

## Colgate v. JUUL Labs, Inc.: Addressing the Preemptive Scope of the Tobacco Control Act for Electronic Nicotine Delivery Systems

Daniel S. Hausman

Follow this and additional works at: <https://digitalcommons.law.umaryland.edu/jbtl>

---

### Recommended Citation

Daniel S. Hausman, *Colgate v. JUUL Labs, Inc.: Addressing the Preemptive Scope of the Tobacco Control Act for Electronic Nicotine Delivery Systems*, 15 J. Bus. & Tech. L. 215 (2019)  
Available at: <https://digitalcommons.law.umaryland.edu/jbtl/vol15/iss1/8>

This Notes & Comments is brought to you for free and open access by the Academic Journals at DigitalCommons@UM Carey Law. It has been accepted for inclusion in Journal of Business & Technology Law by an authorized editor of DigitalCommons@UM Carey Law. For more information, please contact [smccarty@law.umaryland.edu](mailto:smccarty@law.umaryland.edu).

# Colgate v. JUUL Labs, Inc.: Addressing the Preemptive Scope of the Tobacco Control Act for Electronic Nicotine Delivery Systems

DANIEL S. HAUSMAN\*©

## ABSTRACT

*The promise offered by e-cigarette manufactures like JUUL Labs, Inc. of a healthier alternative to conventional combustible tobacco products has been eradicated as reports of skyrocketing teenage nicotine addiction and serious health concerns from the use of e-cigarettes continue to emerge. Ever since the Surgeon General declared tobacco a health risk in 1964, Congress and the judiciary have dealt with tobacco manufacturers who falsely advertised their product as safer to assuage the concerns of consumers. The Tobacco Control Act, passed in 2009, is Congress' latest attempt to regulate the tobacco industry to ensure consumers are adequately informed about the health risks of tobacco products, including what tobacco manufactures can say about "modified risk tobacco products" such as e-cigarettes. One of the first major challenges to the preemptive scope of the Tobacco Control Act regarding modified risk tobacco products came in April 2018 when a class action suit filed in the District Court of California alleged JUUL Labs misrepresented the amount of nicotine inhaled by users of its incredibly popular e-cigarette, the JUUL. Although JUUL Labs successfully argued that the Tobacco Control Act preempts them from having to adjust the nicotine warnings labels on its product, the District Court held that the claim that JUUL Labs misrepresented how much nicotine was present in its product in its advertising was not preempted. This comment aims to address the correctness of the District Court's preemption ruling, and the ramifications it will have on the e-cigarette industry. This comment will accomplish this by examining the growth of e-cigarette use in the United States, the legislative and judicial history of tobacco product regulation, and the language of the Tobacco Control Act's preemptive clause. This comment will then address the District Court's motion to dismiss ruling in Colgate v. JUUL Labs, Inc., and why the Court's interpretation of the Tobacco Control Act's preemptive scope was correct. The Comment will then discuss how this ruling will likely not impact the explosive growth of the e-cigarette industry, and why further regulation may be necessary.*

## INTRODUCTION

JUUL Labs, Inc., the maker of the popular electronic cigarette “JUUL,” has recently found itself at the center of controversy as more teenagers become addicted to their product.<sup>1</sup> In April 2018, a class action lawsuit alleging that JUUL Labs misrepresented the true addictive nature of its e-cigarette was filed in the District Court of California.<sup>2</sup> In October 2018, the court dismissed the plaintiff’s claim that the labeling on the JUUL did not adequately warn consumers that its nicotine salt formulation was more addictive than conventional nicotine because the Tobacco Control Act (“TCA”) preempts any additional labeling requirements on tobacco products.<sup>3</sup> However, the court held that the TCA did not preempt the claim and that JUUL Labs misrepresented the amount of nicotine in its advertisements for the JUUL.<sup>4</sup> This holding was reaffirmed after the plaintiffs consolidated several similar class action lawsuits and filed a consolidated class action complaint.<sup>5</sup> The potential ramifications of the District Court’s decision regarding the preemptive scope of the Tobacco Control Act is the focus of this comment.

The federal government’s involvement in tobacco regulation has had a substantial effect on the way tobacco companies advertise their products.<sup>6</sup> Ever since the Surgeon General’s Smoking and Health report of 1964 and the subsequent passage of the Federal Cigarette Labeling and Advertising Act (“FCLAA”),<sup>7</sup> tobacco companies have had to modify how they advertise their products.<sup>8</sup> Tobacco companies were able to withstand numerous private litigant lawsuits, however, by arguing that the FCLAA forbade individual plaintiffs from bringing state tort claims of misrepresentation.<sup>9</sup> Several decades later, the Supreme Court in *Cipollone v. Liggett Group, Inc.*<sup>10</sup> and *Altria Group, Inc. v. Good*<sup>11</sup> clarified that plaintiffs may bring a wide range of state tort claims when trying to combat the deceptive advertising practices of the tobacco industry.<sup>12</sup>

---

©Daniel S. Hausman 2019.

\* Daniel S. Hausman, J.D. Candidate, University of Maryland Francis King Carey School of Law, 2020.

1. See Jamie Ducharme, *Teens Are ‘Juuling’ At School. Here’s What That Means*, TIME (Mar. 27, 2018), <https://time.com/5211536/what-is-juuling/>.

2. See Nitasha Tiku, *Users Sue Juul for Addicting Them to Nicotine*, WIRED (July 23, 2018, 7:00 AM), <https://www.wired.com/story/users-sue-juul-for-addicting-them-to-nicotine/>.

3. *Colgate v. JUUL Labs, Inc.*, 345 F. Supp. 3d 1178, 1189–90 (N.D. Cal. 2018).

4. *Id.*

5. *Colgate v. JUUL Labs, Inc.*, 2019 U.S. Dist. LEXIS 144027 at 29–30.

6. See *infra* Part II. A.

7. Federal Cigarette Labeling and Advertising Act, 15 U.S.C.A §1334 (1965).

8. See *infra* Part II. A.

9. See *infra* text accompanying note 101.

10. 505 U.S. 504 (1992).

11. 129 U.S. 70 (2008).

12. See *Altria Group, Inc. v. Good*, 129 U.S. 70, 82-3 (2008).

After the passage of the TCA in 2008, it appeared many state tort claims involving the false advertising of cigarettes would be able to survive a preemptory challenge.<sup>13</sup> However, the TCA still contained the FCLAA provisions restricting state modification of tobacco product warning labels.<sup>14</sup> After the FDA ruled in 2016 that electronic nicotine delivery systems (“ENDS”) such as the JUUL would be regulated as tobacco products under the TCA,<sup>15</sup> questions arose as to what extent the congressional preemptive scope afforded to conventional tobacco products would apply to ENDS.<sup>16</sup>

This comment suggests that the District Court’s decision regarding the preemptive scope of the TCA was correct. As a result, electronic cigarette manufacturers, including JUUL Labs, will not be required to place labels on their products indicating nicotine salts may be more addictive or dangerous than traditional nicotine.<sup>17</sup> Although existing laws can protect consumers from false advertisements, more stringent regulations will be needed to ensure consumers are protected from the effects of modified risk tobacco products like e-cigarettes.

