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## How States and Localities are in a Better Position than the FDA to Address Youth Use of E-Cigarettes

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# HOW STATES AND LOCALITIES ARE IN A BETTER POSITION THAN THE FDA TO ADDRESS YOUTH USE OF E-CIGARETTES

*Kevin Kanavy\**

Introduction.....	606
I. History of FDA and Tobacco Regulation.....	608
II. Rise of Electronic Cigarettes in the U.S. and FDA’s Regulatory Authority.....	610
A. FDA Deems ENDS as Tobacco Products.....	612
B. FDA Exercises Enforcement Discretion.....	613
C. FDA’s Cracks Down on ENDS.....	614
III. State and Local Government Powers under the TCA.....	615
A. Taxation.....	616
B. Increased Age Requirements.....	619
C. Licensing.....	620
Conclusion.....	622

## INTRODUCTION

A recent study published in the *Annals of Internal Medicine* revealed that nearly 10.8 million Americans are currently using e-cigarettes.<sup>1</sup> Their popularity has increased drastically since they came on the market in the mid-2000s.<sup>2</sup> While the Food and Drug Administration (“FDA”) has acknowledged that, in general, they

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<sup>1</sup> Mohammadhassan Mirbolouk et al., *Prevalence and Distribution of E-Cigarette Use Among U.S. Adults: Behavioral Risk Factor Surveillance System, 2016*, *ANNALS OF INTERNAL MEDICINE* (Aug. 2018).

<sup>2</sup> See Jordan Paradise, *No Sisyphean Task: How the FDA Can Regulate Electronic Cigarettes*, 13 *YALE JOURNAL OF HEALTH, POLICY, LAW, AND ETHICS* 1, 17 (2013).

contain far fewer toxic chemicals and cancer causing agents than traditional combustible tobacco products,<sup>3</sup> it has been critical of the perception that they are ‘safer’ because there is little information on their long-term health risks.<sup>4</sup> In order to address this misconception, the FDA initially attempted to regulate electronic nicotine delivery system (“ENDS”) products as medical devices under the Food, Drug, and Cosmetic Act, which has strict requirements for premarket approval for safety and effectiveness.<sup>5</sup> However, the D.C. Circuit ruled that absent overt therapeutic or drug-like claims, ENDS products were considered “tobacco products” to be regulated under the Family Prevention and Tobacco Control Act (“TCA”) of 2009.<sup>6</sup>

Thus, in regulating ENDS as tobacco products under the TCA, the FDA has attempted to strike a balance between ensuring that adults have access to ENDS as a viable alternative to traditional combustible tobacco and sowing caution about their unknown long-term effects. Complicating this delicate balance is the recent surge in underage use of ENDS products.<sup>7</sup> In an effort to address youth use of ENDS products, the FDA has engaged in an “enforcement blitz,” cracking down on ENDS manufacturers and retailers.<sup>8</sup> However, the FDA’s current enforcement policy could result in ENDS products being regulated out of the market,<sup>9</sup> thus leaving adults with no options for an alternative to traditional combustible tobacco. The availability of ENDS products is of the utmost importance to the 10.8 million consumers who use them, due mostly in part to their smoking cessation abilities. Being able to strike a balance between curbing youth use and ensuring these products are available to consumers who need them is paramount. That is why the FDA should take a backseat to state and local

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<sup>3</sup> See CENTER FOR DISEASE CONTROL, ELECTRONIC CIGARETTES INFOGRAPHIC [hereinafter E-CIGARETTES INFOGRAPHIC], [https://www.cdc.gov/tobacco/basic\\_information/e-cigarettes/pdfs/Electronic-Cigarettes-Infographic-p.pdf](https://www.cdc.gov/tobacco/basic_information/e-cigarettes/pdfs/Electronic-Cigarettes-Infographic-p.pdf).

<sup>4</sup> See *id.*

<sup>5</sup> See *Sottera, Inc. v. FDA* 627 F.3d 891, 865 (D.C. 2010).

<sup>6</sup> See *id.*

<sup>7</sup> See Stacey Simon, *FDA Proposes Regulations as Teen E-Cigarette Use Skyrockets 78% in 1 Year*, AM. CANCER SOCIETY (Nov. 21, 2018), <https://www.cancer.org/latest-news/fda-proposes-regulations-as-teen-e-cigarette-use-skyrockets-78-percent-in-1-year.html>.

<sup>8</sup> See Warning Letter from U.S. Food and Drug Admin., 2 (Sept. 12, 2018) [hereinafter Warning Letter], <https://www.fda.gov/media/119669/download>.

<sup>9</sup> *Id.* (FDA requiring Juul to remove flavored products from the market as part of the crackdown).

regulation, which is better equipped to achieve that balance.

Part I of this Article will briefly discuss the history the FDA's attempts to regulate tobacco products. Part II will discuss the rise of ENDS products in the U.S. and the FDA's response to their popularity as a "healthier alternative" to traditional combustible tobacco products. Part III will analyze what powers the TCA grants to state and local governments and examine how state and local governments have exercised their powers under the TCA, demonstrating that they are in a better position to achieve the FDA's goal of ensuring that ENDS products are not used by underage consumers but also available to adults as a viable alternative to traditional combustible tobacco products.

