODUCTION

Pursuant to the Food, Drug, and Cosmetic Act of 1938 (the “FDCA”), the Federal Drug Administration (the “FDA”) has possessed the power to regulate food, drugs, and cosmetic products for almost an entire century.<sup>1</sup> The same cannot be said about tobacco products. Prior to 2009, tobacco products were largely exempt from federal health and safety laws.<sup>2</sup> Nonetheless, after the ratification of the Family Smoking Prevention and Tobacco Control Act of 2009, the FDA was granted the authority necessary to regulate tobacco products.<sup>3</sup> Despite being the primary federal regulatory command with respect to tobacco, the FDA currently does not regulate the cigarette’s distant counterpart: the e-cigarette.<sup>4</sup>

Since e-cigarettes were introduced into the United States in 2007, they have continuously become popular among adolescents.<sup>5</sup> According to the Centers for Disease and Control (the “CDC”), high school student e-cigarette usage has increased by 78% since 2017 and that same usage has increased by 48% among middle schoolers.<sup>6</sup> Moreover, in 2017, the e-cigarette market

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<sup>1</sup> See Federal Food, and Drug Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301-397 (1994 & Supp. II 1997)).

<sup>2</sup> See Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009).

<sup>3</sup> *Id.*

<sup>4</sup> See FOOD & DRUG ADMIN., MODIFICATIONS TO COMPLIANCE POLICY FOR CERTAIN DEEMED TOBACCO PRODUCTS, <https://www.fda.gov/media/121384/download> (last visited Apr. 19, 2019).

<sup>5</sup> Kristy Marynak et al., *Exposure to Electronic Cigarette Advertising Among Middle School and High School Students – United States, 2014-2016*, 67 MORBIDITY & MORTALITY WKLY. REP. 294, 298 (2018).

<sup>6</sup> Karen A. Cullen et al., *Notes from the Field: Use of Electronic Cigarettes and any Tobacco Product Among Middle and High School Students – United States, 2011-2018*, 67 MORBIDITY & MORTALITY WKLY. REP. 1276, 1276 (2018).

expanded by 40% to \$1.16 billion.<sup>7</sup> Majority of that economic growth is attributable to Juul, the United States' most prominent vaporizer manufacturer, whose vaping products have become quite appealing due to wide array of flavored e-cigarette liquid offered by the corporation.<sup>8</sup> In response to the upward spike in adolescent e-cigarette usage, former FDA Commissioner Scott Gottlieb issued a statement in 2018 discussing the proposed policy framework he sought to advance to restrain youth appeal of e-cigarettes.<sup>9</sup> Gottlieb's proposed regulations would establish that all flavored e-cigarette products (*i.e.*, e-liquids and cartridge-based systems) must be sold in age-restricted, in-person locations to prevent underaged youth from accessing e-cigarette products online.<sup>10</sup>

The ultimate objective of this article is to holistically assess the e-cigarette and its impact on society's youth and evaluate the probable implications generated by the FDA's proposed e-cigarette regulations. In Part I, I will explore tobacco's vast history within the United States by examining (1) the FDA's legislative history, (2) the statute that purportedly authorized the agency to assert jurisdiction over tobacco products, and (3) modern case law that limits the FDA's authoritative power to regulate tobacco products. In Part II, I will (1) examine the factors that have contributed to the swift increase in adolescent e-cigarette usage as well as the safety data that coincides with such usage, (2) analyze the FDA's most recent e-cigarette regulations, and (3) ascertain whether those restrictions are sufficient to curb youth appeal.

## **PART 1: HISTORICAL OVERVIEW OF THE FDA'S REGULATION OF TOBACCO**

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<sup>7</sup> Julia Belluz, *FDA: we might have to ban some e-cigarettes to stop teens from vaping*, VOX, <https://www.vox.com/2018/9/12/17850598/fda-juul-vaping> (last updated Sept. 21, 2018).

<sup>8</sup> *Id.*

<sup>9</sup> *Statement from FDA Commissioner Scott Gottlieb, M.D., on new steps to address epidemic of youth e-cigarette use*, 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>.

<sup>10</sup> *Id.*

Although cigarettes and tobacco products alike may be revered by some, the health consequences engendered by tobacco usage have turned the lives of many Americans upside down. The injurious nature of tobacco cannot be overstated. Cigarettes are responsible for more than 480,000 deaths per year in the United States and more than sixteen million Americans currently live with a disease caused by smoking.<sup>11</sup> As each day passes, more than 3,200 youth younger than eighteen years of age smoke their first cigarette.<sup>12</sup> Approximately 500,000 annual—albeit preventable—deaths is a mystifying number. Surely the government was cognizant of the multitude of health hazards associated with cigarette usage when Camel released an advertisement in 1937 contending that its cigarettes assisted digestion by increasing the movement of alkaline digestive fluids.<sup>13</sup> Maybe it was aware, but then again, it is entirely plausible that the government was genuinely ignorant of tobacco’s wounding nature. Even so, in order for the FDA to create change and alter the cultural hegemony that, at the time, had completely inundated society with unproven proclamations and deceitful advertisements concerning cigarette side effects, the FDA needed unequivocal authoritative power.

In 1938, Congress passed the FDCA.<sup>14</sup> The FDCA provided the FDA with the power to regulate food, drugs, medical devices, and cosmetics.<sup>15</sup> Specifically, the FDCA prohibits the “. . . introduction or delivery for introduction into interstate commerce of any food, drug, device or cosmetic that is adulterated or misbranded.”<sup>16</sup> The FDCA provided the FDA with an immense

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<sup>11</sup> *Smoking & Tobacco Use*, CTR.S’ FOR DISEASE CONTROL & PREVENTION, [https://www.cdc.gov/tobacco/data\\_statistics/fact\\_sheets/index.htm?s\\_cid=osh-stu-home-spotlight-001](https://www.cdc.gov/tobacco/data_statistics/fact_sheets/index.htm?s_cid=osh-stu-home-spotlight-001) (last visited Nov. 17, 2019).

<sup>12</sup> *Id.*

<sup>13</sup> *Cigarette Advertising Themes*, STAN. UNIV. RES. INTO IMPACT TOBACCO ADVERT., [http://tobacco.stanford.edu/tobacco\\_main/main.php](http://tobacco.stanford.edu/tobacco_main/main.php) (last visited Apr. 17, 2019).

<sup>14</sup> *How did the Federal Food, Drug, and Cosmetic Act come about?*, FOOD & DRUG ADMIN., <https://www.fda.gov/about-fda/fda-basics/how-did-federal-food-drug-and-cosmetic-act-come-about> (last visited Nov. 28, 2019).

<sup>15</sup> 21 U.S.C. § 301(a) (1994 & Supp. II 1997).

