

NO “E”-ASY WAY OUT: WHY THE FDA  
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UNDER THE CURRENT TCA FRAMEWORK,  
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Samantha J. Gagliardo

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# NO “E”-ASY WAY OUT: WHY THE FDA SHOULD NOT REGULATE E-CIGARETTES UNDER THE CURRENT TCA FRAMEWORK, EVEN WITH NEW DEEMING REGULATIONS

Samantha J. Gagliardo\*

## INTRODUCTION

A new global trend has caught fire. Catching fire, however, may no longer be the correct term. Rather, this trend has vaporized. E-Cigarettes, ENDS (Electronic Nicotine Delivery Systems), or vapes are all terms for the latest craze in nicotine usage.<sup>1</sup> Although e-cigarettes were, for all intents and purposes, patented in 2003, the e-cigarette frenzy began reaching new heights in 2014.<sup>2</sup> The verb “vape,” which is the act of inhaling the nicotine vapor through e-cigarettes, became Oxford’s 2014 word of the year after the term was nearly doubled in usage from 2013 to 2014.<sup>3</sup> Vape shops, retailers who specialize in the sale of e-cigarettes and the synthesized nicotine used in them, have sprung up across the United States.<sup>4</sup> Including other

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\* J.D., 2017, University of Pittsburgh School of Law; B.A., Political Science/Spanish, 2014, *summa cum laude*, Washington & Jefferson College.

<sup>1</sup> Kevin Oliver, *Regulations Are a Drag: The WHO Framework Convention on Tobacco Control and its Potential Application to Electronic Cigarettes*, 16 CHI. J. INT’L L. 185, 187 (2015); see also Wendy Parmet, *In Regulating E-Cigarettes, No Easy Fix For The FDA*, HEALTH AFFAIRS BLOG (Feb. 20, 2015), <http://healthaffairs.org/blog/2015/02/20/in-regulating-e-cigarettes-no-easy-fix-for-the-fda/>.

<sup>2</sup> See Nick Dantonio, Comment, *Vape Away: Why a Minimalist Regulatory Structure Is the Best Option for FDA E-Cigarette Regulation*, 48 U. RICH. L. REV. 1319, 1326–27 (2014).

<sup>3</sup> Katy Steinmetz, *Oxford’s 2014 Word of the Year is Vape*, TIME (Nov. 17, 2014), <http://time.com/3590093/oxfords-2014-word-of-the-year-is-vape/>.

<sup>4</sup> Jilian Mincer, *The US Vaporizer Market is Booming*, BUSINESS INSIDER (July 29, 2015, 7:44 AM), <http://www.businessinsider.com/r-in-rise-of-us-vape-shops-owners-eye-new-marijuana-market-2015-7> (“Since 2008, the number of U.S. vape shops has grown to about 8,500, and the sale of electronic cigarettes and supplies climbed to \$3.5 billion[.]”); see also Norm Bour, *How Many Vape Shops Are There in the*

retailers that also sell e-cigarettes, there were approximately 35,000 vendors selling these products in that time period.<sup>5</sup> What seemed to start as a fad has quickly become an impactful mainstay in what had appeared to be a stagnant, or even dying, tobacco industry.<sup>6</sup>

Numerous reasons have been cited for the popularity of e-cigarettes vaping over cigarette smoking, such as the novelty of the product.<sup>7</sup> Some may believe that it is safer, while others enjoy the lack of restrictions currently in place for e-cigarette use in public places.<sup>8</sup> Regardless of the reasons, vaping appears to be moving from a trend to a lasting alternative to traditional tobacco smoking.<sup>9</sup>

The actual risks associated with the effects of e-cigarettes, however, are still largely unknown, as long-term studies are not yet available.<sup>10</sup> The Food and Drug Administration (FDA) has attempted to regulate these products as a drug under the Federal Food, Drug and Cosmetic Act (FDCA), which they attempted to do before the e-cigarette industry developed into the industry that exists today.<sup>11</sup> However, in *Sottera, Inc. v. FDA*, the D.C. Circuit Court determined that, because e-cigarettes are not marketed as a cessation method or as having therapeutic value, they do not fit the definition of a drug under the FDCA.<sup>12</sup> This definition was consistent with the Supreme Court's ruling in *FDA v. Brown & Williamson Tobacco Corp.*, where the Court first ruled that tobacco products could not be characterized as drugs for the same reasons that the D.C. Circuit Court cited to in *Sottera*.<sup>13</sup>

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U.S.A.?, VAPE NEWS MAG. (Jan. 3, 2015), <http://vapenewsmagazine.com/november-2014/how-many-vape-shops-are-there-in-the-u-s-a>.

<sup>5</sup> *Id.*

<sup>6</sup> See Eric A. Feldman, *Layers of Law: The Case of E-Cigarettes*, 10 FIU L. REV. 111, 111 (2014).

<sup>7</sup> See Jordan Paradise, *No Sisyphean Task: How the FDA Can Regulate Electronic Cigarettes*, 13 YALE J. HEALTH POL'Y L. & ETHICS 326, 365–66 (2013).

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

<sup>9</sup> See Steinmetz, *supra* note 3.