This comment proceeds in three parts. Part I will examine what is an e-cigarette, how JUUL came to dominate the e-cigarette market, and controversies concerning the health risks of the product, especially amongst teenage users. Part II will explain the history of ‘healthier’ cigarette litigation, and the preemptive scope of the FCLAA and TCA. Part III will address the JUUL lawsuit, the District Court’s ruling on JUUL’s Motion to Dismiss, and the implications this may have for electronic cigarette manufacturers like JUUL Labs, Inc.

## I. THE RISE OF E-CIGARETTES

### A. *What Are Electronic Cigarettes?*

Electronic cigarettes, commonly known as e-cigarettes, “aim to provide a similar sensation to inhaling tobacco smoke, without the smoke.”<sup>18</sup> These devices are sometimes referred to as “e-cigs, e-hookahs, mods, vape pens, vapes, tank systems and electronic nicotine delivery systems.”<sup>19</sup> Some e-cigarettes are made to appear like regular cigarettes or cigars, while others closely resemble pens and USB sticks.<sup>20</sup>

---

13. See *infra* note 135 and accompanying text.

14. *Id.*

15. See *infra* note 120 and accompanying text.

16. See *infra* note 136.

17. See *infra* Part III. C.

18. Yvette Brazier, *Are E-Cigarettes a Safe Alternative to Smoking?*, MEDICAL NEWS TODAY (Jun. 25, 2018), <https://www.medicalnewstoday.com/articles/216550.php>.

19. CDC, ABOUT ELECTRONIC CIGARETTES (2018), [https://www.cdc.gov/tobacco/basic\\_information/e-cigarettes/about-e-cigarettes.html](https://www.cdc.gov/tobacco/basic_information/e-cigarettes/about-e-cigarettes.html).

20. *Id.*

Several companies that develop e-cigarettes market their product as a means to help users quit traditional tobacco products or quit smoking altogether.<sup>21</sup>

The first device resembling the modern e-cigarette was created in 1960 by Herbert A. Gilber,<sup>22</sup> and the first commercially successful e-cigarette was created in 2003 by Hon Lik, a Chinese pharmacist.<sup>23</sup> Mr. Lik created the e-cigarette in the hopes that it would be a safer alternative to inhaling nicotine through conventional means after his father passed away from lung cancer.<sup>24</sup> The company for which Mr. Lik developed the e-cigarette, Golden Dragon Holdings, changed its name to Ruyan, which means “like smoke,” and began selling the device all over the world.<sup>25</sup> E-cigarettes were first introduced to America in approximately 2006<sup>26</sup> and grew to 5.5 billion dollars in sales in just 12 years.<sup>27</sup>

Most e-cigarettes contain a battery and heating element to vaporize a liquid which usually contains nicotine, the addictive chemical found in cigarettes and cigars.<sup>28</sup> When the user sucks on the mouthpiece of the device, a sensor activates the heating element, vaporizing the liquid solution and creating an aerosol solution that the user inhales.<sup>29</sup> The solution, known as e-liquid or e-juice, comes in flavors ranging from traditional tobacco flavors to fruity flavors like watermelon.<sup>30</sup> Most e-cigarettes are reusable and have refillable cartridges.<sup>31</sup>

---

21. See JUUL, <https://www.JUUL.com/mission-values> (last visited Feb. 1, 2018) (“We envision a world where fewer people use cigarettes, and where people who smoke cigarettes have the tools to reduce or eliminate their consumption entirely, should they so desire”); see also JOYTECH, <https://www.joyetech.com/news/electronic-cigarette-helps-people-stop-smoking/> (last visited Oct. 12, 2018) (“At a time when the government is ostensibly trying to cut health costs, why is it trying to ban something that might help people quit smoking tobacco, perhaps the most devastating health problem in the U.S.?”).

22. *A Historical Timeline of Electronic Cigarettes*, CONSUMER ADVOCATES FOR SMOKE FREE ALTERNATIVES ASS’N, <http://www.casaa.org/historical-timeline-of-electronic-cigarettes/> (last visited Sept. 14, 2018).

23. *Id.*

24. *Id.*

25. *Id.*

26. *Id.*

27. Nicole M. Kuiper et al., *Trends in Unit Sales of Flavored and Menthol Electronic Cigarettes in the United States, 2012–2016*, 15 PREVENTING CHRONIC DISEASE: PUB. HEALTH RES., PRACTICE AND POL. (2018).

28. CDC, ABOUT ELECTRONIC CIGARETTES (2018), [https://www.cdc.gov/tobacco/basic\\_information/e-cigarettes/about-e-cigarettes.html](https://www.cdc.gov/tobacco/basic_information/e-cigarettes/about-e-cigarettes.html).

29. Yvette Brazier, *Are e-cigarettes a safe alternative to smoking?*, MEDICAL NEWS TODAY (Jun. 25, 2018), <https://www.medicalnewstoday.com/articles/216550.php>.

30. *Id.* Several states, including Michigan and New York, have enacted outright bans on flavored e-cigarettes. See Sheila Kaplan, *Trump Administration Plans to Ban Flavored E-Cigarettes*, N.Y. TIMES (Sept. 19, 2019), <https://www.nytimes.com/2019/09/11/health/trump-vaping.html>. Furthermore, the Trump administration is considering a nationwide ban on flavored e-cigarettes. *Id.*

31. See Brazier, *supra* note 29.

### B. JUUL Takes Over the E-Cigarette Market

One year after Hon Lik developed the modern e-cigarette, Stanford product-design graduate students Adam Bowen and James Monsees began developing their own e-cigarette.<sup>32</sup> Bowen and Monsees smoked traditional tobacco products for many years, and sought to create a viable alternative to cigarettes.<sup>33</sup> In 2012, their first company, Ploom, developed the Pax, an e-cigarette roughly the shape and size of an iPhone and selling for approximately \$250.<sup>34</sup> After selling the Ploom brand in 2015, Bowen and Monsees rebranded the company as Pax Labs<sup>35</sup> and began working on what would be their most successful device, the JUUL.<sup>36</sup>

Unlike most vaping devices which were “unattractively large or required users to monitor finicky temperature settings, coils, and wicks,”<sup>37</sup> Bowen and Monsees’s creation, the JUUL, is simple and small<sup>38</sup>—roughly the shape and size of a USB flash drive.<sup>39</sup> The device avoids the glowing tip of a cigarette because “they wanted people who used the JUUL to feel as if they were doing something new.”<sup>40</sup>

The company used focus groups with longtime smokers to develop a “flavor strategy” which includes “a tobacco profile, a mint profile, a fruit profile, [and] a dessert profile.”<sup>41</sup> A JUUL “starter” kit, which includes a rechargeable JUUL device, a USB charger, four pods with the company’s four main flavor profiles,<sup>42</sup> and a one year warranty sells for approximately \$20.<sup>43</sup> A pack of four flavor pods costs approximately \$16,<sup>44</sup> with each pod lasting for approximately 200 puffs, or the equivalent of one pack of cigarettes.<sup>45</sup> Using a JUUL can be cheaper than smoking conventional

---

32. See Jia Tolentino, *The promise of Vaping and the Rise of JUUL*, NEW YORKER (May 7, 2018), <https://www.newyorker.com/magazine/2018/05/14/the-promise-of-vaping-and-the-rise-of-juul>.