## I. HISTORY OF FDA AND TOBACCO REGULATION

The Food and Drug Administration ("FDA") has long struggled in its efforts to assert regulatory authority over tobacco products. Congress passed The Food, Drug, and Cosmetic Act ("FDCA"), the enabling statute that grants the FDA power to regulate food, drugs, and cosmetic products, in its original form in 1938.<sup>10</sup> In addition to giving the FDA the authority to regulate these areas, the FDA has general discretionary power to determine whether a product is a food, drug, or cosmetic based on the statutory language.<sup>11</sup> The FDA has not, however, enjoyed the same type of deference in its attempts to assert regulatory authority over tobacco products under the FDCA.

In 1996, then FDA Commissioner David Kessler announced that the FDA had determined that nicotine was a drug and therefore fell under the jurisdictional authority of the FDA.<sup>12</sup> The FDCA has a three-pronged definition for what constitutes a "drug": A) articles recognized in the United States Pharmacopoeia; B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease; and C) articles (other than food) intended to affect the structure or function of the body.<sup>13</sup> The FDA reasoned that since nicotine was an addictive substance

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<sup>10</sup> 21 U.S.C. § 301 (1938).

<sup>11</sup> See *U.S. v. Bacto-Unidisk*, 394 U.S. 784 (1969); *National Nutritional Food Ass'n. v. Mathews*, 423 U.S. 827 (1975) (illustrating the Court's deference to the FDA in determining what constitutes a food, drug, or cosmetic under the FDCA).

<sup>12</sup> See *Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents*, 61 Fed. Reg. 44,397 (Aug. 28, 1996) (codified at 21 C.F.R. part. 801 et seq.).

<sup>13</sup> 21 U.S.C. 321(g)(1) (2006).

affecting the “structure or function of the body” and had significant pharmacological effects, it could be regulated as a drug under the statute.<sup>14</sup> Similarly, the FDA determined that cigarettes and smokeless tobacco were drug delivery devices<sup>15</sup> because they constituted “an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, which...was intended to affect the structure or any function of the body”<sup>16</sup> by delivering nicotine to the body. The FDA promulgated a slew of regulations that attempted to address the known health risks of tobacco products and limit youth access.<sup>17</sup> These regulations were met with harsh criticism by the tobacco industry and prompted a challenge of the FDA’s authority to regulate nicotine as a drug, and therefore, cigarettes and smokeless tobacco as drug delivery devices.

In *FDA v. Brown-Williamson*, the Supreme Court addressed the issue of whether or not the FDA had statutory authority to regulate tobacco products under the FDCA.<sup>18</sup> The Court found that the FDA lacked regulatory authority over tobacco products because “Congress specifically intended to exempt tobacco from the FDA’s regulatory purview.”<sup>19</sup> It determined that nothing in the FDCA specifically addressed tobacco products, and given subsequent tobacco-specific legislation, “it was plain that Congress never intended the FDA to regulate tobacco under the FDCA.”<sup>20</sup> Most importantly, however, the Court found that the motivating factor for the drug provisions of the FDCA was to ensure safety and efficacy of drugs prior to market and considering the known health risks of tobacco products, their inherent danger would require the FDA to remove them from the market entirely, “something that Congress surely did not intend.”<sup>21</sup> After the *Brown-Williamson* decision, the FDA withdrew its regulations, leaving the tobacco industry untouched by FDA regulatory authority until Congress acted nine years later

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<sup>14</sup> See Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. 44,397 (Aug. 28, 1996).

<sup>15</sup> See *id.* at 44,402.

<sup>16</sup> 21 USC § 321(h).

<sup>17</sup> See Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. at 44,687 (Aug. 28, 1996).

<sup>18</sup> 529 U.S. 120 (2000).

<sup>19</sup> *Id.* at 121.

<sup>20</sup> *Id.* at 161.

<sup>21</sup> *Id.* at 121-22.

by passing The Family Smoking Prevention and Tobacco Control Act of 2009 ("TCA").<sup>22</sup>

The TCA was Congress's response to the *Brown-Williamson* decision. It amended the FDCA to give the FDA regulatory authority over tobacco products, including cigarettes and smokeless tobacco and their manufacturers.<sup>23</sup> Specifically, the TCA created the Center for Tobacco Products within the FDA,<sup>24</sup> and defined a tobacco product as "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 component, part, or accessory of a tobacco product)."<sup>25</sup> Under the TCA, manufacturers of tobacco products are subject to manufacturing guidelines laid out by the FDA, disclosure of ingredients, health and safety information reporting, and advertising and packaging requirements.<sup>26</sup> These regulations were crucial to the TCA's mission of raising awareness of the adverse health effects of tobacco products, reducing the number of Americans who use tobacco products, and ensuring that underage consumers could not get their hands on them.<sup>27</sup> While the TCA has no doubt contributed to the decline in the number of youth and adults who use traditional tobacco products,<sup>28</sup> the relatively recent advent and increased use of electronic cigarettes has produced a completely new set of regulatory challenges for the FDA.