<sup>16</sup> *Id.*

amount of power to enforce the FDCA’s statutory provisions.<sup>17</sup> For example, the district courts of the United States and the United States courts of the Territories have jurisdiction to issue injunctions if provisions within the FDCA are violated.<sup>18</sup> Moreover, any person who violates any of the provisions enumerated in § 301 will be imprisoned for no more than a year or fined no more than \$1,000—or both.<sup>19</sup> Lastly, the FDA may seize any article of food, drug, or cosmetic that is adulterated or misbranded when such article is introduced, or discovered, in interstate commerce.<sup>20</sup> These seized articles are proceeded against on libel of information and condemned in any district court of the United States or United States court of a Territory within the jurisdiction where the article is found.<sup>21</sup> This type of plenary power was not at the FDA’s disposal under the FDCA’s predecessor, the Food and Drug Act of 1906 (the “1906 Act”).<sup>22</sup> The 1906 Act merely provided each district attorney with power to commence legal proceedings to enforce the penalties of the Act against parties who violated its provisions.<sup>23</sup> Even so, the district attorney could only initiate legal proceedings provided that satisfactory evidence of any violation of the Act was presented to him or her by a health, food, or drug officer; or agent of any State, Territory, or the District of Columbia.<sup>24</sup> Even though the enactment of the FDCA mitigated the administrative shortcomings of its predecessor and bestowed more authoritative power onto the FDA, the FDCA still possessed its own deficiencies. Under the FDCA, the FDA did not have the authority to explicitly regulate

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<sup>17</sup> *See id.*

<sup>18</sup> *See id.* at §§ 302(a)-(b).

<sup>19</sup> *Id.* at § 303(a)(1).

<sup>20</sup> *Id.* at § 304(3)(A)(b).

<sup>21</sup> *Id.* at § 304(a)(1).

<sup>22</sup> Pure Food and Drug Act of 1906, Pub. L. No. 59-384, 34 Stat. 768 (codified as amended at 21 U.S.C. §§ 1-15 (1934)).

<sup>23</sup> *See id.*

<sup>24</sup> *Id.* at § 5, 34 Stat. 769.

tobacco and tobacco-related products.<sup>25</sup> This deprivation of managerial control would become accentuated in the coming years as tobacco usage—and tobacco harm—drastically increased.

In light of the fact that many adolescents are introduced to cigarettes before their eighteenth birthday, the FDA decided to intervene and do something that the agency had not done before.<sup>26</sup> In August 1996, the FDA asserted jurisdiction—known as the FDA Rule of 1996—over cigarettes and smokeless tobacco under the Federal Food, Drug, and Cosmetic Act.<sup>27</sup> The FDA proclaimed that it was permitted to assert jurisdiction over tobacco under the drug and device provisions of the FDCA for the following reason:

“FDA has concluded that cigarettes and smokeless tobacco are combination products consisting of nicotine, a drug that causes addiction and other significant pharmacological effects on the human body, and device components that deliver nicotine to the body . . . . This evidence includes the emergence of a scientific consensus that cigarettes and smokeless tobacco cause addiction to nicotine and the disclosure of thousands of pages of internal tobacco company documents detailing that these products are intended by the manufacturers to affect the structure and function of the human body.”<sup>28</sup>

Pursuant to the FDCA, a product is a drug if it is an article (other than food) “intended to affect the structure or any function of the body of man . . . .”<sup>29</sup> Consequently, it was this provision that catalyzed the FDA’s decision to devise a two-part conclusion explaining why it was permitted to assert jurisdiction over tobacco.

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<sup>25</sup> Pursuant to the Federal Food, Drug, and Cosmetic Act, the FDA possessed the regulatory power to solely forbid the introduction of *adulterated* tobacco products into interstate commerce; *See also* 21 U.S.C. § 301(a).

<sup>26</sup> *Youth and Tobacco*, CTR.S’ FOR DISEASE CONTROL & PREVENTION, [https://www.cdc.gov/tobacco/data\\_statistics/fact\\_sheets/youth\\_data/tobacco\\_use/index.htm](https://www.cdc.gov/tobacco/data_statistics/fact_sheets/youth_data/tobacco_use/index.htm) (last visited Nov. 17, 2019).

<sup>27</sup> *See Nicotine Is a Drug Under the Federal Food, Drug, and Cosmetic Act: Jurisdictional Determination*, 61 Fed. Reg. 44619, 45208 (Aug. 28, 1996).

<sup>28</sup> *Id.* at 44629.

<sup>29</sup> Federal Food, Drug, and Cosmetic Act § 201(g)(1)(C).

First, the FDA asserted that nicotine in cigarettes and smokeless tobacco does “affect the structure or any function of the body.”<sup>30</sup> The FDA’s contention was primarily based on nicotine’s pharmacological effect on the structure and function of the user’s body.<sup>31</sup> Nicotine creates an addiction that induces repeated cigarette use merely to acquire more nicotine.<sup>32</sup> Along with dependency and addiction, nicotine also impairs the user’s nervous system and accelerates loss of body weight.<sup>33</sup> Because nicotine was analogous to drugs that the FDA had traditionally regulated—“including stimulants, tranquilizers, [and] appetite suppressants . . .”—the FDA argued that cigarettes and smokeless tobacco affected the “structure or any function of the body” within the meaning of the FDCA.<sup>34</sup>

Second, the FDA asserted that the pharmacological effects generated by nicotine metabolization were “intended” by the tobacco manufacturers.<sup>35</sup> “Intended use” refers to the objective intent of persons legally responsible for the labeling of drugs.<sup>36</sup> Intent may be determined by such persons’ expressions or may be shown by the circumstances surrounding distribution of the article.<sup>37</sup> Objective intent may be demonstrated by (1) labeling claims, (2) advertising matter, or (3) oral or written statements.<sup>38</sup> The FDA posited that a substantial amount of evidence indicated that manufacturers intended for tobacco to affect the structure and function of the body: (1) the evidence of the foreseeable pharmacological effects and uses of cigarettes and smokeless tobacco; (2) the evidence of the actual consumer use of cigarettes and smokeless tobacco for

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<sup>30</sup> Nicotine Is a Drug Under the Federal Food, Drug, and Cosmetic Act: Jurisdictional Determination, 61 Fed. Reg. at 44629.

<sup>31</sup> *Id.*

<sup>32</sup> Nicotine Is a Drug Under the Federal Food, Drug, and Cosmetic Act: Jurisdictional Determination, 61 Fed. Reg. at 44649.

<sup>33</sup> *Id.* at 44632.

<sup>34</sup> *Id.*

<sup>35</sup> *Id.* at 44686.

<sup>36</sup> See 21 C.F.R. § 201.128 (2019).