33. OUR STORY, <https://www.JUUL.com/our-story> (last visited Oct. 11, 2018).

34. David H. Freedman, *How you Sell a Product When You Can’t Really Say What it Does?*, INC., <https://www.inc.com/magazine/201405/david-freedman/james-monsees-ploom-ecigarette-company-marketing-dilemma.html>.

35. See *JTI Buys Ploom Name and Product; Ploom becomes Pax Labs*, TOBACCO REPORTER (Feb. 16, 2015), <https://www.tobaccoreporter.com/2015/02/jti-buys-ploom-name-and-product-ploom-becomes-pax-labs/>.

36. See Tolentino, *supra* note 32.

37. *Id.*

38. *Id.*

39. CDC, E-CIGARETTES SHAPED LIKE USB FLASH DRIVES: INFORMATION FOR PARENTS, EDUCATORS, AND HEALTH CARE PROVIDERS (2019), <https://www.cdc.gov/tobacco/infographics/youth/pdfs/e-cigarettes-usb-flash-508.pdf>.

40. See Tolentino, *supra* note 32.

41. *Id.*

42. *Id.*

43. STARTER KIT, <https://www.JUUL.com/shop/devices/starter-kit> (last visited Oct. 12, 2018).

44. Hayley Peterson, *‘I Go Crazy If I Don’t Have It’: American Teens Are Going Wild Over an Addictive E-Cigarette Developed by Stanford Graduates*, BUSINESS INSIDER (Mar. 5, 2018, 11:14 AM), <https://www.businessinsider.com/juul-e-cigarettes-are-taking-over-high-schools-2018-3>.

45. *Id.*; However, the amount of nicotine in each pod is disputed. See JUUL, <https://www.juul.com/calculator> (last visited Oct 4. 2019) (explaining that the a JUUL pod’s nicotine content gives an equivalent yield to a

cigarettes as it is not subject to the high cigarette taxes found in places like New York, New England, and Chicago.<sup>46</sup>

An innovation that had a substantial impact on the success of Bowen and Monsees' device was the use of nicotine salts as the core ingredient in their liquid-nicotine juice.<sup>47</sup> Prior to the launch of the JUUL, e-cigarette brands were not creating many return customers because the sensation of smoking an e-cigarette did not compare to the sensation of smoking a traditional cigarette.<sup>48</sup> The JUUL solved this problem by using a liquid that contains nicotine salts.<sup>49</sup> The body absorbs nicotine salts at almost the same speed as nicotine in regular cigarettes, "delivering a hit of nicotine similar to that of a traditional cigarette."<sup>50</sup> Unlike cigarette smoke, however, which causes irritation to the chest and lungs when inhaled, the vapor created by nicotine salts goes down smoothly.<sup>51</sup>

These innovations have contributed to the JUUL's tremendous commercial success. JUUL represents over 50 percent of sales in the e-cigarette traditional retail market despite only being launched in 2015.<sup>52</sup> JUUL Labs, which was spun off from the parent company Pax Labs in 2017, was recently valued at \$15 billion.<sup>53</sup> JUUL Labs' year-over-year sales, ending June 16, 2018, grew 783 percent, reaching approximately \$942.6 million.<sup>54</sup> In the same period, e-cigarette sales as a whole grew 97 percent to \$1.96 billion.<sup>55</sup> In 2018, JUUL Labs raised \$1.2 billion in a financing round to help fund an international expansion.<sup>56</sup> However, international expansion

---

pack of cigarettes). *But see* Tiku, *supra* note 2 (citing James F. Pankow et. al., *Benzene Formation in Electronic Cigarettes*, PLOS, (Mar. 8, 2017) (arguing that "JUUL may deliver higher levels of nicotine than advertised.")).

46. *See* Tolentino, *supra* note 32.

47. Ryan Lawler, *Vaporization Startup Pax Labs Introduces JUUL, Its Next-Gen E-Cigarette*, TECH CRUNCH (Apr. 21, 2015), <https://techcrunch.com/2015/04/21/pax-JUUL/>.

48. *Id.*

49. Julia Belluz, *JUUL, The Vape Device Teens Are Getting Hooked On, Explained*, VOX (Aug. 22, 2018, 5:44 PM), <https://www.vox.com/science-and-health/2018/5/1/17286638/JUUL-vaping-e-cigarette>.

50. *Id.*

51. *Id.*

52. *See What's the Hype? JUUL Electronic Cigarette's Popularity with Youth & Young Adults*, PUBLIC HEALTH LAW CENTER, <http://www.publichealthlawcenter.org/sites/default/files/JUUL-Webinar-Slides-Apr262018.pdf> (last visited Oct. 4, 2019)).

53. Angelica LaVito, *Popular E-Cigarette JUUL's Sales Have Surged Almost 800 Percent Over the Past Year*, CNBC (Sep. 11, 2018, 2:24 PM), <https://www.cnbc.com/2018/07/02/juul-e-cigarette-sales-have-surged-over-the-past-year.html>.

54. *Id.*

55. *Id.*

56. Olivia Zaleski, *E-Cigarette Maker JUUL Labs is Raising \$1.2 Billion*, BLOOMBERG (June 29, 2018, 5:22 PM), <https://www.bloomberg.com/news/articles/2018-06-29/e-cigarette-maker-JUUL-labs-is-raising-1-2-billion>.

may be difficult in some parts of the world as the JUUL is banned in the European Union and Israel due to health concerns.<sup>57</sup>

*C. The Tremendous Growth of E-Cigarettes leads to Increased Scrutiny*

The success of e-cigarettes like JUUL has led to increased public scrutiny of the products' safety.<sup>58</sup> At the direction of Congress, the FDA commissioned the National Academies of Sciences, Engineering and Medicine ("NAS")<sup>59</sup> to conduct a study to help inform future regulations on the product.<sup>60</sup> The NAS analyzed the findings of 800 peer-reviewed studies on the health effects of e-cigarettes, leading to mixed conclusions regarding the safety of the product.<sup>61</sup>

One positive finding revealed in the NAS study was that "completely substituting e-cigarettes for combustible tobacco cigarettes reduces users' exposure to numerous toxicants and carcinogens present in combustible tobacco cigarettes."<sup>62</sup> This finding prompted former FDA commissioner Scott Gottlieb to state that there is a place for e-cigarettes in the US market even though some of the findings in the study are worrisome.<sup>63</sup>

The NAS study did not find enough evidence to conclude that e-cigarettes help users of conventional tobacco products quit smoking.<sup>64</sup> This finding was based on the strength of the evidence available to them.<sup>65</sup> With only three experimental studies using randomized controlled trials to work with, the NAS concluded that there was "insufficient evidence that e-cigarettes can help people quit smoking."<sup>66</sup> In observational studies, which carry less weight than the experimental studies, the NAS did find "moderate evidence . . . that more frequent use of e-cigarettes is associated with increased likelihood of cessation."<sup>67</sup> Taken together, however, the NAS

---

57. Dan Williams, *Israel Bans JUUL E-Cigarettes Citing 'Grave' Public Health Risk*, REUTERS (Aug. 21, 2018, 2:48 PM), <https://www.reuters.com/article/us-ecigarettes-israel/israel-bans-JUUL-e-cigarettes-citing-grave-public-health-risk-idUSKCN1L61YW>.