## II. RISE OF ELECTRONIC CIGARETTES IN THE U.S. AND FDA'S REGULATORY AUTHORITY

The development of e-cigarettes can be traced to Hon Lik, a Chinese pharmacist and inventor who, in 2003, developed the product as an attempt to create safer alternative to traditional cigarettes.<sup>29</sup> Lik's company, Ruyan, is responsible for bringing the

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<sup>22</sup> 21 U.S.C. § 387.

<sup>23</sup> See 21 U.S.C. § 387(a).

<sup>24</sup> See 21 U.S.C. § 387a(e) (2006).

<sup>25</sup> 21 U.S.C. § 201(rr)(1) (2006).

<sup>26</sup> See 21 U.S.C. § 387d-g (2006).

<sup>27</sup> See Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, § 2, 123 Stat. 1776 (2009) (codified as amended in scattered sections of 5 U.S.C., 15 U.S.C., and 21 U.S.C. (2006)).

<sup>28</sup> See CDC MORBIDITY AND MORTALITY WKLY. REP. 44 (2015), [https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6444a2.htm?s\\_cid=mm6444a2\\_w](https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6444a2.htm?s_cid=mm6444a2_w).

<sup>29</sup> See Jonathan Foulds et al., *Electronic Cigarettes (E-Cigs): Views of*

first e-cigarette to market in the U.S. in the mid-2000s.<sup>30</sup> The modern e-cigarettes are smokeless, battery-operated devices that people use to inhale an aerosol, typically containing nicotine, flavoring, and other chemicals.<sup>31</sup> Most ENDS consist of three parts: the nicotine cartridge, an atomizer which vaporizes the nicotine, and a rechargeable battery.<sup>32</sup> The main appeal of ENDS products is that they do not contain tobacco and lack many of the additives found in traditional cigarettes, leading manufacturers to claim that ENDS are a healthier alternative to traditional cigarettes.<sup>33</sup>

The health related and smoking cessation claims related to ENDS has put the FDA in a difficult position. Since ENDS are a relatively new phenomena, there are no studies showing their long-term health risks. However, the FDA has generally embraced them as a safer alternative to traditional combustible tobacco products because they contain far fewer toxic chemicals and cancer causing agents.<sup>34</sup> Being safer than traditional combustible tobacco products, however, doesn't necessarily render them "safe," as many ENDS still contain potentially harmful substances like heavy metals, volatile organic compounds, and cancer-causing agents.<sup>35</sup> Therefore, the FDA was put in the precarious position of trying to ensure that adult smokers have access to a safer alternative to traditional combustible tobacco products and navigating the treacherous regulatory waters associated with an innovative product for which there is little long-term health risk information. The problems stemming from this dichotomy came to a head in *Sottera Inc. v. FDA*<sup>36</sup> in 2010.

Due to the drastic increase in Americans using ENDS in the late 2000s,<sup>37</sup> the FDA sought to assert regulatory authority over

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*Aficionados and Clinical/Public Health Perspectives*, 65 INT'L J. CLINICAL PRAC. 1037, 1037 (2011).

<sup>30</sup> See U.S. Patent No. 7,832,410 (filed Mar. 18, 2005).

<sup>31</sup> See NATIONAL INSTITUTE ON DRUG ABUSE, DRUGFACTS – ELECTRONIC CIGARETTES (2018), <https://www.drugabuse.gov/publications/drugfacts/electronic-cigarettes-e-cigarettes>.

<sup>32</sup> See *id.*

<sup>33</sup> See UMDNJ, *Trinkets and Trash: Artifacts of the Tobacco Epidemic* (searching for e-cigarette manufacturers marketing claims).

<sup>34</sup> See E-CIGARETTES INFOGRAPHIC, *supra* note 3.

<sup>35</sup> See *id.*

<sup>36</sup> 627 F.3d 891(D.C. Cir. 2010)

<sup>37</sup> See John Tierney, *A Tool to Quit Smoking Has Some Unlikely Critics*, N.Y. TIMES

ENDS as medical devices under the FDCA.<sup>38</sup> As stated above, the FDCA permits the FDA to regulate medical devices under a strict statutory framework that requires rigorous pre-market testing for safety and effectiveness prior to approval.<sup>39</sup> The FDA's main argument was that ENDS were medical devices because they were marketed as smoking cessation products and thus "intended to affect the structure or function of the body, and to prevent, mitigate, or treat the withdrawal symptoms of nicotine addiction."<sup>40</sup> However, the D.C. Circuit held that there was insufficient evidence that Sottera was making therapeutic claims about its ENDS and, therefore, its products were considered tobacco products and not medical devices.<sup>41</sup> The court reasoned that Sottera was marketing their products for smoking pleasure rather than a therapeutic reason or for smoking cessation.<sup>42</sup> Further, the court relied heavily on the *Brown-Williamson* decision, emphasizing that unless the manufacturer is making drug-like claims, tobacco products are exempt from the FDCA's drug/medical device regulatory framework.<sup>43</sup> Significantly, for the first time, this created a presumption that ENDS are tobacco products to be regulated under the TCA. In response to the ruling, the FDA chose not to appeal the decision to the Supreme Court and, instead choosing to officially assert its regulatory authority over ENDS as tobacco products under the TCA.<sup>44</sup>