<sup>10</sup> See Paradise, *supra* note 7, at 359–60; *but see* Dantonio, *supra* note 2, at 1359–60.

<sup>11</sup> *Sottera, Inc. v. FDA*, 627 F.3d 891, 893 (D.C. Cir. 2010).

<sup>12</sup> *Id.* at 894–98.

<sup>13</sup> See *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000).

Following *Brown & Williamson*, Congress passed the Family Smoking Prevention and Tobacco Control (TCA)<sup>14</sup> in 2009, which gives the FDA jurisdiction to regulate the tobacco products.<sup>15</sup> Although the *Sottera* court declared that its decision did not prevent the FDA from regulating e-cigarettes under the TCA, the FDA has still been hesitant to regulate the new industry.<sup>16</sup> In order to regulate e-cigarettes under the TCA, the FDA would need to deem e-cigarettes as tobacco products.<sup>17</sup> The FDA has attempted to do so with the proposed “deeming” rule, which deems new products in the tobacco industry as tobacco products.<sup>18</sup> All of the sections of the TCA could then apply to e-cigarettes, which in turn could stifle a still-developing industry.<sup>19</sup> Just like cigarettes and smokeless tobacco before them, the regulation of e-cigarettes faces the struggle between unknown health risks versus the economic impact of placing regulations on a growing market.<sup>20</sup>

In early Fall of 2015, as research for this Note began, the above information did make it seem that the regulation of e-cigarettes and the vaping industry was going to be a legitimate issue. However, that was before “Big Tobacco” had its first quarterly decline of e-cigarette and vaping products for the period ending October 31, 2015.<sup>21</sup> E-cigarettes were projected to have a growth rate of just 57% in 2016, which is down from a 114% compounded growth rate from the previous five years.<sup>22</sup> Additionally, subsequent to the submission of this Note, but prior to its publication, the FDA promulgated its deeming rule, subject to some limitations.<sup>23</sup>

This Note argues that, although the e-cigarette industry should not continue to go unregulated, the FDA is not the most appropriate body to make that decision at

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<sup>14</sup> Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111–31, 123 Stat. 1776 (codified as amended at 21 U.S.C. § 387 (2012)).

<sup>15</sup> *Sottera*, 627 F.3d at 902 (Garland, J., concurring).

<sup>16</sup> Parmet, *supra* note 1.

<sup>17</sup> *Id.*

<sup>18</sup> 21 C.F.R. §§ 1100, 1140, 1143 (2016).

<sup>19</sup> Parmet, *supra* note 1.

<sup>20</sup> *Id.*

<sup>21</sup> Tripp Mickle, *E-Cigarette Sales Rapidly Lose Steam*, WALL ST. J., <http://www.wsj.com/articles/e-cig-sales-rapidly-lose-steam-1447798921> (last updated Nov. 17, 2015, 7:15 PM).

<sup>22</sup> *Id.*

<sup>23</sup> 21 C.F.R. §§ 1100, 1140, 1143 (2016).

this juncture.<sup>24</sup> Rather, Congress should pass legislation that allows for the safeguarding of public health without gross economic harm to the developing market.<sup>25</sup> This could be done by passing “safe regulations,” such as limiting sales to minors or increasing labeling standards.<sup>26</sup> While these propositions are not out of the ordinary, this Note takes the argument a step further to say that going off of Congress’s long legislative history concerning the same, yet more difficult, conflict with traditional tobacco products, Congress will be able to come to a solution much more efficiently than they would with most pieces of legislation.<sup>27</sup> The recent FDA deeming regulation, which went into effect on August 8, 2016, did promulgate “safe regulations.”<sup>28</sup> However, the deeming aspect of the regulation leaves open the opportunity for further regulations to be promulgated for e-cigarettes.<sup>29</sup> Congress is the better body for further legislation, not the FDA, despite the recent deeming regulation.

Additionally, this Note posits the larger argument that any new industry that does not fit squarely within the confines of a regulatory agency should be governed through the legislative process. This is due to the fact that new industries may no longer be as pressing of an issue by the time Congress is able to create a legislative framework for them. Allowing the FDA to regulate the e-cigarette and vaping industry would have slowed down what economic progress it has had, which could affect the public health.<sup>30</sup> However, Congress should not have an issue passing at least minimal legislation for this industry based upon the legislative history of the tobacco industry.<sup>31</sup>

Part I of this Note discusses the background information concerning the regulation of e-cigarettes, including a description of what an e-cigarette actually is and the relevant legal history of *Brown and Williamson* and *Sottera*. Part II argues that Congress should look to its own legislative history that has led to the regulation

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<sup>24</sup> *But see* Paradise, *supra* note 7, at 330–32.

<sup>25</sup> Parmet, *supra* note 1.

<sup>26</sup> *Id.*

<sup>27</sup> *See* Sottera, Inc. v. FDA, 627 F.3d 891, 901 (D.C. Cir. 2010). *See also* Dantonio, *supra* note 2, at 1331; Paradise, *supra* note 7, at 344.

<sup>28</sup> 21 C.F.R. §§ 1100, 1140, 1143 (2016).