58. See Kathleen Stratton, et al., *Public Health Consequences of E-Cigarettes*, THE NATIONAL ACADEMIES OF SCIENCES ENGINEERING MEDICINE CONSENSUS STUDY REPORT, JAN. 23, 2018 ["Hereinafter referred to as "NAS Study"].

59. Press Release, FDA, FDA In Brief: National Academies of Sciences, Engineering, and Medicine releases FDA-commissioned report on the potential public health consequences of e-cigarettes (Jan. 23, 2018) (on file with author).

60. See Stratton, *supra* note 58.

61. Julia Belluz, *4 Big Takeaways from the Most Comprehensive Report on E-Cigarettes Yet*, VOX (Jan. 22, 2018, 2:18 PM), <https://www.vox.com/science-and-health/2018/1/23/16923070/nas-report-e-cigarettes-health-risks>.

62. See Belluz, *supra* note 61.

63. *Id.*

64. *Id.*

65. *Id.*

66. *Id.*

67. See Belluz, *supra* note 61.



concluded there is insufficient evidence to support the assertion that e-cigarettes help users quit smoking.<sup>68</sup>

Though the NAS study made no findings on the long-term health impacts of e-cigarette use,<sup>69</sup> e-cigarettes have been the alleged cause of hypersensitivity pneumonitis, or “wet lung,” a condition that can lead to respiratory failure.<sup>70</sup> E-cigarettes that use diacetyl in their e-liquid have been the alleged cause of bronchiolitis obliterans, or popcorn lung,<sup>71</sup> a condition that can cause lasting respiratory damage.<sup>72</sup> A 2015 study by *The England Journal of Medicine* indicated that formaldehyde, a carcinogen, was detected in e-juice when heated at high voltage.<sup>73</sup>

The immense popularity of JUULs among students in middle and high schools has led to growing concerns amongst public health officials.<sup>74</sup> In 2018, the National Institute on Drug Abuse released its findings that 37 percent of 12th graders reported using a vaping device at least once in the past 12 months.<sup>75</sup> Most teens, however, were not aware that JUUL pods contained nicotine,<sup>76</sup> a chemical that “is highly addictive and may harm the developing teenage brain by increasing the risk of

---

68. *Id.*

69. *Id.* Since the NAS Study was published, vaping related illnesses have prompted the Centers for Disease Control and Prevention and the U.S. Food and Drug Administration to issue warnings on using these products. See *Outbreak of Lung Injury Associated with E-cigarette Use, or Vaping*, CDC (Oct. 3, 2019, 4:00 PM), [https://www.cdc.gov/tobacco/basic\\_information/e-cigarettes/severe-lung-disease.html#latest-outbreak-information](https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html#latest-outbreak-information) (as of October 1, 2019, there have been 1,080 cases of lung injury and 15 confirmed deaths from the use of e-cigarette or other vaping products in the United States); see also *Lung Illnesses Associated with Use of Vaping Products*, FDA, <https://www.fda.gov/news-events/public-health-focus/lung-illnesses-associated-use-vaping-products> (last visited Oct. 6, 2019) (“[b]oth the U.S. Food and Drug Administration and the U.S. Centers for Disease Control and Prevention are working tirelessly to investigate the distressing incidents of severe respiratory illness associated with use of vaping products.”).

70. See Casey G. Sommerfeld, et al., *Hypersensitivity Pneumonitis and Actus Respiratory Distress Syndrome from E-Cigarette Use*, PEDIATRICS, Jun. 28, 2017).

71. See Tolentino, *supra* note 32.

72. *What Is Popcorn Lung?*, WEBMD, <https://www.webmd.com/lung/popcorn-lung#2> (last visited Oct 18, 2018).

73. See R. Paul Jensen, et al. *Hidden Formaldehyde in E-Cigarette Aerosols*, THE NEW ENGLAND JOURNAL OF MEDICINE, (2015). But see Toni Clarke, *Ramping Up E-Cigarette Voltage Produces More Dangerous Formaldehyde*, SCIENTIFIC AMERICAN, <https://www.scientificamerican.com/article/ramping-up-e-cigarette-voltage-produces-more-dangerous-formaldehyde/> (explaining that critics of this study are not convinced of the risk because “most “vapers” do not push the voltage to the levels seen in the study as the taste would become unpalatable.”).

74. See Peterson, *supra* note 44.

75. Moriah Balingit, *In the ‘Juul room’: E-cigarettes spawn a form of teen addiction that worries doctors, parents and schools*, WASH POST (July 26, 2019), [https://www.washingtonpost.com/local/education/helpless-to-the-draw-of-nicotine-doctors-parents-and-schools-grapple-with-teens-addicted-to-e-cigarettes/2019/07/25/e1e8ac9c-830a-11e9-933d-7501070ee669\\_story.html](https://www.washingtonpost.com/local/education/helpless-to-the-draw-of-nicotine-doctors-parents-and-schools-grapple-with-teens-addicted-to-e-cigarettes/2019/07/25/e1e8ac9c-830a-11e9-933d-7501070ee669_story.html).

76. See Anna Edney, *Teens say they don’t vape, they ‘Juul.’ That makes the activity hard to track*, LOS ANGELES TIMES (Apr. 29, 2019), <https://www.latimes.com/business/la-fi-juul-vape-ecigarette-suorin-20190429-story.html> (the Truth Initiative, an anti-tobacco group, found that 63% of Juul users ages 15 to 24 were unaware the product contained nicotine).

attention problems and depression.”<sup>77</sup> Furthermore, teens who use e-cigarettes are more likely to try conventional cigarettes.<sup>78</sup> This comes at a time when youth smoking rates have been falling in recent years.<sup>79</sup>

Former FDA commissioner Scott Gottlieb sounded a more worrisome tone in a September 2018 public statement compared to his reaction to the NAS study. In the statement, he referred to the rise in adolescent use of and addiction to e-cigarettes as an “epidemic.”<sup>80</sup> He further elaborated that, “[e]-cigs have become an almost ubiquitous — and dangerous trend among teens. The disturbing and accelerating trajectory of use we’re seeing in youth, and the resulting path to addiction, must end.”<sup>81</sup>

To combat the dramatic rise in the use of e-cigarettes by teens, the FDA sent notices to five e-cigarette manufacturers whose products represent more than ninety-seven percent of the market for e-cigs, including JUUL Labs.<sup>82</sup> The notice required these companies to come up with a plan to combat the widespread use of their products by minors in sixty days or face increased regulatory enforcement.<sup>83</sup> As a response, JUUL Labs announced it would suspend all social media promotions and the sale of most of its flavored pods in retail stores.<sup>84</sup> However, Commissioner Gottlieb responded in a Tweet, stating “[v]oluntary action is no substitute for regulatory steps . . . But we want to recognize actions by JUUL today and urge all manufacturers to immediately implement steps to start reversing these trends.”<sup>85</sup>

---

77. Zen Vuong, *Teens Who Vape Higher Doses of Nicotine Are More Likely to Become Regular Smokers*, USC News (Oct. 23, 2017), <https://news.usc.edu/130102/teens-who-vape-higher-doses-of-nicotine-are-more-likely-to-become-regular-smokers/>.