#### A. FDA Deems ENDS as Tobacco Products

Pursuant to the *Sottera* decision, the FDA promulgated regulations deeming ENDS as tobacco products and subject to regulation under the TCA.<sup>45</sup> Significantly, ENDS products are now subject to the same regulatory requirements as traditional tobacco products under TCA § 387.<sup>46</sup> ENDS manufacturers now must comply with industry manufacturing practices and

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(Nov. 8, 2011), <http://www.nytimes.com/2011/11/08/science/e-cigarettes-help-smokersquit-but-they-have-some-unlikely-critics.html>.

<sup>38</sup> See *Sottera, Inc. v. FDA*, 627 F.3d 891 (D.C. Cir. 2010).

<sup>39</sup> See 21 U.S.C. 201(h).

<sup>40</sup> *Sottera*, 627 F.3d at 65.

<sup>41</sup> *Id.* at 898.

<sup>42</sup> *Id.* at 893.

<sup>43</sup> See *id.*

<sup>44</sup> See 81 Fed. Reg. 28,974 (May 10, 2016) (codified as 21 C.F.R. part. 1100 et seq.).

<sup>45</sup> See *id.*

<sup>46</sup> See 21 U.S.C. § 387.

advertising and retail requirements, as well as provide a list of ingredients and health/safety information to the FDA and the public.<sup>47</sup> Additionally, ENDS products are subject to the same adulteration and misbranding provisions that allow the FDA to commence enforcement actions such as seizures and injunctions.<sup>48</sup>

Most notable for this discussion, however, is ENDS applicability as “new tobacco products” under the TCA. A “new tobacco product” is “any tobacco product that was not on the market in the U.S. as of 2007” or “was modified since 2007.”<sup>49</sup> Considering almost all ENDS products currently on the market came after 2006, ENDS qualify as “new tobacco products” under the statute. Significantly, “new tobacco products” are subject to pre-market review for safety.<sup>50</sup> Pre-market review requires “new tobacco products” to submit any health and safety information related to the product, ingredients, methods for use, and clinical data if available.<sup>51</sup> The application would then have to be approved by the FDA prior to the ENDS manufacturer bringing the product market.<sup>52</sup> Requiring ENDS to submit to pre-market approval would significantly hamper their ability to get to market and therefore limit the options for adults looking to switch from traditional combustible tobacco to ENDS.<sup>53</sup> The FDA is again put in the difficult position of ensuring that ENDS products are safe for use but also available to adults as an alternative to traditional combustible tobacco.

### *B. FDA Exercises Enforcement Discretion*

In May 2017, the FDA issued a guidance in which it stated that it was exercising its enforcement discretion by waiving the pre-market approval requirement for ENDS as “new tobacco products.”<sup>54</sup> Essentially, ENDS manufacturers were free to bring their products to market without going through the rigorous pre-

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<sup>47</sup> See 21 U.S.C. § 387d-e.

<sup>48</sup> See 21 U.S.C. § 387b-c.

<sup>49</sup> 21 U.S.C. § 387j(a)(1).

<sup>50</sup> 21 U.S.C. § 387j(a)(2).

<sup>51</sup> See 21 U.S.C. § 387j(b)(1).

<sup>52</sup> 21 U.S.C. § 387(c).

<sup>53</sup> See Warning Letter, *supra* note 8 at 1 (threatening to require Juul to submit to pre-market approval and take its products off the market until approved).

<sup>54</sup> See U.S. FOOD & DRUG ASS'N, EXTENSION OF CERTAIN TOBACCO PRODUCT COMPLIANCE DEADLINES RELATED TO THE FINAL DEEMING RULE: GUIDANCE FOR INDUSTRY (2018).

market review process typically required.<sup>55</sup> In March 2019, then Commissioner Scott Gottlieb released a statement confirming that the exercise in enforcement discretion was intended to “encourage the development of products that can deliver nicotine to currently addicted adult smokers without all of the harmful effects of combustion.”<sup>56</sup> In that same statement, however, Gottlieb acknowledged that more than 3.6 million middle school and high school students were current ENDS users – up 1.5 million from 2016-2017.<sup>57</sup> In response to this troubling statistic, Gottlieb announced the FDA was reconsidering its enforcement discretion policy and focusing on protecting youth from becoming addicted to nicotine.<sup>58</sup> The FDA’s attempt to address the youth use statistics began with a ramped up enforcement effort aimed at retailers selling ENDS to minors.