<sup>37</sup> *Id.*

<sup>38</sup> *Id.*

pharmacological purposes; and (3) the evidence of the statements, research, and actions of the manufacturers themselves.<sup>39</sup> Accordingly, because a robust, scientific consensus established that cigarettes and smokeless tobacco caused nicotine addiction and many tobacco manufacturers referred to nicotine as both “pharmacological agent[s]” and “extremely biologically active compound[s],” the FDA contended that cigarettes were “intended” by tobacco manufacturers to affect the structure and function of the body within the meaning of the FDCA.<sup>40</sup>

The FDA’s assertion of jurisdiction over cigarettes and smokeless tobacco products was not premised on effectively banning nicotine.<sup>41</sup> On the contrary, the FDA’s assertion of regulatory control was predicated on the fact that “tobacco use [had] become . . . one of the most serious public health problems facing the United States . . . .”<sup>42</sup> Even though many states prohibited minors from purchasing tobacco, minors still possessed unfettered access to tobacco products via vending machines and over-the-counter sales.<sup>43</sup> Based on these findings, the FDA promulgated a series of regulations cemented on two fundamental objectives: (1) restricting access and (2) redefining advertisements.<sup>44</sup> The FDA sought to nullify the role marketing played in engraining the desire to smoke in the adolescent mind by restricting cigarette advertisements to a black and white, text-only format.<sup>45</sup> But if the advertisement appeared in a publication that was read almost exclusively by adults, the restriction was inapplicable.<sup>46</sup> Marketing regulations also prohibited outdoor advertising within 1,000 feet of any public playground or school<sup>47</sup>; prohibited the distribution of

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<sup>39</sup> Nicotine Is a Drug Under the Federal Food, Drug, and Cosmetic Act: Jurisdictional Determination, 61 Fed. Reg. at 44687.

<sup>40</sup> *Id.*

<sup>41</sup> *Id.*

<sup>42</sup> *Id.* at 45428.

<sup>43</sup> *Id.* at 45244.

<sup>44</sup> *Id.* at 45243.

<sup>45</sup> See 21 C.F.R. § 897.32(a) (1996).

<sup>46</sup> *Id.*

<sup>47</sup> See 21 C.F.R. § 897.30(b) (1996).



any promotional items, such as T-shirts or hats bearing the tobacco manufacturer's brand name<sup>48</sup>; and prohibited tobacco manufacturers from sponsoring any athletic, musical, artistic, or cultural event using its brand name.<sup>49</sup> Access regulations prohibited the distribution of cigarettes via vending machines; banned free samples; prohibited the sale of cigarettes to people under the age of eighteen; and required retailers to check photo identification before making a sale.<sup>50</sup> The FDA presumably concluded that if the number of adolescents who begin tobacco use could be substantially diminished, then the prevalence of tobacco-related illness could be correspondingly reduced because scientific data suggested that anyone who did not begin smoking during their adolescent years was unlikely to ever begin.<sup>51</sup> The FDA hoped that its assertion of jurisdiction and preliminary regulations would withstand a constitutional challenge. The livelihood of the FDA Rule of 1996 was contingent upon the United States Supreme Court's interpretation of the FDCA in *FDA v. Brown & Williamson*.

### *Modern Case Law Limiting the FDA's Regulatory Authority*

In *FDA v. Brown & Williamson*, the Supreme Court of the United States was tasked with determining whether the FDA was permitted to regulate tobacco products according to the express language of the FDCA.<sup>52</sup> The Court of Appeals for the Fourth Circuit held that Congress had not granted the FDA jurisdiction to regulate tobacco products.<sup>53</sup> According to the Fourth Circuit, it

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<sup>48</sup> See 21 C.F.R. § 897.34(a) (1996).

<sup>49</sup> See *id.* at § 897.34(c).

<sup>50</sup> See 21 C.F.R. § 897.14 (1996).

<sup>51</sup> Nicotine Is a Drug Under the Federal Food, Drug, and Cosmetic Act: Jurisdictional Determination, 61 Fed. Reg. at 45238.

<sup>52</sup> Food & Drug Admin. v. Brown & Williamson Tobacco Co., 120 S. Ct. 1291, 1297 (2000).

<sup>53</sup> *Id.*

was impermissible for the FDA to assert jurisdiction over tobacco products because a number of provisions within the FDCA require the FDA to ascertain whether any regulated product is “safe” before it can be sold or allowed to remain on the market.<sup>54</sup> Because the FDA had previously declared that tobacco products were “dangerous” and “unsafe,” the Fourth Circuit concluded that tobacco products could not be made safe and effective for their intended uses.<sup>55</sup> Therefore, if tobacco products fell within the scope of the FDA’s jurisdiction, the FDA would be forced to remove tobacco products from the market immediately—a result that would be contrary to congressional intent.<sup>56</sup> Consequently, the Fourth Circuit reasoned that tobacco regulation was forbidden under the FDCA’s present statutory framework.<sup>57</sup> Surprisingly, before the FDA Rule of 1996, the FDA had repeatedly disclosed that tobacco products fell outside the agency’s regulatory domain.<sup>58</sup>

The Supreme Court affirmed the Fourth Circuit’s ruling and held that Congress had not given the FDA authority to assert jurisdiction over tobacco products.<sup>59</sup> The Supreme Court based its holding on two concrete principles: (1) the FDCA’s core objective was to ensure that any product regulated by the FDA is “safe” and “effective” for its intended use<sup>60</sup> and (2) Congress enacted tobacco-specific legislation against the backdrop of the FDA’s repeated statements that it lacked authority under the FDCA to regulate tobacco absent claims of therapeutic benefit by the manufacturer.<sup>61</sup> Under the FDCA, the FDA shall prevent marketing of any drug or device where the “potential for inflicting death or physical injury is not offset by the possibility of therapeutic

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<sup>54</sup> *Id.*

<sup>55</sup> *Id.*

<sup>56</sup> *Id.*; *See also* 7 U.S.C. § 1311(a) (2018) (repealed 2004).

<sup>57</sup> *Williamson & Brown Tobacco Co.*, 120 S. Ct. at 1299.

<sup>58</sup> *Id.*

<sup>59</sup> *Id.* at 1315.

<sup>60</sup> *Id.* at 1301.