<sup>29</sup> *See* Paradise, *supra* note 7, at 330–32.

<sup>30</sup> *See* Mickle, *supra* note 21; *see also* Paradise, *supra* note 7, at 331.

<sup>31</sup> *See* Sottera, 627 F.3d at 901. *See also* Dantonio, *supra* note 2, at 1331; Paradise, *supra* note 7, at 344.

of traditional tobacco products. Lastly, Part III suggests the type of legislation that should be passed in order to both protect the public health while maintaining the opportunity for growth for the new industry. Part III also stresses the importance of allowing Congress to make decisions rather than having regulatory agencies try to force new products into their existing regulatory schemes.

## I. RELEVANT BACKGROUND INFORMATION DEMONSTRATING HOW THE PROCESS OF REGULATING E- CIGARETTES HAS REACHED THE POINT THAT IT HAS TODAY

E-Cigarettes pose a dilemma for the FDA in that, although they were invented by the time Congress passed the TCA, Congress did not specifically add e-cigarettes as “tobacco products” under the TCA.<sup>32</sup> Although the TCA was directed toward the regulation of traditional forms of smoking tobacco and smokeless tobacco, the term “tobacco product” was left vague enough to incorporate newly-invented tobacco vessels into the act.<sup>33</sup> Under the TCA, a tobacco product is “any product made or derived from tobacco that is intended for human consumption, including any component, part, 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>34</sup> Although e-cigarettes seemingly fit the definition, the FDA at this juncture does not want to have to apply all of the provisions of the TCA.<sup>35</sup> To understand why the FDA is hesitant to do this, one must first have the appropriate background information. This section, then, intends to describe what an e-cigarette actually is, the impact of both *Brown and Williamson* and *Sottera* had on the regulation of the industry, and how the TCA works.

### A. E-Cigarettes: The “ENDS” of Traditional Tobacco Use?

E-Cigarettes, according to the National Institute on Drug Abuse, “are battery-operated devices designed to deliver nicotine with flavorings and other chemicals to users in vapor instead of smoke.”<sup>36</sup> The actual “cigarette” part of the e-cigarette is

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<sup>32</sup> See Paradise, *supra* note 7, at 345–46; see also Parmet, *supra* note 1.

<sup>33</sup> See Paradise, *supra* note 7, at 346.

<sup>34</sup> Family Smoking Prevention and Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (codified as amended at 21 U.S.C. § 387 (2012)).

<sup>35</sup> Parmet, *supra* note 1.

<sup>36</sup> Electronic Cigarettes (e-Cigarettes), NATIONAL INSTITUTE ON DRUG ABUSE, <http://www.drugabuse.gov/publications/drugfacts/electronic-cigarettes-e-cigarettes> (last updated May 2016).

made up of three parts: a nicotine cartridge, an atomizer used to vaporize the nicotine using heat, and a battery.<sup>37</sup> All the user has to do is inhale, and the device does the rest, unlike a traditional cigarette which must be lit.<sup>38</sup> The e-cigarette does this by vaporizing the refillable nicotine fluid in the cartridge.<sup>39</sup>

Because e-cigarettes use only liquid nicotine synthesized from tobacco, some feel that this form of smoking is a safer alternative to traditional combustible tobacco.<sup>40</sup> Many believe that, since they are receiving only the nicotine without more harmful byproducts like tar, this is a safer alternative to traditional smoking.<sup>41</sup> However, most medical researchers still will not conclusively say that this is a better alternative for those with nicotine addiction because the long-term effects of e-cigarette use are still relatively unknown.<sup>42</sup>

Regardless of the unknown health concerns surrounding e-cigarettes, vaping has become a global phenomenon, and the United States is not alone in its inability to find a way to properly regulate the market.<sup>43</sup> Much of the reason why e-cigarettes continued to go unregulated, at least in the United States, is because of the large economic impact that the novel product bring to the marketplace.<sup>44</sup> Although the vaping market began to slowdown in late 2015, the United States had seen a compound annual growth rate of 114% over the previous five years.<sup>45</sup> This is partially due to the fact that consumers are realizing that e-cigarettes are not a direct substitute for cigarettes, similar to the way that diet soda is not a direct substitute for

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<sup>37</sup> See Dantonio, *supra* note 2, at 1328.

<sup>38</sup> See *id.*

<sup>39</sup> *Id.*

<sup>40</sup> *Id.* at 1326.

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

<sup>42</sup> Feldman, *supra* note 6, at 114; but see Dantonio, *supra* note 2, at 1327 (claiming “other groups, such as the American Association of Public Health Physicians, actually recommend that those suffering from a nicotine addiction should consider using e-cigarettes as a long-term replacement for smoking combustible cigarettes”).

<sup>43</sup> See Feldman, *supra* note 6, at 120; see also An Hertogen & Anita Killen, *The Burning Issue of Combustible Tobacco: The Inconvenient Truth*, 2014 NZ L. REV. 239 (2014); see also Sarah Moore, *Where There’s Smoke . . .*, 164 NLJ 7606, 6 (2014).

<sup>44</sup> See Dantonio, *supra* note 2, at 1327.