### C. FDA’s Cracks Down on ENDS

In response to the rising number of underage ENDS users, the FDA engaged in an “enforcement blitz” of ENDS retailers, issuing 1,100 warning letters and 130 monetary penalties for retailers selling ENDS to minors.<sup>59</sup> Most notably, the FDA sent a warning letter to Juul Labs, Inc.<sup>60</sup> (“Juul”), which, as of September 2018, has the largest market share of the ENDS market at 72%.<sup>61</sup> The warning letter detailed the FDA’s enforcement actions to address youth use of ENDS and threatened to end its enforcement discretion, and subject Juul products to pre-market review, if it did not comply with FDA recommendations.<sup>62</sup> In effect, this would require Juul to pull their products from the market as they would

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<sup>55</sup> See *id.* at 3.

<sup>56</sup> See Press Release, Scott Gottlieb, Commissioner, U.S. Food and Drug Admin. Commissioner Statement on Advancing New Policies Aimed at Preventing Youth Access to, and Appeal of, Flavored Tobacco Products, Including E-Cigarettes and Cigars (March 13, 2019), <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm633291.html>.

<sup>57</sup> See *id.*

<sup>58</sup> See *id.*

<sup>59</sup> See Warning Letter, *supra* note 8.

<sup>60</sup> See *id.*

<sup>61</sup> See Richard Carver, *Juul Expands E-Cig Market Share Gap with Reynolds Vuse*, WINSTON-SALEM JOURNAL (Aug. 25, 2018), [https://www.journalnow.com/business/juul-expands-e-cig-market-share-gap-with-reynoldsvuse/article\\_0bb4d442-fc0f-5c00-8b05-29bbf95dc985.html](https://www.journalnow.com/business/juul-expands-e-cig-market-share-gap-with-reynoldsvuse/article_0bb4d442-fc0f-5c00-8b05-29bbf95dc985.html).

<sup>62</sup> See Warning Letter, *supra* note 8.

be considered adulterated under the statute.<sup>63</sup> In order to address the youth use of its products, the FDA requested that Juul discontinue sales to retail establishments that have been subject to an FDA civil monetary penalty for sale of tobacco products to minors within the prior twelve months, develop or strengthen any internal program to check on retailers, eliminate online sales or prove that their online sales are not ending up in youth hands, and revise current marketing practices to ensure youth are not being targeted.<sup>64</sup>

Juul's CEO Kevin Burns released an "action plan" to address youth use of its products.<sup>65</sup> Juul agreed to stop selling flavored nicotine pods to all 90,000 of its retail stores, restricted flavors to adults 21+ on their website, strengthened retail compliance, overhauled its social media and advertising practices, and developed new technology to restrict youth access.<sup>66</sup> Considering Juul's substantial market share, it has the ability to work with the FDA while also ensuring that some of its products stay on the market and continue to generate revenue. Similar actions would likely spell disaster for a smaller, independent ENDS manufacturer who could not afford to remove products and flavors in an effort to comply with FDA mandates. This begs the question of whether the FDA's heavy handed, top-down approach is the best way to regulate the ENDS market.

### III. STATE AND LOCAL GOVERNMENT POWERS UNDER THE TCA

While the TCA affords most of its regulatory authority to the FDA, it preserves some important aspects for state and local governments, giving these local governments the tools to better address youth use of ENDS than the FDA. Specifically, the TCA preempts state and local governments from establishing any requirement which is different from, or in addition to, the FDA requirements for tobacco product standards, premarket review, adulteration, misbranding, labeling, registration, good manufacturing standards, or modified risk tobacco products.<sup>67</sup> The

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<sup>63</sup> See 21 U.S.C. § 387b-c.

<sup>64</sup> See Warning Letter, *supra* note 8 at 3.

<sup>65</sup> See Press Release, Kevin Burns, CEO, Juul Labs, Inc. Action Plan to Address Teen Use (Nov. 13, 2018), <https://newsroom.juul.com/2018/11/13/juul-labs-action-plan/>.

<sup>66</sup> *Id.*

<sup>67</sup> See 21 U.S.C. § 387p(a)(2)(A).

regulatory authority afforded to the FDA focuses on manufacturing rather than retail, with most enforcement actions limited to seizures and injunctions against manufacturers for adulteration and misbranding violations.<sup>68</sup> While effective in scaring companies like Juul into compliance,<sup>69</sup> this heavy-handed enforcement approach limits consumer choice in ENDS products and stifles innovation by forcing companies to pull products from the market or be regulated out of existence. The powers left to state and local governments allow for a more retail-focused enforcement approach, which is nimbler and more responsive to consumers.

The TCA grants state and local governments regulatory authority of ENDS in several key areas which can be utilized to address youth use of ENDS. The TCA preserves the right for state and local governments to enact and enforce laws in addition to, or more stringent than, what is required by the FDA relating to the sale, distribution, possession, or access to, and advertising and promotion of ENDS products.<sup>70</sup> Additionally, state and local governments are free to tax ENDS products as they see fit.<sup>71</sup> In effect, the law gives state and local government autonomy over five distinct areas of ENDS regulation: taxation, licensing, age requirements, advertising/promotion, and information reporting.<sup>72</sup> Therefore, state and local governments have the power to address youth use at the access point, which is more effective than the FDA's top-down approach at ensuring that adults still have access to an alternative to traditional combustible tobacco.