78. See *Teens and E-Cigarettes*, NAT’L INST. ON DRUG ABUSE, <https://www.drugabuse.gov/related-topics/trends-statistics/infographics/teens-e-cigarettes> (last visited Oct. 6, 2019) (“30.7 percent of e-cig users started smoking within 6 months while 8.1 percent of non-users started smoking. Smoking includes combustible tobacco products (cigarettes, cigars, and hookahs”); see also Belluz, *supra* note 61 (“[t]he evidence base was large enough and consistent enough and strong enough to conclude that there’s an association between e-cigarette use and ever-use of combustible tobacco”).

79. See Belluz, *supra* note 61.

80. See U.S. FOOD & DRUG ADMIN., STATEMENT FROM FDA COMMISSIONER SCOTT GOTTLIEB, M.D., ON NEW STEPS TO ADDRESS EPIDEMIC OF YOUTH E-CIGARETTE USE (2018).

81. *Id.*

82. *Id.*

83. *Id.*

84. Sheila Kaplan & Jan Hoffman, *JUUL Suspends Selling Most E-Cigarette Flavors in Stores*, N.Y. TIMES (Nov. 13, 2018), <https://www.nytimes.com/2018/11/13/health/juul-ecigarettes-vaping-teenagers.html>. Recently, JUUL Labs suspended all product advertisements and will refrain from lobbying against a proposed ban on its flavored products. Laurie McGinley, *Juul says its chief executive is stepping down, accepts proposed ban on flavored vaping products*, WASH. POST (Sept. 25, 2019), [https://www.washingtonpost.com/health/juul-announces-it-is-replacing-chief-executive-accepting-proposed-ban-on-most-flavored-vaping-products/2019/09/25/563ee81e-df8a-11e9-b199-f638bf2c340f\\_story.html](https://www.washingtonpost.com/health/juul-announces-it-is-replacing-chief-executive-accepting-proposed-ban-on-most-flavored-vaping-products/2019/09/25/563ee81e-df8a-11e9-b199-f638bf2c340f_story.html).

85. Scott Gottlieb (@SGottliebFDA), TWITTER. (Nov. 13, 2018, 2:52 PM), <https://twitter.com/SGottliebFDA/status/1062432968277397504>.

Amidst the growing concern from parents, health officials, and the FDA on the rise in teenage usage of e-cigarettes, JUUL Labs now faces a class action lawsuit alleging it deceived users into thinking the product was a safer alternative to conventional cigarettes.<sup>86</sup> To give historical context to the arguments in the class action lawsuit *Colgate v. JUUL Labs*, the next section in this comment will examine the history of tobacco product litigation and regulation.

## II. A HISTORY OF TOBACCO PRODUCT LITIGATION AND REGULATION

### A. *The Regulation of “Reduced Risk” Cigarettes*

In the early 1950’s, a growing body of scientific literature asserted that the usage of tobacco products increased the possibility of fatal health risks such as lung cancer.<sup>87</sup> The tobacco industry responded by developing filtered cigarettes and advertising these products as a healthier alternative.<sup>88</sup> However, the tobacco industry eventually moved away from explicit health claims regarding filtered cigarettes in favor of subtler tactics to imply their product was healthier.<sup>89</sup> Advertising tactics such as labeling their cigarettes as “light” or “low tar” would result in decades of litigation as addicted consumers sought to hold the industry accountable for their deceptive marketing.<sup>90</sup>

The 1964 Surgeon General report ushered in several new laws that had a significant impact on the success of consumer litigation against tobacco manufacturers. Many consumers of tobacco products first became aware of the dangerous health consequences of using these products after the 1964 Surgeon General report found evidence of a substantial link between fatal health risks such as lung cancer and cigarette usage.<sup>91</sup> As a result of the report, Congress passed the FCLAA which required cigarette packages to contain warnings about the adverse health effects of

---

86. See Tiku, *supra* note 2.

87. See Tara Parker-Pope, “Safer” Cigarettes: A History, PBS (Oct. 2, 2001), <https://www.pbs.org/wgbh/nova/article/safer-cigarettes-history/>.

88. See Richard W. Pollay & Timothy Dewhirst, *The Dark Side of Marketing Seemingly “Light” Cigarettes: Successful Images and Failed Fact*, 11 TOBACCO CONTROL 18, 18 (2002) (explaining that tobacco companies advertised filters as scientific breakthroughs, and even implied in their advertisements that these filters were endorsed by the American Medical Association).

89. *Id.*

90. See generally *id.* (discussing the tobacco industries’ use of dubious health claims to convince wary consumers their product is safe); see “Light” Cigarettes and Cancer Risk, NAT’L CANCER INST, <https://www.cancer.gov/about-cancer/causes-prevention/risk/tobacco/light-cigarettes-fact-sheet> (last visited Oct. 12, 2019) (although many smokers chose light cigarettes because they believed it would be less harmful to their health, light cigarettes are no safer than regular cigarettes).

91. See Pollay, *supra* note 88. See *Smoking & Tobacco Use A Brief History*, CDC, [https://www.cdc.gov/tobacco/data\\_statistics/sgr/history/index.htm](https://www.cdc.gov/tobacco/data_statistics/sgr/history/index.htm) (last visited Sept. 26, 2019) (the 1964 Surgeon General report concluded that cigarette smoking causes lung cancer and chronic bronchitis).

smoking.<sup>92</sup> To overcome the issue of inconsistent state labeling requirements, the FCLAA prohibited the requirements of additional statements relating to smoking and health on cigarette packages.<sup>93</sup>

In the absence of federal action, several states such as California prepared regulations that would restrict or outright ban print and electronic cigarette advertisements.<sup>94</sup> In keeping with the declared purpose of the FCLAA to promote uniform labeling and advertising measures,<sup>95</sup> Congress enacted the Public Health Cigarette Smoking Act of 1969 (“the 1969 Act”).<sup>96</sup> The 1969 Act required tobacco companies to change the warnings on cigarette packages from cigarettes “may be hazardous” to smoking is “dangerous.”<sup>97</sup> Furthermore, the 1969 Act’s modified preemption provision replaced the FCLAA’s with the following language: “[n]o requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes that packages of which are labeling in conformity with the provisions of this Act.”<sup>98</sup>

In the years prior to the Supreme Court’s decision in *Cipollone v. Liggett Group, Inc.* the preemption provision in the 1969 Act was interpreted by courts to give tobacco companies insurmountable defenses for product liability claims.<sup>99</sup> Tobacco companies successfully argued that Congress intended to preempt different forms of state regulation with the new language of the 1969 Act.<sup>100</sup> If that argument failed, tobacco companies were successful in arguing that tobacco users were adequately warned of the risk of smoking by Congress.<sup>101</sup>

#### B. Defining the Scope of the FCLAA

##### 1. *Cipollone v. Liggett Group, Inc.*

The Supreme Court addressed the scope of preemption under the FCLAA in *Cipollone v. Liggett Group*. The plaintiff, the spouse of a lifelong smoker who died of lung cancer, claimed tobacco manufacturer Liggett Group should be held liable for his wife’s death because the company failed to adequately warn consumers about the

---

92. See 15 U.S.C.A. § 1331.

93. *Altria v. Good*, 129 U.S. 70, 78 (2008).