<sup>45</sup> Mickle, *supra* note 21.

soda.<sup>46</sup> Like diet soda, however, there is still a demand for it concurrently with regular soda, though it does not take the actual place of soda.<sup>47</sup> Even if the market for e-cigarettes does not take over the traditional tobacco market like was once projected, it cannot continue go unregulated as long as there is at least some market for it.<sup>48</sup>

*B. The Effect of Brown and Williamson on the Tobacco Industry*

Following centuries of being a dominate force in the American economy, the tobacco industry faced the regulatory framework of the FCA under the FDA. In 1996, after years of claiming that they did not have the jurisdiction to do so, the FDA asserted jurisdiction to regulate the tobacco industry under the FDCA.<sup>49</sup> The FDA argued that nicotine was in fact a drug under the FDCA, and cigarettes and smokeless tobacco were considered “combination product” used to take nicotine into the body.<sup>50</sup> The main goal of the regulation was to prevent access to tobacco products by minors, based on the belief that most tobacco users begin before the age of 18.<sup>51</sup>

Although agencies by and large are given *Chevron* deference in interpreting the statutes that they use in regulation, the Court here said that “court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.”<sup>52</sup> Therefore, if the intentions of Congress were not to include tobacco products as drugs and devices under the FDCA, then the FDA would not be able to regulate tobacco products as such.

The FDA claimed that their interpretation of the FDCA’s definitions for “combination products” (both a drug and a device for taking said drug) gave them the discretion to regulate.<sup>53</sup> However, tobacco products would first have to meet the Congress’s definition of both a drug and a device before they could be considered a

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

<sup>47</sup> *See id.*

<sup>48</sup> *Id.*

<sup>49</sup> *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 125 (2000).

<sup>50</sup> *Id.*

<sup>51</sup> *Id.*

<sup>52</sup> *Id.* at 125–26, citing *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842–43 (1984).

<sup>53</sup> *Brown & Williamson*, 529 U.S. at 129.

combination product. To be considered a drug capable of being regulated under the FDCA, there would have to be, from the vendor, “some express claim concerning the product’s therapeutic benefits.”<sup>54</sup> No such claims were made by the tobacco companies.<sup>55</sup>

Additionally, finding that Congress did not intend to include tobacco products, the Court upheld the decision of the Court of Appeals for the Fourth Circuit, due to inconsistencies that would result if the Court were to rule otherwise.<sup>56</sup> The inconsistency lies in the fact that the FDA had already found that tobacco was an inherently “unsafe” product.<sup>57</sup> However, the FDCA is only to be used to regulate products that the FDA finds “safe.”<sup>58</sup> Regulating tobacco products under the FDCA would have resulted in an overall ban of tobacco products in the United States.<sup>59</sup> The Court reasoned that there was no way that Congress intended to give the FDA such authority over an industry that had so much “economic and political significance” in the United States.<sup>60</sup>

*C. Obama Administration Passes the Family Smoking  
Prevention and Tobacco Control Act in Response to Brown  
& Williamson*

On June 22, 2009, the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) “was passed to protect the public and create a healthier future for all Americans.”<sup>61</sup> The TCA is designed to give the FDA “authority to regulate the manufacture, distribution, and marketing of tobacco products.”<sup>62</sup> The main objective to come out of the provisions of the TCA is to limit the sale of tobacco to minors.<sup>63</sup> Although the TCA grants broad authority for regulation of tobacco

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<sup>54</sup> *Id.* at 131.

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

<sup>56</sup> *Id.* at 130.

<sup>57</sup> *Id.* at 134–35.

<sup>58</sup> *Brown & Williamson*, 529 U.S. at 134.

<sup>59</sup> *Id.* at 133.

<sup>60</sup> *Id.* at 160.

<sup>61</sup> *Tobacco Control Act*, U.S. FOOD DRUG ADMIN., <http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm246129.htm> (last updated Mar. 16, 2017).

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

<sup>63</sup> *See id.*

products, not all of those powers, if any, would be appropriate for the regulation of e-cigarettes.<sup>64</sup> The TCA, according to its preamble, generally,

requires manufacturers to register their products, mandates adherence to manufacturing practice requirements, requires disclosure to FDA of ingredients for all tobacco products, grants the FDA authority to establish product standards, permits the FDA to reduce nicotine (though not eliminate it) and other harmful ingredients, bans misleading descriptors without substantiation, enlarges tobacco product warning labels and requires graphic images on packaging, and bans fruit and candy flavorings in cigarettes.<sup>65</sup>

To be considered a “tobacco product” subject to regulation under the FDA, the device would have to be “a product made or derived from tobacco.”<sup>66</sup> However, this definition does not include “raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product.”<sup>67</sup> The TCA would be able to “fill the gaps” that both the Federal government and States face in regulating the tobacco industry.<sup>68</sup> Although e-cigarettes were invented and being sold at the time that the TCA was passed, e-cigarettes were not specifically written into the TCA.<sup>69</sup> Some might believe that Congress had intentionally left the definition broad, while others believe that e-cigarettes still do not fit into the definition of a tobacco product.<sup>70</sup>

*D. D.C. Circuit Rules that E-Cigarettes Cannot be Regulated Under the FDCA in Sottera, but FDA Still Hesitant to Regulate Under TCA*

In *Sottera*, Sottera, Inc., doing business as NJOY, an importer and distributor of e-cigarettes, sought a preliminary injunction from a 2009 FDA order stating that these e-cigarettes did not meet the regulation set for combination device under the

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<sup>64</sup> See Dantonio, *supra* note 2 at 1323–24.