<sup>61</sup> *Id.* at 1306.

benefit.”<sup>62</sup> Additionally, for all devices regulated by the FDA, there must at least be a “reasonable assurance of the safety and effectiveness of the device.”<sup>63</sup> In its 1996 Rule, the FDA described the adverse ramifications of tobacco usage in considerable detail, highlighting that “more than 400,000 people die each year from tobacco-related illnesses such as cancer, respiratory illnesses, and heart disease, often suffering long and painful deaths . . . .”<sup>64</sup> Because the FDA had continually acknowledged that “tobacco products are unsafe,” “dangerous,” and “cause great pain and suffering from illness,” it was statutorily impossible for the FDA to assert jurisdiction over tobacco products.<sup>65</sup> Once the FDA concludes that a drug or device cannot be used safely for any therapeutic purpose, the FDA is barred from regulating such drug or device.<sup>66</sup>

The FDCA expressly emphasizes that any product regulated by the FDA must be safe for its intended use.<sup>67</sup> Although the FDA had determined that tobacco products are effective in transmitting specific pharmacological effects to its users, those products deliver such effects in an unsafe and dangerous manner.<sup>68</sup> The Supreme Court decided that if tobacco products were within the FDA’s reach pursuant to the FDCA, then the FDCA would require the FDA to eradicate tobacco products entirely.<sup>69</sup> But an indefinite ban on tobacco would contravene the tobacco-specific regulatory scheme set in place by Congress to address tobacco and health.<sup>70</sup> Thus, in the words of the Court, “[i]f [tobacco products] cannot be used safely for any therapeutic purpose, and

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<sup>62</sup> *Id.* at 1301.

<sup>63</sup> 21 U.S.C. § 393(b)(2)(C) (2018).

<sup>64</sup> *Brown & Williamson Tobacco Corp.*, 120 S. Ct. at 1302.

<sup>65</sup> *Id.*

<sup>66</sup> *See id.* at 1306.

<sup>67</sup> *Id.*

<sup>68</sup> *Id.*

<sup>69</sup> *Id.*

<sup>70</sup> *Id.*

yet [tobacco products] cannot be banned, [tobacco products] simply do not fit” within the confines of the FDA’s regulatory power pursuant to the Federal Food, Drug and Cosmetic Act.<sup>71</sup>

After determining that the FDCA barred the FDA from exercising jurisdiction over tobacco products, the Court confirmed its holding by evaluating the tobacco-specific legislation that Congress had enacted.<sup>72</sup> In response to the FDA’s proclamation that it lacked regulatory power, Congress sought to implement its own regulatory scheme for tobacco products by enacting the Alcohol and Drug Abuse Amendments in 1983, the Comprehensive Smoking Act in 1994, and the Comprehensive Smokeless Tobacco Health Education Act of 1986.<sup>73</sup> Many of these laws precluded any administrative agency from playing a significant role in constructing tobacco policy.<sup>74</sup> For example, the Alcohol and Drug Abuse Amendments required the Secretary of Health and Human Services to report directly to Congress every three years on the “addictive property of tobacco” and to include recommendations for action that the Secretary may deem appropriate.<sup>75</sup> The Supreme Court reasoned that Congress’s collective legislative action proscribed any interpretation of the FDCA that would empower the FDA to regulate tobacco products.<sup>76</sup> Congress had developed a distinct regulatory scheme for the tobacco industry premised on the FDA’s inability to regulate tobacco products.<sup>77</sup> Thus, Congress “effectively ratified the FDA’s previous position that it lack[ed] jurisdiction to regulate tobacco”—rendering the FDA’s 1996 Rule invalid.<sup>78</sup>

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<sup>71</sup> *Id.*

<sup>72</sup> *Id.*

<sup>73</sup> *Id.* at 1311.

<sup>74</sup> *Id.* at 1313.

<sup>75</sup> *Id.* at 1311–12.

<sup>76</sup> *Id.*

<sup>77</sup> *Id.*

<sup>78</sup> *Id.* at 1313.

*The Family Smoking Prevention and Tobacco Control Act and the FDA's "Deeming" Authority*

The Supreme Court's decision in *Brown v. Williamson* invalidated the FDA's 1996 Rule.<sup>79</sup> Accordingly, even in light of congressional action, cigarette smoking continued to generate serious illness resulting in approximately 440,000 annual deaths and \$157 billion health-related economic costs.<sup>80</sup> Nearly a decade after the *Brown* decision, President Barack Obama ratified the Family Smoking Prevention and Tobacco Control Act ("FSPTCA"), which gave the FDA sweeping authority to regulate the manufacturing, marketing, and sale of tobacco products.<sup>81</sup> The FSPTCA's predecessor, the FDCA, was premised on a public standard of "safety and efficacy."<sup>82</sup> Importantly, the FSPTCA departed from the FDCA's traditional standard as the more recent statute enables the Secretary of Health and Human Services to regulate tobacco products in a manner that is "appropriate for the protection of the public health."<sup>83</sup>

The FSPTCA likely embodies a more hands-on, proactive standard because at the time the law was enacted, Congress was thoroughly aware of tobacco's effect on the health of not only society's adults—but its youth as well.<sup>84</sup> Many adolescents are attracted to fruit assorted flavoring; therefore, the FSPTCA prohibits cigarettes from containing an artificial or natural flavor (other than tobacco or menthol), or an herb or spice, including "strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee" that acts as characterizing flavor of

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<sup>79</sup> *Id.*

<sup>80</sup> C. Husten et al., *Cigarette Smoking Among Adults – United States, 2002*, MORBIDITY & MORTALITY WKLY. REP. (May 28, 2004), <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5320a2.htm>.

<sup>81</sup> Family Smoking Prevention and Tobacco Control Act § 910(a)-(c).

<sup>82</sup> Federal Food, Drug, and Cosmetic Act § 306(g)(1)(A)(I).

<sup>83</sup> Family Smoking Prevention and Tobacco Control Act § 907(a)(3)(A).

<sup>84</sup> *Id.* at § 2(14).

the tobacco product or tobacco smoke.<sup>85</sup> Furthermore, in an effort to combat public ignorance of tobacco and health, the FSPTCA discloses that it is illegal for cigarette packages to be sold, distributed, or imported for sale within the United States unless the package bears one of the labels enumerated within the statute.<sup>86</sup> For example, one label reads, “WARNING: Smoking can kill you.”<sup>87</sup> Although the FSPTCA authorized the FDA to promulgate certain marketing restrictions and to increase the visibility of tobacco warning labels, the FDA’s true power under the FSPTCA stems from its “deeming” authority.

The statutory provision that effectuates the FDA’s “deeming” authority states as follows: “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.*”<sup>88</sup> Under the FSPTCA, a “tobacco product” is “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).”<sup>89</sup> In 2016, acting under the “deeming” provision of the FSPTCA, the FDA issued a final rule that extended the Agency’s “tobacco product” authority to all other categories of products that meet the FSPTCA’s definition of “tobacco.”<sup>90</sup> According to the FDA, the terms “component” and “part” embedded in the FSPTCA’s “tobacco product” definition refer to “any software or assembly of materials intended or reasonably expected to (1) alter or affect the tobacco product’s performance, composition, constituents or characteristics; or

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<sup>85</sup> *Id.* at § 907(a)(1)(A).

<sup>86</sup> *Id.* at § 201(a)(1).

<sup>87</sup> *Id.*

<sup>88</sup> *Id.* at § 901(b) (emphasis added).

<sup>89</sup> *Id.* at § 101(rr)(1).