94. *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 515 n.11 (1992).

95. 15 U.S.C.A. § 1331(2).

96. *Cipollone*, 505 U.S. at 515 (1992).

97. See *Cipollone*, 505 U.S. at 515 (1992).

98. 15 U.S.C.A. § 1334(b).

99. See Sam F. Halabi, *The Scope of Preemption under the 2009 Family Smoking and Tobacco Control Act*, 71 FOOD & DRUG L.J. 300, 305 (2016) (“When Congress changed the warning from cigarettes “may be hazardous” to smoking “is dangerous” they also broadened the scope of the federal warning requirement’s preemptive effect on state law.”).

100. *Id.*

101. *Id.*

hazards of smoking its product.<sup>102</sup> The Court held that while both the 1965 and 1969 Acts preempted states from regulating advertisements relating to smoking and health,<sup>103</sup> a manufacturer's duty to not deceive consumers was not intended to be preempted by the Acts.<sup>104</sup> The result of this decision was that plaintiffs could now successfully claim the tobacco manufacturers deceived them into thinking its product was safe, survive summary judgment, and let a jury decide the merit of their claims.<sup>105</sup>

2. *Altria Group, Inc. v. Good*

*Altria Group Inc. v. Good* further defined the relationship between the FCLAA and tobacco litigation involving state law tort claims. The question faced by the Supreme Court was whether the FCLAA preempted a claim of false advertisement under the Maine Unfair Trade Practices Act ("MUTPA").<sup>106</sup> The plaintiffs, longtime smokers of Marlboro Lights and Cambridge Lights cigarettes, alleged that the tobacco manufacturer Altria Group violated MUTPA because it advertised the unfounded claim that its "light" cigarette delivered less harmful chemicals like tar and nicotine than regular brands.<sup>107</sup> The District Court granted summary judgment to Altria Group, holding that a state tort failure-to-warn claim is preempted by the FCLAA per the Supreme Court's ruling in *Cipollone*.<sup>108</sup> The Court of Appeals reversed, and the Supreme Court affirmed the decisions of the Court of Appeals.<sup>109</sup>

Justice Stevens, who authored the prior decision of *Cipollone*, explained that the labeling requirement and preemption provisions of the FCLAA "express Congress' determination that the prescribed federal warnings are both necessary and sufficient to achieve its purpose of informing the public of the health consequences of smoking."<sup>110</sup> Consequently, "[s]tates may not impede commerce in cigarettes by enforcing rules that are based on assumption that the federal warnings are inadequate."<sup>111</sup> However, Justice Stevens found that Congress did not intend to preempt

---

102. See *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 508 (1992).

103. See *id.* at 528–29. Justice Stevens explained that "congress' enactment of a provision defining the preemptive reach of a statute implies that matters beyond that reach are not pre-empted." *Id.* at 517.

104. *Id.* at 528–29.

105. See Christopher J. Gagin, *Cipollone v. Liggett Group, Inc.: A Preemptive Lucky Strike?*, 26 AKRON L. REV. 311, 321 (1992) (explaining that plaintiffs claiming tobacco related health injuries still faced obstacles at trial, such as convincing a jury they did not assume the risk, and competing with the vast legal resources at tobacco companies' disposal).

106. *Altria Group, Inc. v. Good*, 129 U.S. 70, 72–73 (2008).

107. *Id.* at 73.

108. *Id.* at 74–75.

109. *Id.* at 75–76; 91.

110. *Id.* at 79.

111. *Id.*

state tort claims that plaintiffs were induced to purchase the tobacco products by fraudulent claims that they were “light” or had less nicotine.<sup>112</sup>

### 3. *The Passage of the Tobacco Control Act*

Before 2009, restrictions on the sale and use of tobacco products were almost entirely done through state and local regulations.<sup>113</sup> Tobacco was not regulated under federal health and safety laws, including the Food, Drug, and Cosmetic Act, except in the rare circumstances when manufacturers of tobacco products made explicit health claims.<sup>114</sup> In order to give the federal government increased authority to restrict the sale and distribution of unsafe tobacco products, Congress passed the TCA, which adds a new section (Chapter IX) to the Food, Drug, and Cosmetic Act.<sup>115</sup> The TCA gives the FDA authority to regulate new and existing tobacco products, including the ability to “restrict tobacco product marketing and advertising, strengthen cigarette and smokeless tobacco warning labels, reduce federal preemption of certain state cigarette advertising restrictions, and increase nationwide efforts to block tobacco product sales to youth.”<sup>116</sup>

The TCA also enables the FDA to prohibit health claims on tobacco products unless supported by scientific evidence.<sup>117</sup> Section 387k(g) defines any product that makes an explicit health claim as a modified risk tobacco product.<sup>118</sup> The TCA regulates these products, rather than outright banning them, in the hope that harm reduction products could achieve the individual and public health objectives of the law.<sup>119</sup> On May 5, 2016, the FDA released a new rule that extends the FDA’s authority to ENDS, which includes the JUUL.<sup>120</sup>

---

112. Altria Group, Inc., 129 U.S. at 82–83.

113. See Jonathan Gruber, *The Economics of Tobacco Regulation*, 21 HEALTH AFFAIRS 146, 159 (2002) (explaining how states used excise taxes on cigarettes, restrictions on smoking in public places, and age-related restrictions to curb the use of tobacco products).

114. See *Federal Regulation of Tobacco: A Summary*, TOBACCO CONTROL LEGAL CONSORTIUM, July 2009.

115. See *Family Smoking Prevention and Tobacco Control Act – An Overview*, FDA, <https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/family-smoking-prevention-and-tobacco-control-act-overview> (last visited Oct. 12, 2019).

116. *Federal Regulation of Tobacco*, PUB. HEALTH L. CTR., <https://www.publichealthlawcenter.org/topics/commercial-tobacco-control/federal-regulation-tobacco> (last visited Oct. 12, 2019); see Tobacco Control Act, 21 USCA §387k.