### A. Taxation

By enacting an excise tax on ENDS products, states can limit youth access while ensuring that adults still have access to an alternative to traditional combustible tobacco products. As of January 2019, nine jurisdictions have enacted an excise tax on ENDS products: Minnesota, Pennsylvania, North Carolina, West Virginia, Kansas, Louisiana, Washington D.C., and California.<sup>73</sup>

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<sup>68</sup> 21 U.S.C. § 387(a)-(b).

<sup>69</sup> See *Supra* FDA Cracks Down on ENDS.

<sup>70</sup> See 21 U.S.C. 387p(a)(1).

<sup>71</sup> See *id.*

<sup>72</sup> See Michael Freiberg, *Options for State and Local Governments to Regulate Non-Cigarette Tobacco Products*, ANNALS OF HEALTH LAW, Vol. 21: Iss. 2 (2012).

<sup>73</sup> TOBACCO CONTROL LEGAL CONSORTIUM, STATES WITH LAWS TAXING E-CIGARETTES (2018), <https://publichealthlawcenter.org/sites/default/files/E-Cigarette-Legal-Landscape-50-State-Review-March-2019.pdf>.

Additionally, three states are home to local municipalities that have enacted an excise tax on ENDS products sold in their jurisdiction: Alaska, Illinois, and Maryland.<sup>74</sup> States such as Pennsylvania, Minnesota, and California, elect to place a tax on a percentage of the wholesale price of the product as in,<sup>75</sup> while others like Kansas, Louisiana, North Carolina, and West Virginia elect to place a tax per milliliter of nicotine liquid sold.<sup>76</sup> The wholesale taxes range from the highest at 95% of the product price in Minnesota, to the lowest at 40% in Pennsylvania.<sup>77</sup> The per milliliter tax generally hovers around .05% per ml in most states that choose that application.<sup>78</sup> The differences in application and amount illustrate the accountability and flexibility state and local governments possess which the FDA lacks.

Most importantly, empirical research shows that states that have implemented an excise tax on ENDS products have successfully reduced the number of units sold. For example, a recent study in Minnesota demonstrates that enacting excise taxes on ENDS products can lead to a decline in use.<sup>79</sup> In 2013, Minnesota raised its taxes on ENDS products from 70% to 95% of the wholesale price.<sup>80</sup> The study took data on the sales of ENDS products in convenience stores in Minneapolis, Minnesota during 2012 and 2013 and compared it to data from sales of ENDS products in convenience stores in St. Louis, Missouri during the same time period.<sup>81</sup> Specifically, the study focused on the sales data of two ENDS manufacturers, NJOY and Blu, as they were the two highest selling brands in both cities at the time.<sup>82</sup> In the months prior to the tax increase, which took place on July 2013, both cities had relatively the same number of ENDS units purchased.<sup>83</sup> After the tax increase, however, their research showed that sales of e-cigarettes in Minneapolis “steadily declined, reaching a nadir of

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<sup>74</sup> See Scott Drenkard, *Vapor Taxes by State-2018*, TAX FOUNDATION, (Mar. 28, 2018), <https://taxfoundation.org/vapor-taxes-2018/>.

<sup>75</sup> See *id.*

<sup>76</sup> See *id.*

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

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

<sup>79</sup> Michael S. Amato & Raymond G. Boyle, *Evaluating an Excise Tax on Electronic Cigarette Consumption: Early Result*, TOBACCO REGULATORY SCIENCE (2016).

<sup>80</sup> See *id.* at 124.

<sup>81</sup> See *id.* at 125 (mentioning that St. Louis didn't have an ENDS excise tax in place during the same time period).

<sup>82</sup> See *id.*

<sup>83</sup> See *id.* at 130.

40% below expected values approximately 4 months later.”<sup>84</sup> Also notable was that the researchers found evidence that the prices of all ENDS products increased by more than the amount of the tax increase, indicating that the common tobacco industry practice of over-shifting prices to consumers after tax increases is also prevalent in the ENDS industry.<sup>85</sup>

The empirical study clearly demonstrates that increased taxes on ENDS products can lead to a decline in number of units sold in comparison to state lacking such a tax. While the study did not differentiate between youth and adult use, it can be extrapolated that a decline in overall use coincided with a decline in youth use. Therefore, raising taxes on ENDS products is a viable means of reducing youth use while also ensuring their availability to adults who are willing to pay for them.