<sup>90</sup> See Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act, 81 Fed. Reg. 28974, 28975 (2016).

(2) to be used with or for the human consumption of a tobacco product.”<sup>91</sup> These terms acted as regulatory hooks for the FDA, thereby expanding the FDA’s authoritative reach to components and parts used with electronic nicotine delivery systems (“ENDS”).<sup>92</sup> Examples of ENDS components and parts that fall within the scope of the FDA’s regulatory command are e-cigarettes, E-liquids, atomizers, batteries and cartomizers.<sup>93</sup> The FDA’s “deeming” authority begs the question: if the FDA has definite, unambiguous authority to ultimately subject any tobacco product to the provisions enumerated within the FSPTCA, why is adolescent e-cigarette usage at an all-time high?

## **PART II: A SPIKE IN ADOLESCENT E-CIGARETTE USAGE: A CAUSE FOR CONCERN**

Since 2011, e-cigarette usage has increased at an exponential rate; in 2014, e-cigarettes became the most commonly used tobacco among *middle school* and high school students.<sup>94</sup> Specifically, in 2014, 16% of 10<sup>th</sup> graders reported use of e-cigarettes in the past 30 days and 43% of those students reported that he or she had never smoked a combustible cigarette.<sup>95</sup> This statistic is unsettling because it undoubtedly exemplifies the rationale that encourages a vast majority of society’s youth to partake in e-cigarette usage: many adolescents—even those who have yet to smoke a Marlboro or Kool—adamantly believe that by smoking e-cigarettes, they are covertly evading the damaging side-effects linked to combustible cigarettes. Youth are impressionable; the

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<sup>91</sup> *Id.*

<sup>92</sup> *Id.*

<sup>93</sup> *Id.*

<sup>94</sup> Tushar Singh et al., *Vital Signs: Exposure to Electronic Cigarette Advertising Among Middle School and High School Students – United States, 2014*, 64 MORBIDITY & MORTALITY WKLY. REP. 1403, 1403–08 (2016).

<sup>95</sup> Adam M. Leventhal et al., *Association of Electronic Cigarette Use with Initiation of Combustible Tobacco Product Smoking in Early Adolescence*, 314 [J]AMA 700, 700–07 (2015).

way in which an e-cigarette delivers nicotine to its user naturally induces curiosity in second-hand viewers. In a 2015 survey, e-cigarette consumers were asked to disclose the most important reason for utilizing the device.<sup>96</sup> Tellingly, the response garnering the most submissions was “to experiment—to see what [e-cigarettes are] like.”<sup>97</sup> Despite the fact that the decision to “experiment” with a device possessing such convoluted intricacies may indeed be a naive and uninformed one, should society’s youth themselves solely bear the blame for this uptick in e-cigarette usage or should the blame be allocated to the FDA for failing to have the foresight necessary to prevent this phenomenon from occurring? The short answer: blame both.

**A. *What is an e-cigarette and how is it mechanized?***

Electronic cigarettes are primarily battery-powered devices capable of delivering nicotine to its user in an aerosol form.<sup>98</sup> When a user activates an e-cigarette, a metal coil is heated which in turn vaporizes a solution (*i.e.*, e-liquid) mainly consisting of propylene glycol, vegetable glycerin, distilled water, and flavorings that frequently contain nicotine.<sup>99</sup> This mechanism of action is colloquially referred to as “vaping” and nicotine, which is dissolved inside the e-liquid, is released in the aerosolized vapor produced by the heated coil inside the e-cigarette.<sup>100</sup>

A combustible cigarette is mechanized in a drastically different fashion.<sup>101</sup> Combustible cigarettes are activated by a process commonly known as “combustion.”<sup>102</sup> Combustion requires

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<sup>96</sup> LLOYD D. JOHNSTON ET AL., MONITORING THE FUTURE. NATIONAL SURVEY RESULTS ON DRUG USE 1975–2017. 2017 OVERVIEW: KEY FINDINGS ON ADOLESCENT DRUG USE, <https://files.eric.ed.gov/fulltext/ED589762.pdf> (last visited Apr. 19, 2019).

<sup>97</sup> *Id.*

<sup>98</sup> Tushar Singh et al., *supra* note 94.

<sup>99</sup> Riccardo Polosa et al., *Health Impact of E-cigarettes: A Prospective 3.5-year Study of Regular Daily Users who have Never Smoked*, SCI. REPS., Nov. 17, 2017, at 1.

<sup>100</sup> Curtis C. Harris, *Tobacco Smoking, E-cigarettes, and Nicotine Harm*, 115 PROC. NAT’L. ACAD. SCI. U.S. 1406, 1406–07 (2018).

<sup>101</sup> *Glossary: Combustion*, PHILLIP MORRIS INT’L, <https://www.pmi.com/glossary-section/glossary/combustion> (last visited Apr. 17, 2019).

<sup>102</sup> *Id.*



the user of the cigarette to ignite the end of the cigarette with fire.<sup>103</sup> Once the cigarette is ignited, the combination of tobacco, fire, and oxygen induces a self-sustaining combustion process that continuously engulfs the tobacco.<sup>104</sup> Principally, it is this combustion process that has prompted the substantial increase in adolescent e-cigarette usage over the years.<sup>105</sup> From the layman's perspective, combustible cigarettes create smoke and that smoke contains volatile components that induce fatal and debilitating health disorders.<sup>106</sup> Because e-cigarette aerosols neither involve combustion nor tobacco smoke, adolescents have concluded that e-cigarettes are safer than combustible cigarettes.<sup>107</sup> Notably, boundless empirical data exist substantiating the adolescent presumptive deduction: combustible cigarettes accounted for over 48% of all cancer-related deaths between 2005-2009 and cause more than 7 million deaths per year.<sup>108</sup> Still, do the previous statistics definitively suggest that inhalation of aerosols emitted from e-cigarette devices are safer than the smoke emitted by a combustible cigarette?

**B. *Are e-cigarettes safer than combustible cigarettes?***

Many e-cigarettes and all combustible cigarettes deliver nicotine to their respective users. Nicotine, a highly addictive chemical, has not been deemed carcinogenic in humans.<sup>109</sup> Scientific studies suggest that combustible cigarette byproducts generate most of cigarette smoke's harmful

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<sup>103</sup> *Id.*

<sup>104</sup> *Id.*

<sup>105</sup> Karen A. Cullen et al., *supra* note 6.

<sup>106</sup> Stephen I. Rennard, *Cigarette Smoke in Research*, 31 AM. J. RESPIRATORY CELL & MOLECULAR BIOLOGY 479, 479–80 (2004).

<sup>107</sup> Paul Truman Harrell et al., *Electronic Nicotine Delivery Systems (“E-Cigarettes”): Review of Safety and Smoking Cessation Efficacy*, 151 OTOLARYNGOLOGY HEAD NECK SURGERY 381, 381–93 (2014).