117. See Tobacco Control Act, 21 USCA §387k(b)(2)(A).

118. *Id.*

119. See Halabi, *supra* note 99 at 308.

120. See Final Rule, 81 Fed. Reg. 28973 (May 10, 2016).

C. *Preemptive scope of the Tobacco Control Act*

Article VI of the Constitution states that the laws of the United States “shall be the supreme Law of the Land.”<sup>121</sup> When dealing with issues pertaining to the Supremacy Clause, state law is not intended to be superseded by a federal act unless there is a clean and manifest purpose of Congress.<sup>122</sup> The intent of Congress can be found explicitly stated in the language of the statute or implied based on structure and purpose of the act.<sup>123</sup> Without express language to the contrary, state law is preempted if the law conflicts with federal law.<sup>124</sup>

The Supreme Court has identified several ways in which a statute implicitly preempts state law. Impossibility preemption occurs when state and federal law are in direct conflict, making it impossible to comply with both laws.<sup>125</sup> Obstacle preemption results when compliance with both federal and state law is possible, but still imposes an obstacle to compliance with the federal law.<sup>126</sup> Field preemption occurs when the courts determine congress intended to so thoroughly occupy a legislative field as to make reasonable the inference that Congress left no room for the States to supplement it.<sup>127</sup>

In a preemption analysis, courts will consider the preemption clause in a statute.<sup>128</sup> These preemption clauses, typically forbidding states from adopting certain requirements, need to be unambiguous in their restrictions for the court to conclude state law is expressly preempted.<sup>129</sup> Courts will also look at the comprehensiveness of the federal scheme,<sup>130</sup> the opinion of the applicable federal agency, and the agency’s policy objectives.<sup>131</sup>

Section 387p of the TCA titled “Preservation of State and Local Authority” dictates the intent of Congress regarding the preemptive scope of the legislation:

(1) Preservation

Except as provided in paragraph (2)(A), nothing in this subchapter, or rules promulgated under this subchapter, shall be construed to limit the

---

121. U.S. CONST. art. VI, cl. 2.

122. *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992).

123. *Id.*

124. *Id.*

125. *Sprietsma v. Mercury Marine*, 537 U.S. 51, 64 (2002).

126. *See Crosby v. National Foreign Trade Council*, 530 U.S. 363, 372 (2000).

127. *See Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992).

128. *See Halabi, supra* note 99 at 313.

129. *See e.g., Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 146–147 (1963) (explaining that the California statute in question would not be preempted without “an unambiguous congressional mandate to that effect.”).

130. *See Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947) (“federal regulation may be so pervasive as to make reasonable the inference that Congress left no room for the States.”).

131. *See Halabi, supra* note 99 at 313.

authority of a Federal agency (including the Armed Forces), a State or political subdivision of a State, or the government of an Indian tribe to enact, adopt, promulgate, and enforce any law, rule, regulation, or other measure with respect to tobacco products that is in addition to, or more stringent than, requirements established under this subchapter, including a law, rule, regulation, or other measure relating to or prohibiting the sale, distribution, possession, exposure to, access to, advertising and promotion of, or use of tobacco products by individuals of any age, information reporting to the State, or measures relating to fire safety standards for tobacco products. No provision of this subchapter shall limit or otherwise affect any State, tribal, or local taxation of tobacco products.

(2) Preemption of certain State and local requirements

No State or political subdivision of a State may establish or continue in effect with respect to a tobacco product any requirement which is different from, or in addition to, any requirement under the provisions of this subchapter relating to tobacco product standards, premarket review, adulteration, misbranding, labeling, registration, good manufacturing standards, or modified risk tobacco products.<sup>132</sup>

The findings of the Federal Trade Commission (“FTC”) played an important role in the language of the preemption scope of the TCA. The FTC found that “consumers have misinterpreted advertisements in which one product is claimed to be less harmful than a comparable product, even in the presence of disclosures and advisories intended to provide clarification.”<sup>133</sup> The TCA purports to fix this issue by unifying what the tobacco industry can and cannot say on their labels.<sup>134</sup>

This language led many scholars to believe that the statute should not be read as preempting state tort and consumer protection laws.<sup>135</sup> This would allow states to implement a broad range of protections to combat the use of tobacco products. What was less certain, however, was the scope of constitutional preemption for conventional products under the TCA would apply to the same extent for ENDS.<sup>136</sup> The full preemptive scope of the TCA in regards to ENDS was addressed by the District Court’s decision on JUUL Labs’ Motion to Dismiss in the class action suit *Colgate v. JUUL Labs, Inc.*<sup>137</sup>

---

132. Tobacco Control Act, 21 U.S.C.A. §387p (2009).

133. Tobacco Control Act, Public Law 111-31 [H.R. 1256] Section 2 Findings 7 and 8 para. 41.

134. See *supra* note 117 and accompanying text.

135. See Halabi, *supra* note 99 at 326 (discussing how the most loyal interpretation of the TCA is that it was drafted “to apply to a narrow class of state regulatory mechanisms like parallel and confliction review of an MRTP label.”).

136. See *generally id.* (discussing the possible preemptive scope of modified risk tobacco products under the TCA).

137. See *infra* Part III.



### III. THE PREEMPTIVE SCOPE OF THE TCA

#### A. *Colgate v. JUUL Labs, Inc.*

This class action lawsuit was filed in the United States District Court for the Northern District of California on April 26, 2018.<sup>138</sup> The lead plaintiffs, Bradley Colgate of La Jolla, California and Kaytlin McKnight of Arroyo Grande, California, claim they each used several JUUL pods a week after becoming addicted to the nicotine salts.<sup>139</sup> Colgate alleges he purchased the JUUL device to help him quit conventional cigarettes, but was unable to because “[t]he intense dosage of nicotine salts delivered by the JUUL products resulted in an increased nicotine addiction, and an increased consumption of nicotine by Colgate.”<sup>140</sup>

In the complaint, the plaintiffs alleged JUUL Labs’ marketing targeted adolescents, which had the foreseeable effect of causing adolescents to use their product.<sup>141</sup> The complaint alleges JUUL Labs’ advertisements, which featured young, attractive models in Times Square billboards, magazines spreads, and social media promotions, were “specifically aimed at convincing young people who were not previously cigarette smokers to purchase JUUL, to make the use of JUUL appear fun and without long-term negative consequences, to position the JUUL e-cigarette as the e-cigarette of choice for young adults, and to attract even younger persons who were not adults to the “hipness” of using the JUUL product.”<sup>142</sup> The Complaint alleges JUUL Labs’ non-tobacco store retail locations are specifically situated near high schools to increase the chances adolescents see the product.<sup>143</sup> Furthermore, the Complaint alleges that the selection of fruity flavors offered by JUUL has the foreseeable consequence of appealing to adolescents.<sup>144</sup> Plaintiffs point to several studies that indicate adolescents are more likely to use a flavored e-cigarette because it hides the unpleasant characteristic of cigarette smoke.<sup>145</sup>

The Complaint cites several studies that indicate JUUL’s e-cigarette delivers a higher, faster dose of nicotine than a traditional cigarette, even though the company advertised the dose was equivalent.<sup>146</sup> One study indicated that the nicotine salts used by JUUL caused more than “20 percent more nicotine to enter the blood than a Pall Mall cigarette.”<sup>147</sup> The Complaint also states that JUUL Labs’ advertisement claiming its product is a safer alternative to cigarettes is misleading because

---

138. See Tiku, *supra* note 2.

139. Pl. Compl. 18.

140. *Id.*

141. *Id.* at 11.

142. *Id.* at 8.

143. *Id.* at 8–9.

144. Pl. Compl. 11.

145. *Id.*

146. *Id.* at 13.