<sup>65</sup> Paradise, *supra* note 7, at 344.

<sup>66</sup> Dantonio, *supra* note 2, at 1334; Paradise, *supra* note 7, at 345.

<sup>67</sup> Paradise, *supra* note 7, at 345.

<sup>68</sup> Dantonio, *supra* note 2, at 1334.

<sup>69</sup> *Id.* at 1343.

<sup>70</sup> See Dantonio, *supra* note 2, at 1335; *but see* Paradise, *supra* note 7, at 347.

FDCA.<sup>71</sup> Additionally, NJOY joined Smoking Everywhere, Inc.'s preliminary injunction.<sup>72</sup> Both claimed that *Brown & Williamson* prohibited the FDA from asserting FDCA drug/device jurisdiction over tobacco products that do not have a therapeutic effective.<sup>73</sup>

The main crux of NJOY and Smoking Everywhere's argument was that, to be subject to FDCA jurisdiction, e-cigarettes would have to be labeled for a therapeutic use, or for "diagnosis, cure, mitigation, treatment, or prevention of disease."<sup>74</sup> However, their products were never marketed as such. Rather, they were marketed for "smoking pleasure."<sup>75</sup> The question, then, became whether or not the FDA could regulate e-cigarettes under the FDCA or would tobacco specific legislation like the TCA be the appropriate avenue.<sup>76</sup> Implicit in that question, however, was the broader question of whether the *Brown & Williamson* decision applied to only tobacco products for which Congress had passed specific regulatory statutes or to all tobacco products.<sup>77</sup>

However, the D.C. Circuit pointed out that the *Brown & Williamson* Court went through and examined the individual statutes relating to tobacco products for the purpose of demonstrating how "Congress was actively thinking about the 'Tobacco Problem.'"<sup>78</sup> Additionally, this aided in demonstrating that "Congress knew of both 'the adverse consequences of tobacco use' and of 'nicotine's pharmacological effects.'"<sup>79</sup> What lay at the heart of tobacco-related legislation, however, was that tobacco products were not marketed for therapeutic purposes.<sup>80</sup> The *Brown & Williamson* Court took this into consideration when making their decision.<sup>81</sup> The D.C. Circuit in *Sottera*, therefore, concluded that the *Brown & Williamson* decision

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<sup>71</sup> *Sottera, Inc. v. FDA*, 627 F.3d 891, 892–93 (D.C. Cir. 2010).

<sup>72</sup> *Id.* at 893.

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

<sup>74</sup> *Id.* at 894.

<sup>75</sup> *Id.* at 893.

<sup>76</sup> *Id.* at 895.

<sup>77</sup> *Sottera, Inc.*, 627 F.3d at 895.

<sup>78</sup> *Id.* at 895–96.

<sup>79</sup> *Id.* at 896.

<sup>80</sup> *Id.*

<sup>81</sup> *Id.*

should be read to hold that no tobacco product should be regulated under the FDCA because tobacco products are not marketed for therapeutic purposes.<sup>82</sup> For this reason, the D.C. Circuit held that, “properly read in light of the Supreme Court’s decision in *FDA v. Brown & Williamson*,” e-cigarettes are better located under the Tobacco Act.<sup>83</sup>

Despite the *Sottera* decision, e-cigarettes still remain unregulated. In fact, the FDA took the position at oral argument in *Sottera* that it did not believe the TCA granted them jurisdiction over tobacco products outside of cigarettes and smokeless tobacco.<sup>84</sup> However, the FDA is allegedly very close to finalizing a “deeming” rule, which would allow for them to regulate any new tobacco-related product not specifically defined in the TCA to be deemed a tobacco product.<sup>85</sup> Passage of this rule would be crucial as new tobacco products must be “deemed” as tobacco products under the TCA.<sup>86</sup> Additionally, under the TCA, each new tobacco product would have to be authorized by the FDA if it was not in stores before February 15, 2007.<sup>87</sup> The main concern here is that, if the FDA does in fact pass the “deeming” rule, no e-cigarette product will be authorized by the FDA.<sup>88</sup> This rule, then, could potentially stifle the entire industry.<sup>89</sup>

## II. LEGISLATIVE HISTORY OF THE TOBACCO INDUSTRY AND ITS IMPACT ON E-CIGARETTES AND VAPING

“The first successful commercial crop was cultivated in Virginia in 1612 by Englishman John Rolfe.”<sup>90</sup> Within a matter of a few years, tobacco became the

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<sup>82</sup> *Id.* at 897 (stating that “Congress had consciously developed a statutory scheme for tobacco and health that distinguished tobacco products as customarily marketed for therapeutic purposes from ones marketed for therapeutic purposes”).

<sup>83</sup> *Sottera, Inc.*, 627 F.3d at 892.