<sup>108</sup> *Id.*

<sup>109</sup> *Id.*

health effects—primarily cancer.<sup>110</sup> Therefore, the belief that the e-cigarette is a safer alternative must be assessed. It must be determined whether such belief is compelling or wholly conjectural.

**i. Combustible Cigarettes and Cancer**

Outside of nicotine, combustible cigarettes—via the smoke emitted—generate approximately 7,000 toxic compounds and more than 70 identified carcinogens.<sup>111</sup> At the moment the cigarette is ignited, the compounds present in the cigarette smoke undergo complex chemical reactions; the duration and extent of these chemical reactions is dependent upon the number of puffs taken by a user and puff duration.<sup>112</sup> Both factors induce extreme variability in the number of toxins produced over the life of a single cigarette.<sup>113</sup> The process that activates carcinogens in cigarette smoke is referred to as tobacco carcinogenesis.<sup>114</sup> Despite the fact that cancer’s biological pathway remains an unfortunate mystery, tobacco carcinogenesis can be explained by examining rudimentary scientific principles. For cigarette smokers who develop cancer, cancer inception begins with nicotine as the substance’s addictive properties provoke an overindulgence in combustible cigarette usage.<sup>115</sup> In turn, this progressively heightened usage of combustible cigarettes inundates the user’s body with an unfathomable number of carcinogens.<sup>116</sup> As the carcinogens are metabolically activated, DNA adducts, which consists of carcinogen metabolites covalently

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<sup>110</sup> See Robert West, *Tobacco Smoking: Health Impact, Prevalence, Correlates and Interventions*, 32 PSYCH. & HEALTH 1018, 1020 (2017).

<sup>111</sup> Curtis C. Harris, *supra* note 100.

<sup>112</sup> Stephen I. Rennard, *supra* note 106.

<sup>113</sup> *Id.*

<sup>114</sup> See Stephen S. Hecht, *Tobacco Smoke Carcinogens and Lung Cancer*, 91 J. NAT’L CANCER INST., 1194, 1194–1210 (1999).

<sup>115</sup> *Id.* at 1194.

<sup>116</sup> *Id.*

bonded to DNA, form.<sup>117</sup> At this stage, DNA bound to carcinogens either (1) normalizes itself through enzymatic repair mechanisms (*i.e.*, covalent bond between carcinogen and DNA is destroyed) or (2) the DNA adduct persists and carcinogenesis commences.<sup>118</sup> This persistence may prompt genetic miscoding, which may ultimately result in a permanent mutation of DNA.<sup>119</sup> Chronic tobacco smokers unconsciously trigger this process an innumerable amount of times over the course of their lives and the potential for permanent, genetic mutations acutely increases as a result.<sup>120</sup>

## ii. *Combustible Cigarettes and Cardiovascular Disease*

It is well-documented that combustible cigarette use is responsible for a variety of disorders including cardiovascular disease, which is the single largest cause of death in the United States, killing more than 800,000 people a year.<sup>121</sup> Tobacco smoke is an independent risk factor of cardiovascular atherosclerosis.<sup>122</sup> Atherosclerosis, the process by which the arteries narrow and become less flexible,<sup>123</sup> has been conclusively linked to tobacco smoking.<sup>124</sup> But the underlying causal nexus between tobacco smoke and atherosclerosis has not yet been discovered.<sup>125</sup> On the surface, inhalation of tobacco smoke—even secondhand smoke—has the potential to directly

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<sup>117</sup> *Id.*

<sup>118</sup> *Id.* at 1195.

<sup>119</sup> *Id.*

<sup>120</sup> *Id.*

<sup>121</sup> CTR.S' FOR DISEASE CONTROL & PREVENTION, SMOKING AND CARDIOVASCULAR DISEASE, [https://www.cdc.gov/tobacco/data\\_statistics/sgr/50th-anniversary/pdfs/fs\\_smoking\\_CVD\\_508.pdf](https://www.cdc.gov/tobacco/data_statistics/sgr/50th-anniversary/pdfs/fs_smoking_CVD_508.pdf) (last visited Apr. 19, 2019).

<sup>122</sup> Guangwei Zhang et al., *Safety Assessment of Electronic Cigarettes and their Relationship with Cardiovascular Disease*, INT'L J. ENVIRONMENTAL RES. & PUB. HEALTH, Jan. 5, 2018, at 8.

<sup>123</sup> CTR.S' FOR DISEASE CONTROL & PREVENTION, *supra* note 121.

<sup>124</sup> See Salman Salahuddin et al., *Pathophysiological Mechanisms of Tobacco-Related CVD*, 7 GLOB. HEART 113, 113–20 (2012).

<sup>125</sup> *Id.*

damage artery walls and severely impair endothelial function, thereby inhibiting vasodilation of normal coronary arteries and reducing coronary flow reserve.<sup>126</sup> Moreover, combustible cigarettes have been associated with evidence of chronic inflammation<sup>127</sup> of the arteries and this inflammatory response is a symptom of atherosclerosis.<sup>128</sup> A number of studies have demonstrated that smoking causes a 20-25% increase in the peripheral blood leukocyte count and an increased level of inflammatory markers.<sup>129</sup> Cigarette smoking leads to elevations of various proinflammatory cytokines and an increase in leukocyte-endothelial cell interaction which leads to leukocyte recruitment—an event triggered early on in the development of atherosclerosis. Tellingly, a study has documented that these inflammatory markers return to their baseline levels five years after smoking cessation; this not only indicates that cigarette-induced cardiovascular disease may be reversible, it also reveals that tobacco smoke is the primary trigger of inflammation in the blood and at the vessel wall.<sup>130</sup>

### iii. *E-Cigarette Safety and the Renormalization of Smoking*

According to an independent evidence review published by Public Health England (“PHE”) in 2015, best estimates specify that “e-cigarettes are 95% less harmful to [one’s] health than [combustible] cigarettes, and when supported by a smoking cessation service, [e-cigarettes] help most smokers . . . quit tobacco altogether.”<sup>131</sup> Admittedly, the preceding data seems earnestly

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<sup>126</sup> *Id.*

<sup>127</sup> *Id.*

<sup>128</sup> See John A. Ambrose & Rajat S. Barua, *The Pathophysiology of Cigarette Smoking and Cardiovascular Disease: an Update*, 43 J. AM. C. CARDIOLOGY 1731, 1731–37 (2004).

<sup>129</sup> *Id.*

<sup>130</sup> Salman Salahuddin et al., *supra* note 124, at 116.