However, there is evidence that retailers that sell ENDS products have been forced to close in states that have enacted similar taxes, thus reducing options for adults looking to switch.<sup>86</sup> This unfortunate consequence is a result of a state enacted policy for which legislators are accountable and can be justified based on the will of state’s citizens. Additionally, states like Pennsylvania have still been receiving millions in tax revenue even though many ENDS retailers have closed.<sup>87</sup> This proves that while some retailers have closed, ENDS products are still available to adults who want them. This would not be the case if the FDA forced manufacturers to pull products from their shelves as they would not be available anywhere and both retailers and consumers would be negatively affected. Therefore, a state imposed excise tax is a better alternative to curb youth use of ENDS products and ensure they are still available to adults than unilateral action by the FDA against a manufacturer.

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<sup>84</sup> *Id.* Notably, while the number of ENDS units sold in St. Louis also showed a slight decline in the same time period, it was to a far lesser extent than in Minneapolis.

<sup>85</sup> *See id.*

<sup>86</sup> See Michael Carroll, *More Pennsylvania Vape Shops Expected to Close Unless Tax is Repealed*, PENN. WATCHDOG, (Oct. 4, 2017), [https://www.watchdog.org/pennsylvania/more-pennsylvania-vape-shops-expected-to-close-unless-tax-is/article\\_3e42b7fc-a7df-11e7-a229-7f3c9038a908.html](https://www.watchdog.org/pennsylvania/more-pennsylvania-vape-shops-expected-to-close-unless-tax-is/article_3e42b7fc-a7df-11e7-a229-7f3c9038a908.html).

<sup>87</sup> See Justine McDaniel, *Pennsylvania’s Vape Tax Brings in Millions but 100-plus Businesses Close*, PHILADELPHIA INQUIRER (Sept. 11, 2017), <https://www.wtae.com/article/pennsylvania-vape-tax-businesses-close/1222304>.

### B. Increased Age Requirements

Increasing age requirements is another tool that state and local governments can employ to curb youth use of ENDS products while ensuring that they are still available to adults. As of January 2019, ten states have raised the minimum age for the purchase tobacco products.<sup>88</sup> Seven states have raised the minimum age to twenty-one, as well as many localities including Chicago, New York, and Washington D.C.<sup>89</sup> Three other states have raised the minimum age to 19.<sup>90</sup>

Increased age requirements are supported by a 2015 study by the National Institute of Medicine (“NIM”) which suggests that raising the minimum age for tobacco purchases to twenty-one would have a significant impact on youth access in the U.S.<sup>91</sup> It found that the most significant factor of youth use of tobacco was easy access prior to eighteen.<sup>92</sup> This is largely attributed to younger teens having access to eighteen year old peers who can purchase tobacco for them.<sup>93</sup> If, however, the age were raised to twenty-one, those who can legally obtain tobacco are less likely to be in the same social networks as high schoolers, limiting teens’ ability to access tobacco.<sup>94</sup> The NIM’s projection was substantiated in a recent empirical study focusing on the impact of California’s decision to raise the minimum legal age for tobacco products to twenty-one, including ENDS products.<sup>95</sup>

In June 2016, California raised the minimum legal age for the purchase of tobacco products to twenty-one.<sup>96</sup> Seven months after the law went into effect, researchers evaluated four statewide tobacco purchase surveys and assessed retailer violation rates on tobacco sales.<sup>97</sup> The study found that retailer violations for selling

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<sup>88</sup> TOBACCO CONTROL LEGAL CONSORTIUM, STATES WITH LAWS RESTRICTING YOUTH ACCESS TO TOBACCO (2018). All include ENDS in their definition of “tobacco product.”

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

<sup>90</sup> *Id.*

<sup>91</sup> NATIONAL INSTITUTE OF MEDICINE, PUBLIC HEALTH IMPLICATIONS OF RAISING THE MINIMUM AGE OF LEGAL ACCESS TO TOBACCO PRODUCTS (2015) [hereinafter NIM].

<sup>92</sup> *See id.* at 2.

<sup>93</sup> *See id.*

<sup>94</sup> *See id.*

<sup>95</sup> *See* Xueying Zhang, et. al., *Evaluation of California’s Tobacco 21 Law*, TOBACCO CONTROL, Vol. 27: Iss 6 (2018)

<sup>96</sup> *See id.* at 656.

<sup>97</sup> *See id.*

tobacco and ENDS products to underage persons had decreased significantly – from 10.3% to 5.7%. The study attributed the decrease in violations partly due to increased vigilance on the part of retailers, but more significantly, teens were less likely to even attempt to purchase tobacco products due to the law.<sup>98</sup>

This empirical evidence that regarding the law's deterrent effect supports the conclusion that it is the access point that is most crucial at stopping teen use. Additionally, as the NIM study indicates, one of the main factors contributing to underage use of tobacco products is youth access to peers who can purchase products for them.<sup>99</sup> This can be extrapolated to include ENDS products, as it's easy to assume eighteen year-olds are also buying ENDS products for their underage peers. Therefore, by raising the minimum age to twenty-one, states can undercut what research suggests is one of the most significant factors leading to underage use of ENDS products. Conversely, raising the minimum age has no negative effect the availability of ENDS products to adults. Where the FDA can only require manufacturers to comply with stricter regulations or be forced to pull their products off shelves, a state imposed age increase directly addresses the root of the problem and has no effect on the availability of ENDS products for adults.