<sup>84</sup> *Id.* at 897.

<sup>85</sup> 21 C.F.R. §§ 1100, 1140, 1143 (2016).

<sup>86</sup> *See* Parmet, *supra* note 1.

<sup>87</sup> Family Smoking Prevention and Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (codified as amended at 21 U.S.C. § 387 (2012)).

<sup>88</sup> Lydia Wheeler, *E-cig Firms Steel for Legal Battle*, THE HILL (Oct. 29, 2015), <http://thehill.com/regulation/258465-e-cig-firms-steel-for-legal-battle>.

<sup>89</sup> *Id.*

<sup>90</sup> *A Brief History of Tobacco*, CNN (2000), <http://edition.cnn.com/US/9705/tobacco/history/>.

leading crop of Virginia.<sup>91</sup> Despite it being a major player in the American market for centuries, the tobacco industry managed itself with little government interference for over 350 years. Then, on January 11, 1964, the report of the Advisory Committee on Smoking and Health was released by the Surgeon General.<sup>92</sup> The main crux of the Report was to demonstrate that “cigarette smoking contributes substantially to mortality from certain specific diseases and to the overall death rate.”<sup>93</sup>

Despite this scientific information, however, Congress did not authorize any administrative agency to regulate the tobacco industry.<sup>94</sup> In fact, any legislation that was passed in order to regulate the tobacco industry was in the sole purview of Congress until the enactment of the TCA, which came 45 years after the initial Report.<sup>95</sup> Additionally, as mentioned above, if Congress were to allow the FDA to regulate e-cigarettes and future ENDS under the TCA framework, this would likely result in an overall ban of ENDS in the United States.<sup>96</sup> However, if Congress instead looks to its own legislative history, as illustrated in this section, it would have no choice but to pass legislation that would safeguard the public health without causing gross economic harm to the developing market.

During the time between the Surgeon General’s Report and the *Brown and Williamson* decision, six pieces of tobacco-regulating legislation were passed. These pieces of legislation were: the Federal Cigarette Labeling and Advertising Act; the Public Health Cigarette Smoking Act of 1969; the Alcohol and Drug Abuse Amendments of 1983; the Comprehensive Smoking Education Act; the Comprehensive Smokeless Tobacco Health and Education Act of 1986; and the Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act.<sup>97</sup> Despite efforts from both the FDA, the FTC, and the FCC to regulate tobacco

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

<sup>92</sup> U.S. DEP’T OF HEALTH, EDUC., AND WELFARE, SMOKING AND HEALTH: REPORT OF THE ADVISORY COMMITTEE TO THE SURGEON GENERAL OF THE PUBLIC HEALTH SERVICE 1 (1964).

<sup>93</sup> *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 144 (2000) (citing U.S. DEP’T OF HEALTH, EDUC., AND WELFARE, SMOKING AND HEALTH: REPORT OF THE ADVISORY COMMITTEE TO THE SURGEON GENERAL OF THE PUBLIC HEALTH SERVICE 31 (1964)).

<sup>94</sup> *Brown & Williamson*, 529 U.S. at 149.

<sup>95</sup> *See id.*

<sup>96</sup> *See Wheeler, supra* note 88.

<sup>97</sup> *Sottera, Inc. v. FDA*, 627 F.3d 891, 895 (D.C. Cir. 2010).

products, none of these Acts gave any power to any agency. Any regulatory powers stayed with Congress.<sup>98</sup>

*A. Regulatory Authority May Not be Inconsistent with the  
Administrative Structure that Congress Enacted*<sup>99</sup>

In both *Brown & Williamson* and *Sottera*, tobacco products and eventually e-cigarettes could not be regulated under the FDCA as doing so would be inconsistent with prior rulemaking and adjudication of the FDA.<sup>100</sup> The FDA has long declared that tobacco is dangerous.<sup>101</sup> However, the framework of the FDCA is designed to regulate the safe use of drugs and drug devices.<sup>102</sup> To do so, the drug or drug device would have to be safe and effective for its intended use.<sup>103</sup> It could not follow, then, that the FDA had jurisdiction under the FFCA to regulate tobacco or tobacco-related products if they were not safe products.

Regulating tobacco products and e-cigarettes under the FDCA would result in an outright ban of the industry.<sup>104</sup> Clearly, as demonstrated by the enactment of the above pieces of legislation and the lack of other legislation concerning tobacco, this was not Congress’s intention. In fact, the Federal Cigarette Labeling and Advertising Act’s express policy is that “‘commerce and the national economy may be . . . protected to the maximum extent consistent with’ consumers ‘being adequately informed about any adverse health effects.’”<sup>105</sup> Therefore, because an overall ban would be necessary if tobacco were regulated under the FDCA and from other legislation since, the legislative history clearly demonstrates that the legislature did not intend to ban tobacco. Likewise, it would be wholly unlikely that Congress would intend for e-cigarettes to be banned, which would likely result from the “deeming” regulation or other types of regulations like it.<sup>106</sup>

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<sup>98</sup> *Brown & Williamson*, 529 U.S. at 145–50.

<sup>99</sup> *Id.* at 125.