<sup>131</sup> McNeill A et al., *E-cigarettes: An Evidence Update. A Report Commissioned by Public Health England*, PUB. HEALTH ENG., Aug. 2015, at 5.

sensible; e-cigarettes deliver nicotine to its user in a manner that appears to circumvent the unstable combustion process that is responsible for subjecting conventional cigarette users to a plethora of ailments.<sup>132</sup> Although PHE’s data seems to be commonsensical, the organization failed to proffer any legitimate scientific data substantiating its position and instead, the organization relied solely upon a single meeting of 12 people convened to develop a multicriteria decision analysis (MDCA) model to synthesize their opinions on the harms associated with different nicotine products.<sup>133</sup>

Even though PHE’s evidence review was premised on inadequate methodological practices, PHE explicitly contended that “there is no evidence to date that [e-cigarettes] are [renormalizing] smoking . . . .”<sup>134</sup> This assertion is utterly false on its face as it has been documented that e-cigarettes became the most commonly used form of tobacco by middle school and high school students in 2014.<sup>135</sup> Though PHE argued that the e-cigarette cannot be characterized as a gateway to combustible cigarettes, one American study arrived at a different conclusion suggesting that “[high school students] who used electronic cigarettes at baseline compared with non-user [high school students] were more likely to report initiation of combustible tobacco use over the next year.”<sup>136</sup> Although safety data suggest that e-cigarettes contain lower levels of toxic substances than combustible cigarettes,<sup>137</sup> the e-cigarette’s impact on society’s health is generally unknown.<sup>138</sup> Accordingly, speculative claims—like the proclamations made by PHE—run the risk of renormalizing smoking.<sup>139</sup> “Renormalization” of smoking has the potential to render the potential

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<sup>132</sup> Riccardo Polosa et al., *supra* note 99.

<sup>133</sup> Martin McKee & Simon Capewell, *Evidence About Electronic Cigarettes: A Foundation Built on Rock or Sand?*, *BMJ*, Sept. 15, 2015, at 2.

<sup>134</sup> McNeill A et al., *supra* note 131, at 7.

<sup>135</sup> Karen A. Cullen et al., *supra* note 6.

<sup>136</sup> Adam M. Leventhal et al., *supra* note 95, at 707.

<sup>137</sup> Riccardo Polosa et al., *supra* note 99.

<sup>138</sup> M. Bradley Drummond & Dona Upson, *Electronic Cigarettes: Potential Benefits and Harms*, 11 *ANNALS AM. THORACIC SOC’Y* 236, 237 (2014).

<sup>139</sup> *Id.* at 240.

benefits that stem from e-cigarette usage irrelevant if, by and through such usage, society's nicotine dependence increases by way of a restored approval of smoking in general.<sup>140</sup>

E-cigarettes are extremely novel devices and that novelty evinces that it is irrefutably premature to support (let alone consciously disseminate) information purporting that e-cigarettes are categorically safer than combustible cigarettes. Recently, the FDA disclosed that e-cigarettes may be associated with seizures as the agency has received 35 reports of e-cigarette induced seizures since 2010.<sup>141</sup> Moreover, vaping-related illnesses and deaths have proliferated out of thin air.<sup>142</sup> Since the e-cigarette's inception in 2007, the CDC and the FDA have reported six-vaping related deaths.<sup>143</sup> Every single vaping-related death has occurred in 2019.<sup>144</sup> Some of the deceased were young and completely healthy minutes before they were hospitalized for acute lung disease; others were old and frail.<sup>145</sup> Health officials believe that vitamin E acetate—a chemical used primarily in cannabis-containing vaping products—is to blame.<sup>146</sup> But neither the CDC nor the FDA have identified an explicit causal link between vaping and the preceding deaths.<sup>147</sup> Yet, e-cigarettes and its progeny remain on the market, flavorful and unregulated. At first glance, it seems pointless for these agencies to disclose such a small number of vaping-related seizures and deaths to the general public. But it is not the diminutive magnitude of the quantity of seizures and deaths that is alarming. On the contrary, it is the fact that such disclosure illuminates that the safety data

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<sup>140</sup> *Id.*

<sup>141</sup> Jamie Ducharme, *The FDA Is Investigating a Possible Link Between Vaping and Seizures*, TIME (Apr. 3, 2019), <http://time.com/5563554/vaping-seizures-fda/>.

<sup>142</sup> Jacqueline Howard, *A sixth person died from vaping-related lung disease. Here's what you need to know*, CNN (Sept. 12, 2019, 5:16 AM), <https://www.cnn.com/2019/09/10/health/vaping-outbreak-2019-explainer/index.html>.

<sup>143</sup> *Id.*

<sup>144</sup> *Id.*

<sup>145</sup> *Id.*

<sup>146</sup> *Id.*

<sup>147</sup> *Id.*

associated with e-cigarette usage is unresolved and inconclusive. As a result, an e-cigarette should be utilized in a fashion that mirrors the device's present uncertainty.

*C. Who is truly at fault: the adolescents for making primarily uneducated decisions or the FDA for failing to regulate e-cigarettes?*

Even though it may be true that most adolescents who partake in recreational e-cigarette use do so without holistically assessing the consequences of that decision, it is also true that the FDA is obligated—by virtue that its existence is inextricably tied to protecting the public health—to inhibit the birth of such a decision. Presently, the FDA's "deeming rule" prohibits e-cigarette retailers from (1) selling e-cigarettes to customers age 17 and younger;<sup>148</sup> (2) distributing free samples; and (3) selling e-cigarettes in vending machines.<sup>149</sup> On the other hand, e-cigarette manufacturers are solely prohibited from distributing free samples.<sup>150</sup> Failure to comply with these regulations may render an e-cigarette adulterated, misbranded, or both, and it is unlawful for any entity to sell or distribute an adulterated and/or misbranded product in interstate commerce.<sup>151</sup>

Clearly, the FDA has instituted express regulations to curb, not only youth appeal, but youth access to e-cigarettes. So, what's the problem? Admittedly, the FDA has made major strides in the realm of e-cigarette regulation. Still, those strides do not overshadow or negate the fact that Congress effectuates laws for those laws to be fully complied with. All products and devices that the FDA has identified to be "tobacco products" pursuant to its "deeming" authority became

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<sup>148</sup> Retailers are also required to corroborate the age of the purchaser by checking the photo ID of purchasers under the age of 27; *See* 21 C.F.R. § 1140 (2019).