### *C. Licensing*

State and local governments can impose stricter licensing requirements on retail stores that sell ENDS products with hefty fines associated with non-compliance or underage sales. As of January 2019, twenty-one states have implemented licensing requirements for retail sales of ENDS products.<sup>100</sup> Licensing enables the state or local government to maintain a comprehensive list of businesses that sell ENDS products which can be used to monitor the number, location, and density of retailers in the locality.<sup>101</sup> Typical licensing requirements include being approved as an ENDS retailer by the state, complying with local and state ordinances regarding retail location and advertising, paying an annual licensing fee (which often covers the costs of inspection and enforcement), and agreeing to increased monitoring and

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<sup>98</sup> See *id.* at 660.

<sup>99</sup> NIM, *supra* note 91.

<sup>100</sup> TOBACCO CONTROL LEGAL CONSORTIUM, STATES WITH LAWS REQUIRING LICENSES FOR RETAIL SALES OF E-CIGARETTES (2018).

<sup>101</sup> See COUNTERTOBACCO.ORG, <https://countertobacco.org/policy/licensing-and-zoning/>.

information reporting.<sup>102</sup> In addition to these requirements, licensed retailers are often subject to stricter penalties for non-compliance and underage sales than their non-licensed counterparts. For example, in Washington state, operating a retail store that sells ENDS products without a license is codified as a class C felony.<sup>103</sup> Additionally, if a licensed store is found selling to minors, it is subject to increased fines and possible license revocation.<sup>104</sup> By requiring retailers to submit to increased monitoring and subjecting them to increased penalties, states can effectively limit youth access by discouraging bad behavior and encouraging increased retailer vigilance.

In addition to encouraging compliance, licensing can be an effective tool to effectively regulate the location, density, and number of ENDS retailers. While licensing requirements for ENDS retailers are too recent for reliable data illustrating their effect on youth use, it can be assumed that a similar licensing system employed by states to regulate traditional tobacco retailers can be extrapolated to ENDS retailers. For example, a 2006 study by the National Institute of Health found that a high density of tobacco retailers in a community is often associated with high rates of youth use.<sup>105</sup> There is no reason why this could not also hold true for a high density of ENDS retailers, especially considering many retailers sell both traditional and ENDS products. By limiting the number of ENDS retailers in a given area, states and localities can effectively curb youth use without completely eliminating options for adults. For example, the San Francisco Tobacco-Free Project, a subset of the San Francisco Department of Public Health, did a case study of the tobacco retail density policy San Francisco implemented in January 2015.<sup>106</sup> The policy put a cap on the number of new tobacco permits issued per district, prohibited a new permit to be issued within 500 feet of a school or another tobacco permit holder, and put an outright ban on permits for bars and restaurants.<sup>107</sup> Just one year after the policy was implemented, the number of tobacco retailer licenses across the city decreased by

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<sup>102</sup> *See id.*

<sup>103</sup> WASH. REV. CODE § 70.345.040.

<sup>104</sup> WASH. REV. CODE § 70.345.180.

<sup>105</sup> *See* Scott P. Novak, et. al., Retail Tobacco Outlet Density and Youth Cigarette Smoking: A Propensity-Modeling Approach, AM. J. PUB. HEALTH (2006).

<sup>106</sup> *See* BRIGHT RESEARCH GROUP FOR THE SAN FRANCISCO TOBACCO-FREE PROJECT, REDUCING TOBACCO RETAIL DENSITY IN SAN FRANCISCO: A CASE STUDY (2016).

<sup>107</sup> *See id.* at 10.

8%.<sup>108</sup> Additionally, districts with the highest densities saw the largest decreases.<sup>109</sup> While the data on the effect of this policy on youth use is not available as of yet, it seems logical to assume that less exposure and access would lead to less use. Therefore, it follows that employing similar licensing density policies as applied to ENDS retailers may result in decreased youth use without significantly impeding adult access.

## CONCLUSION

State and local governments, rather than the FDA, are in the best position to regulate ENDS products to curb youth use. The tools left to the states and localities under the TCA are better suited for addressing the underlying issue of youth access at retail locations without limiting options for adults who want an alternative to traditional combustible tobacco products. As indicated by the research used in support of the arguments for increased taxes, increased age limits, and increased licensing requirements, the main issue with youth use of ENDS is easy access. While the FDA can monitor retail locations, issue fines, and send warning letters, their main enforcement actions are mostly remedial in nature and limited to drastic measures that force manufacturers into compliance but limit access for adult consumers. State and local governments, on the other hand, have the ability to enact proactive legislation tailored to the needs of their communities and have been empirically proven to limit youth access while also having a minimal effect on adult access to an alternative to traditional combustible tobacco. If the FDA is serious about its promise to ensure that adults have access to innovative products that are safer than traditional combustible tobacco, it should let states and localities address youth use at the retail level.

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<sup>108</sup> See *id.* at 13.

<sup>109</sup> See *id.*