<sup>100</sup> *See id.* at 130; *Sottera*, 627 F.3d at 895.

<sup>101</sup> *Brown & Williamson*, 529 U.S. at 134; *Sottera*, 627 F.3d at 895.

<sup>102</sup> *Brown & Williamson*, 529 U.S. at 133–34.

<sup>103</sup> *Id.* at 133.

<sup>104</sup> *See Brown & Williamson*, 529 U.S. at 130; *Sottera*, 627 F.3d at 895.

<sup>105</sup> *Brown & Williamson*, 529 U.S. at 138–39 (quoting Federal Cigarette Labeling and Advertising Act, 15 U.S.C. § 1331 (2012)).

<sup>106</sup> *See Parmet supra* note 1; *see also Wheeler, supra* note 88.

*B. The TCA and Other Legislation Create Frameworks to Inform Citizens of Risks, Not to Take a Product Out of the Market*

As previously mentioned, the main objective of the TCA is to limit the sale of tobacco products to minors.<sup>107</sup> While it does give the “FDA authority to regulate the manufacture, distribution, and marketing of tobacco products,” enabling the FDA to decide what new tobacco and tobacco-like products come into the market would be inconsistent with the lengthy legislative history surrounding the tobacco industry.<sup>108</sup>

Although the damaging effects that tobacco has on a human body are clearer now and were at the time the TCA was passed in 2009 than when other tobacco legislation was passed, it still does not erase the history that Congress believes that tobacco plays an important role in the American economy.<sup>109</sup> Although the TCA does mark the first time that Congress has given an administrative agency authority to regulate tobacco at all, it is still unlikely that it would have intended to allow the FDA to go as far as they would like with its proposed “deeming” regulation.<sup>110</sup>

Until the passage of the TCA, Congress mostly dealt with tobacco products by regulating their advertising and labeling, such as with the warning labels that are found on tobacco products warning that “Cigarette Smoking May Be Hazardous to Your Health.”<sup>111</sup> It is important to remember that this was the main avenue of regulation despite the fact that Congress has been well aware of the health risks associated with tobacco use, including the high risk of cancer caused by cigarettes.<sup>112</sup> This can be understood as Congress wanting to ensure that American citizens were not unaware of the risks, but also signifies their decision to allow citizens the freedom to continue to choose to buy and use tobacco. Congress was able to find somewhat of a balance between maintaining the public health without stifling an industry, an industry of historically great importance to the United States economy.<sup>113</sup>

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<sup>107</sup> See *Tobacco Control Act*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm246129.htm> (last updated Mar. 16, 2017).

<sup>108</sup> *Id.*; but see *Sottera*, 627 F.3d at 894.

<sup>109</sup> See *Brown & Williamson*, 529 U.S. at 125, 159.

<sup>110</sup> See *id.* at 151; see also *Parment*, *supra* note 1.

<sup>111</sup> *Brown & Williamson*, 529 U.S. at 148.

<sup>112</sup> *Id.* at 153.

<sup>113</sup> See *id.* at 159.

### C. Congress Should Follow Legislative History

Following this pattern, then, Congress should not have any difficulty passing legislation specifically for e-cigarette usage rather than allowing the FDA to regulate e-cigarettes under the jurisdiction of the TCA, if the deeming rule would come into effect.

It would be necessary to pass separate legislation for e-cigarettes rather than allow for “deeming” regulations because the FDA would be able to effectively ban the e-cigarette industry from continuing into the United States market.<sup>114</sup> The health effects surrounding e-cigarettes are still unknown, but the economic impact has made waves in a stagnant tobacco industry, at least for the time being.<sup>115</sup> Essentially, then, e-cigarettes have either the potential to become a real player in the tobacco industry, but the novelty might also wear off to the point where it becomes a waste of resources to even regulate the industry. It will never be known, however, if the FDA is allowed to regulate e-cigarettes under the TCA because there is a strong possibility that they will have to be taken off of the market.<sup>116</sup>

Deeming regulations that would effectively ban e-cigarettes, however, are completely inconsistent with both *Brown & Williamson* and *Sottera*. In each of those cases, the respective Court made clear that it was never the intent of Congress to ban tobacco products entirely from the market.<sup>117</sup> This can be seen from the relatively lax ways that Congress has handled the tobacco problem up until the TCA.<sup>118</sup> However, it is also arguable that Congress could have specifically added e-cigarettes to the TCA, but they chose not to in order not to have them included within this regulatory framework.<sup>119</sup> Regardless, it would be wholly inconsistent with legislative history of the tobacco industry to allow the FDA to ban new products under the TCA when it is still relatively unknown as to whether they pose as much of a safety hazard as traditional tobacco products.<sup>120</sup>

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<sup>114</sup> See Parmet, *supra* note 1; see also Wheeler, *supra* note 88.

<sup>115</sup> See Parmet, *supra* note 1. But see Mickle *supra* note 21.

<sup>116</sup> See Parmet, *supra* note 1; see also Wheeler, *supra* note 88.

<sup>117</sup> See *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 159–60 (2000); see also *Sottera, Inc. v. FDA*, 627 F.3d 891, 895 (D.C. Cir. 2010).