<sup>149</sup> *Id.*

<sup>150</sup> *Id.*

<sup>151</sup> *Id.*

subject to the premarket authorization requirements of the FSPTCA as of August 8, 2016.<sup>152</sup> Premarket authorization requires that the product manufacturer receive FDA approval of its premarket approval application before the manufacturer markets the device.<sup>153</sup> Before the FDA grants a manufacturer premarket approval for a product, the FDA assesses the validity of the scientific evidence associated with the manufacturer’s application to confirm that the proposed product is safe and effective for its intended use.<sup>154</sup> In accordance with the FSPTCA, any manufacturer that seeks to introduce a tobacco product intended for human use into interstate commerce must first attain premarket authorization from the FDA.<sup>155</sup> However, if the tobacco product that the manufacturer proposes to introduce into interstate commerce was commercially marketed in the United States prior to February 15, 2007 or the product is “substantially equivalent” to a product that has been previously granted premarket authorization by the FDA, then the FSPTCA’s premarket authorization requirements are inapplicable.<sup>156</sup> Simply put, manufacturers of “new” tobacco products (*i.e.*, products that were commercially marketed in interstate commerce after February 15, 2007) that have not received authorization to be introduced or delivered into interstate commerce via an FDA substantial equivalence order, must file a premarket authorization application with the FDA containing “full reports of all information . . . concerning investigations which have been made to show the health risks of such tobacco product . . . .”<sup>157</sup>

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<sup>152</sup> Ned Sharpless, *How FDA is Regulating E-Cigarettes*, FOOD & DRUG ADMIN., <https://www.fda.gov/news-events/fda-voices-perspectives-fda-leadership-and-experts/how-fda-regulating-e-cigarettes> (last visited Nov. 27, 2019).

<sup>153</sup> *Premarket Approval (PMA)*, FOOD & DRUG ADMIN., <https://www.fda.gov/medical-devices/premarket-submissions/premarket-approval-pma> (last visited Nov. 27, 2019).

<sup>154</sup> *Id.*

<sup>155</sup> Family Smoking Prevention and Tobacco Control Act § 910(a)(2)(A).

<sup>156</sup> *Id.* at § 910(a)(2)(A)(i)(I).

<sup>157</sup> *Id.* at § 910(b)(1)(A).



It has been documented that peer-reviewed toxicology information of the world’s leading e-cigarette brands is extremely limited.<sup>158</sup> Consequently, many, if not all, the premarket approval applications that would be submitted by manufacturers of “new” tobacco products would utterly fail to satisfy the requirement of informing the FDA of the “health risks” associated with such “new” tobacco products.<sup>159</sup> Unsurprisingly, the scarcity of information concerning the health hazards triggered by e-cigarette usage should—conceivably—restrict a “new” tobacco product’s access to interstate commerce on account of the fact that its manufacturer cannot provide the FDA with the requisite information for premarket authorization. However, instead of transforming the preceding reasonable hypothesis into a reality by strictly enforcing § 910 of the FDCA, former FDA Commissioner Scott Gottlieb made an executive decision to allow “new” e-cigarettes to remain unconstrained on the market until August 8, 2021.<sup>160</sup> After that date passes, the FDA has asserted that it “intends to prioritize enforcement for lack of a [premarket authorization] against flavored ENDS products.”<sup>161</sup> Furthermore, the FDA has disclosed that its “decision to prioritize enforcement of [§ 910 of the FD&C Act] against a manufacturer and/or retailer will continue to be determined on a case-by-case basis.”<sup>162</sup>

The FDA’s reasoning for effectively destroying the efficacy of the FDCA is that e-cigarettes have the potential to help adult smokers make the transition “completely off of combustible products.”<sup>163</sup> This is undoubtedly a possibility; it is also entirely possible that the intrinsic properties of vitamin C may one day empower the nutrient to kill cancer.<sup>164</sup> Regardless, this mere

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<sup>158</sup> Michael S. Orr, *Electronic Cigarettes in the USA: A Summary of Available Toxicology Data and Suggestions for the Future*, 23 TOBACCO CONTROL, at ii18, ii21 (2014).

<sup>159</sup> Family Smoking Prevention and Tobacco Control Act § 910(a)(2)(A).

<sup>160</sup> FOOD & DRUG ADMIN., *supra* note 4, at 14.

<sup>161</sup> *Id.*

<sup>162</sup> *Id.* at 6.

<sup>163</sup> *Id.* at 14.

<sup>164</sup> See Jeanne A. Drisko et al., *Treatment of Pancreatic Cancer with Intravenous Vitamin C: A Case Report*, 29 ANTI-CANCER DRUGS 373, 373–79 (2018).

possibility must be juxtaposed against the definitive fact that middle schoolers do not possess the intellectual wherewithal to properly evaluate the consequences—many of which are unknown<sup>165</sup>—of partaking in recreational e-cigarette usage.<sup>166</sup> Importantly, in 2013, it was documented that 61.1% of middle school and 80% of high school e-cigarette-using students reported that they smoked combustible cigarettes in conjunction with e-cigarettes.<sup>169</sup> Conversely, 20.3% and 7.2% of students within those respective groups who documented that they had never smoked an e-cigarette similarly reported that they had never smoked a combustible cigarette either.<sup>170</sup> The correlation between adolescent e-cigarette usage and adolescent combustible cigarette usage is uncomfortably astounding. The preceding data illustrates that youth who smoke e-cigarettes are inclined to smoke combustible cigarettes. On the other hand, if an adolescent is prohibited from “ripping” a Juul during his juvenile years, then it is highly unlikely—nearly theoretically impossible—that he will develop an e-cigarette-induced propensity to smoke Camels or Marlboros. Therefore, the FDA’s actions to date not only clearly defy the FSPTCA, but those actions also fail to sufficiently protect the health of the future citizenry of the United States.

## CONCLUSION

In order to truly combat the epidemic rise in adolescent e-cigarette usage, the solution is quite simple. The FDA must earnestly enforce the FDCA and institute immediate regulations that firmly encroach upon the ability of society’s youth to obtain e-cigarettes. If the FDA continues to defer to e-cigarette manufacturers and retailers, misinformation will linger, deaths will inevitably ensue, and the health of youth nationwide will continue to progressively decline. Tellingly, the

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<sup>165</sup> M. Bradley Drummond & Dona Upson, *supra* note 138.

<sup>166</sup> Adam M. Leventhal et al., *supra* note 95, at 706.

<sup>169</sup> See Catherine Corey et al., *Electronic Cigarette Use Among Middle and High School Students – United States, 2011-2012*, 62 MORBIDITY & MORTALITY WKLY. REP. 729, 729–30 (2013).

<sup>170</sup> *Id.*

unrestrained adolescent usage of e-cigarettes has prompted many states to enact statutes that place strict limitations on public e-cigarette consumption.<sup>171</sup> The FDA must follow suit because if e-cigarettes continue to be conspicuously utilized, then smoking behavior will be expeditiously destigmatized. Destigmatization of smoking will place future generations of youth at an intolerable disadvantage—a disadvantage that can ultimately be deemed null and void if the FDA’s forthcoming acts resolutely embody the administrative agency’s underlying purpose: protection of public health.

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<sup>171</sup> AM. NONSMOKERS’ RTS. FOUND., STATES AND MUNICIPALITIES WITH LAWS REGULATING USE OF ELECTRONIC CIGARETTES, <http://no-smoke.org/wp-content/uploads/pdf/ecigslaws.pdf> (last visited July 31, 2019).