147. *Id.*

the product still poses adverse health risks, including increased vulnerability to nicotine addiction.<sup>148</sup>

Plaintiffs' Complaint alleged 11 causes of action against JUUL; "(1) False Advertising; (2) Violation of Consumers Legal Remedies Act, California Civil Code §§ 1750, et seq., and similar laws of other states; (3) Fraud; (4) Unfair, Unlawful and Deceptive Trade Practices, Business and Professions Code § 17200 and similar laws of other states; (5) Unjust Enrichment, (6) Strict Liability — Failure to Warn; (7) Strict Product Liability — Design Defect; (8) Strict Liability — Manufacturing Defect; (9) Breach of Implied Warranty of Merchantability; (10) Breach of Express Warranty; and (11) Negligent Misrepresentation."<sup>149</sup>

*B. The Motion to Dismiss Ruling*

JUUL Labs argued that the plaintiffs' claims alleging JUUL should be held liable for failing to warn consumers that nicotine salts were more addictive should be dismissed because JUUL met the labeling standards outlined in 21 C.F.R. § 1143.3(a)(1) and 21 C.F.R. § 1143.3(a)(2).<sup>150</sup> JUUL Labs alleged that this is all that was required because the TCA's preemption provision explicitly states that local and state jurisdictions may not make any labeling requirement that differs from the provisions in the TCA.<sup>151</sup>

To determine the scope of preclusion under the TCA, the District Court analyzed the language of §387p with the labeling requirements promulgated by the FDA in 21 C.F.R. § 1143.3(a)(1) and 21 C.F.R. § 1143.3(a)(2).<sup>152</sup> The District Court concluded that congress intended the TCA to expressly preempt labeling requirements on ENDS packaging.<sup>153</sup> The District Court found that that the FDA "unambiguously put forth the required language of the nicotine warning label . . . [and] through its authority under the TCA has prescribed the precise language and placement of warning labels on covered tobacco products such as ENDS."<sup>154</sup>

Furthermore, the District Court concluded that under the TCA's preemption provision, "states and political subdivisions of states may not enact labeling requirements or warnings contrary or in addition to those proscribed under 21 C.F.R. §

---

148. *Id.* at 15.

149. *Colgate v. JUUL Labs, Inc.*, 345 F. Supp. 3d 1178, 1186 (N.D. Cal. Oct. 30, 2018).

150. *See id.* at 1188 (citing 21 C.F.R. § 1143.3(a)(2) ("The FDA Rule contains strict requirements for how the warning is displayed, including, among other things, that it "must appear directly on the package, be clearly visible underneath any cellophane or other clear wrapping; . . . be located in a conspicuous and prominent place on the two principal display panels of the package and the warning area must comprise at least 30 percent of each of the principal display panels; and . . . must be in at least 12-point font size [with] the required warning statement [occupying] the greatest possible proportion of the warning area set aside for the required text)."

151. *See id.* at 1186.

152. *Id.* at 1187.

153. *Id.* at 1888.

154. *Id.*

1143.3(a)(1)(2).<sup>155</sup> As a result, the District Court held that plaintiffs' claims regarding JUUL Labs failure "to warn consumers that JUUL's nicotine formulation is more addictive than other methods of nicotine" is expressly preempted.<sup>156</sup>

The District Court also analyzed the exception clause of § 387p(2)(B)<sup>157</sup> and concluded the TCA does not preempt a claim for fraudulent or misleading advertisements.<sup>158</sup> This means that plaintiffs' claim alleging each JUUL pod actually contains the equivalent nicotine dose of 24 cigarettes instead of 20 as advertised survives JUUL's motion to dismissal because, if true, plaintiffs have legitimate claims for unjust enrichment, design defect, manufacturing defect, breach of implied warranty of merchantability, and negligent misrepresentation.<sup>159</sup>

### *C. The Future of JUUL and the E-Cigarette Industry*

The District Court's ruling is consistent with Congress' intent for the TCA to work along-side state regulatory schemes to provide effective oversight of the tobacco's industries practices.<sup>160</sup> Interpreting the TCA as not preempting a broad range of state tort claims is also consistent with Congress' understanding of the role private litigation has played in exposing the deceptions promulgated by the tobacco industry.<sup>161</sup> Although the ruling is consistent with Congress' intent to allow state law actions, it also highlighted a weakness of the TCA in its ability to effectively warn consumers of the unique dangers of ENDS.

Although JUUL Labs could still be held liable for misrepresenting how much nicotine is in their product, the *Colgate* decision means states cannot force JUUL Labs to alter its warning labels on the JUUL to reflect the correct amount of nicotine. This could have significant consequences as most teenage consumers are not aware JUUL has nicotine, let alone the possibility that it contains more nicotine than cigarettes.<sup>162</sup> While it is possible this lack of knowledge results from JUUL's advertising on social media and other platforms frequented by youths, the lack of sufficient warnings on the products could also play a factor. However, unless the labeling

---

155. *Colgate*, 345 F. Supp. 3d at 1187.

156. *Id.* at 1190.

157. See Tobacco Control Act §387p(a)(2)(B) ("[The preemption clause] does not apply to requirements relating to the sale, distribution, possession, information reporting to the State, exposure to, access to, the advertising and promotion of, or use of, tobacco products by individuals of any age, or relating to fire safety standards for tobacco products.").

158. *Colgate v. JUUL Labs, Inc.*, 345 F. Supp. 3d 1178, 1190 (N.D. Cal. October 30, 2018).

159. See *id.* at 1189–1190.

160. See H.R. Con. Res. 1256, 111th Cong., (2009)(enacted) ("a State or locality may enact statutes and promulgate regulations, based on smoking and health, that take effect after the effective date of the Family Smoking Prevention and Tobacco Control Act, imposing specific bans or restrictions on the time, place, and manner, but not content, of the advertising or promotion of any cigarettes.").

161. See Halabi, *supra* note 99 at 326.

162. See Edney, *supra* note 76 and accompanying text.

requirements are changed, states cannot force JUUL Labs to warn consumers of the unique dangers of the JUUL on the product's label.

The future for JUUL Labs and ENDS in general is uncertain. Although JUUL Labs has altered many of its advertising practices, and support regulations banning its own flavored products,<sup>163</sup> the company is still looking to continue its explosive growth. In December 2018, Altria Group, the owners of Marlboro cigarette manufacture, Philip Morris USA, injected \$12.8 billion in JUUL Labs in exchange for a 35 percent interest in the company.<sup>164</sup> Former CEO of JUUL Labs, Kevin Burns, commented that while initially skeptical, the partnership with Altria will allow JUUL to "accelerate our success switching adult smokers."<sup>165</sup>

#### CONCLUSION

The explosive growth of electronic cigarettes in general suggests the e-cigarette market will soon overtake a large portion of the tobacco market. Effective regulation of these products is therefore vitally important as their popularity continues to grow and the health effects become better understood. Though the passage of the TCA has given states and the FDA important tools to protect consumers, the District Court's ruling in *Colgate* highlights the limitations of this statute.<sup>166</sup>

---

163. See Kaplan, *supra* note 30.

164. Jordan Crook, *Juul Labs Gets \$12.8 Billion Investment from Marlboro Maker Altria Group*, TECH CRUNCH (Dec. 20, 2018), <https://techcrunch.com/2018/12/20/juul-labs-gets-12-8-billion-investment-from-marlboro-maker-altria-group/>.

165. *Id.*

166. See *supra* III. C.