<sup>118</sup> *Sottera*, 627 F.3d at 895.

<sup>119</sup> Dantonio, *supra* note 2, at 1343.

<sup>120</sup> See Paradise, *supra* note 7, at 359–60.

### III. TYPE OF LEGISLATION AND WHY COMMON CONCERNS ABOUT THE LEGISLATIVE PROCESS ARE A NON-ISSUE HERE

One of the biggest concerns surrounding e-cigarettes is the concern that minors will manage to get their hands on them.<sup>121</sup> In this way, the concerns surrounding e-cigarettes are not all that different than the focus of the TCA itself.<sup>122</sup> However, the TCA goes further than might ultimately be necessary for the regulation of e-cigarettes. This does not mean, however, that minors using e-cigarettes might not be a valid concern. General concerns are additionally out there for almost anyone who uses e-cigarettes since we do not yet know the effects.<sup>123</sup> It is just too soon to tell “whether e-cigarettes will prove to be an effective form of harm reduction or a gateway drug.”<sup>124</sup>

However, there is no denying that e-cigarettes have at least made a significant economic impact in recent years on the tobacco industry.<sup>125</sup> While the vaping industry seemed to have begun to cool off toward the end of 2015, there still is the possibility that it might continue to be a substantial part of the tobacco industry.<sup>126</sup> One thing is known, however, which is that deeming regulations will likely extinguishes the vaping industry altogether.<sup>127</sup>

For this reason, Congress should limit legislation at this time to only regulate the e-cigarette industry in similar ways as the six pieces of tobacco legislation passed before the TCA and limit the sale to minors similar to the TCA. By regulating the labeling, advertising, marketing, and sales to minors, Congress would allow the American citizens to educate themselves on the product before purchasing.<sup>128</sup> However, it would be up to them as to whether or not they continue to purchase e-

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<sup>121</sup> See Parmet, *supra* note 1 (“In 2013 more than 250,000 minors who had never smoked had used an e-cigarette.”).

<sup>122</sup> *Tobacco Control Act*, U.S. FOOD AND DRUG ADMIN., <http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm246129.htm> (last updated Mar. 16, 2017).

<sup>123</sup> See Parmet, *supra* note 1.

<sup>124</sup> *Id.*

<sup>125</sup> See Dantonio, *supra* note 2, at 1327.

<sup>126</sup> Mickle, *supra* note 21.

<sup>127</sup> See Wheeler, *supra* note 88.

<sup>128</sup> See Parmet, *supra* note 1.

cigarettes. This would allow for a more hands off approach similar to how the tobacco industry was regulated until the TCA.<sup>129</sup> If the scientific research demonstrates that more regulations are needed, they can be added as necessary.<sup>130</sup> Although health effects might not be irreversible, the regulations can be adapted to meet those needs. Once the vaping market would be affected, however, the effects might be irreparable.<sup>131</sup>

As is typically the concern with leaving a decision up to Congress, many might be concerned that Congress cannot move quick enough to keep up with the needs of the industry. That is really one of the main needs that administrative agencies support.<sup>132</sup> In this situation, however, this is likely not a valid concern. This is because of the recent indications that e-cigarettes and the vaping industry might not be anything more than a novelty.<sup>133</sup> Only limited regulations might be necessary to protect the public health, and it might end up being a small, niche market in which legislation will ultimately effect.

## CONCLUSION

Within the last decade, the centuries-old tobacco industry has finally entered into the technological age with the creation of ENDS or, more commonly referred to as, e-cigarettes. While it appears that there could be some cessation-type benefits with e-cigarettes, or even a healthier alternative to traditional tobacco products, it is still unknown as to the health risks. The scientific research on the product has not been able to keep up with the demand for e-cigarettes.

During this time period, e-cigarettes have managed to continue to go unregulated under a federal scheme. However, that might soon change. Marketed for “smoking pleasure” rather than as a cessation method, the D.C. Circuit Court found in *Sottera* that e-cigarettes could not be regulated as a drug or device under the traditional parts of the FDCA. While it currently only regulates the areas that this Note recommended, the FDA leaves open the opportunity to accept any new tobacco product placed into the stream of commerce after February 15, 2007, which covers a majority of e-cigarettes.

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<sup>129</sup> See *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 155–56 (2000).

<sup>130</sup> See *Parmet*, *supra* note 1.

<sup>131</sup> See *Wheeler*, *supra* note 88.

<sup>132</sup> See *Administrative Agencies*, USLEGAL, INC. (2016), <http://system.uslegal.com/administrative-agencies/>.

<sup>133</sup> See *Mickle*, *supra* note 21.

This new deeming rule could ultimately effectively ban e-cigarettes from the tobacco market because the FDA would likely not authorize them to come into it. As it stands, however, the minimalistic legislation includes the regulating of sales to minors, labeling, and advertising. This allows for the safeguarding of the public health without impinging upon the e-cigarette industry so much that it would stifle economic growth. At the end of the day, because there are signs that the e-cigarette industry might be slowing on its own, it may be best to have as few regulations as possible because the day may soon be near where e-cigarettes are a niche market.