



## GARDEN STATE VAPE

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## Abstract

In February 2018, the New Jersey legislature introduced the A3178 legislative bill, which would completely ban the sale of flavored electronic smoking devices, cartridges, and liquid refills. The regulation of e-cigarettes has been addressed in other states, but New Jersey considered significantly broader restrictions. Some public health experts have criticized this proposed legislation fearing it will turn people back onto regular cigarettes, however this opinion is hardly universal within that field.

While bills like A3178 have been introduced in the legislature before, failing to pass into law, further action regarding state regulation of e-cigarettes will inevitably occur due to the changing landscape and promulgation of e-cigarette smoking. This Note proposes an alternative public policy recommendation for New Jersey regarding the regulation of e-cigarettes. First, it will analyze the differing positions within the public health field. Second, it will discuss existing e-cigarette regulations at the federal level and then examine e-cigarette laws in several other states. Lastly, it will examine the proposed New Jersey legislation and also offer an alternative policy.

### I. Divisions Within Public Health Regarding E-Cigarettes

After decades of research analyzing the harmful effects of tobacco and traditional cigarettes, smoking rates began to decrease throughout the country during the 1990s.<sup>1</sup> In 2007, electronic cigarettes (e-cigarettes) entered the U.S. market from China and quickly grew in popularity opening a new frontier for tobacco

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<sup>1</sup> Elizabeth Cox, Rachel Ann Barry, & Stanton Glantz, *E-cigarette Policymaking by Local and State Governments: 2009-2014*, THE MILBANK Q., Sept. 13, 2016, <http://onlinelibrary.wiley.com/doi/10.1111/1468-0009.12212/abstract>.

companies, researchers, and regulators.<sup>2</sup> E-cigarettes, also known as electronic nicotine delivery systems (ENDS), are small battery-operated devices that deliver aerosolized nicotine, usually flavored, along with other chemicals.<sup>3</sup> The delivery of these chemicals and nicotine is conducted by a heat-not-burn process: heating the e-cigarette liquid rather than burning tobacco as a conventional cigarette does.<sup>4</sup> The introduction of these products into the mainstream opened the floodgates within the public health industry, with scores of articles and studies providing research for two divergent theories regarding the impact of e-cigarettes.

### **A. E-Cigarettes as a Tobacco Cessation Tool**

Supporters of the harm reduction theory view e-cigarettes as the final solution to the tobacco epidemic.<sup>5</sup> This group believes e-cigarettes are a disruptive technology, offering the opportunity to reduce traditional combustible cigarette smoking with the added benefit of reduced nicotine in the devices.<sup>6</sup> E-cigarettes play a part in harm reduction strategies, eventually lowering nicotine intake to zero.<sup>7</sup> The supporters of this theory believe overly restrictive e-cigarette regulations at the state or federal level inadvertently

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<sup>2</sup> *Id.*

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

<sup>4</sup> *Id.*

<sup>5</sup> David B. Abrams, *Promise and peril of e-cigarettes: can disruptive technology make cigarettes obsolete?*, JAMA, Jan. 8, 2014, <https://www.ncbi.nlm.nih.gov/pubmed/24399548>.

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

<sup>7</sup> *Id.*

support the tobacco industry because it would create a feedback cycle and perpetuate increased sales of traditional cigarettes.<sup>8</sup>

The harm reduction theory is the focal point of emergent tobacco research in the public health world. The public health field is converging around the idea that with proper regulation e-cigarettes could assist with cigarette smoking cessation or transitioning to a less harmful product, therefore promoting harm reduction.<sup>9</sup> Dr. Vaughan Rees, professor, interim director of Harvard's Center for Global Tobacco Control, and an expert on substance abuse and dependence, believes effective regulation is key.<sup>10</sup> According to Rees, "harm reduction can only work in a regulatory environment that encourages complete switching among current smokers or tobacco users, and discourages use among adolescents."<sup>11</sup>

### **B. E-Cigarettes Increase Nicotine Addiction**

Supporters of a second theory believe abstinence from all tobacco products is the only solution to the tobacco epidemic, and e-cigarettes will lead to increased smoking. Supporters of this theory point to studies showing that e-cigarette smoking can be as carcinogenic as traditional cigarette smoking. These studies conclude that e-smoking presents a new public health risk that

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

<sup>9</sup> Michael Blanding & Madeline Drexler, *The E-Cig Quandary*, HARVARD PUBLIC HEALTH 20 (Spring 2015), <https://cdn1.sph.harvard.edu/wp-content/uploads/sites/21/2015/05/HPHSPR15FINAL05192015smallfile.pdf>.

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

<sup>11</sup> *Id.*

requires strict regulation and control.<sup>12</sup> A 2014 review published by the U.S. Food and Drug Administration (“FDA”) found that e-cigarettes contain varying levels of harmful chemicals such as “nitrosamines, aldehydes, metals, volatile organic compounds, phenolic compounds, and other substances along with nicotine.”<sup>13</sup> The study found that “various chemical substances and ultrafine particles known to be toxic, carcinogenic and/or to cause respiratory and heart distress have been identified in e-cigarette aerosols, cartridges, refill liquids and environmental emissions.”<sup>14</sup> A Harvard report, led by Michael Blanding and Madeline Drexler, editor of the Harvard T.H. Chan School of Public Health, found that high levels of nanoparticles released from e-cigarettes have been linked to inflammation, “asthma, stroke, and heart disease.”<sup>15</sup>

The proposal to switch completely to e-cigarettes is starkly contrasted by research at the University of California, San Francisco’s Center for Tobacco Control Research and Education.<sup>16</sup> The study found that e-cigarettes made smokers 28% less likely to quit smoking.<sup>17</sup> The study, also in conjunction with the American

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<sup>12</sup> WORLD HEALTH ORG., ELECTRONIC NICOTINE DELIVERY SYSTEMS 13 (Conference of the Parties to the WHO Framework Convention on Tobacco Control ed., July 21, 2014), [http://apps.who.int/gb/fctc/pdf/cop6/fctc\\_cop6\\_10-en.pdf](http://apps.who.int/gb/fctc/pdf/cop6/fctc_cop6_10-en.pdf).

<sup>13</sup> Tianrong Cheng, *Chemical evaluation of electronic cigarettes*, WHO FRAMEWORK CONVENTION ON TOBACCO CONTROL, Apr. 14, 2014, [http://tobaccocontrol.bmj.com/content/23/suppl\\_2/ii11](http://tobaccocontrol.bmj.com/content/23/suppl_2/ii11).

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

<sup>15</sup> Blanding & Drexler, *supra* note 9.

<sup>16</sup> Dennis Thompson, *E-cigarettes Don't Help Smokers Quit Tobacco: Study*, WEBMD, Jan. 14, 2016, <https://www.webmd.com/smoking-cessation/news/20160114/e-cigarettes-dont-help-smokers-quit-tobacco-study#1>.

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

Lung Association, stated that e-cigarettes likely “interfere with efforts to quit smoking by keeping users hooked to nicotine.”<sup>18</sup> This result would proffer that e-cigarettes are in fact accomplishing the opposite of cessation and are encouraging on-going addiction.<sup>19</sup>

The relatively small amount of data has yet to provide clear health implications of long-term e-cigarette smoking, especially when compared to traditional cigarette smoking.<sup>20</sup> State and federal governments have had to create policy frameworks that can be implemented to best protect the health of citizens with what data is available.<sup>21</sup>

### **C. The National Academies of Sciences, Engineering, and Medicine Report**

On January 23, 2018, the National Academies of Sciences, Engineering, and Medicine (NASEM) published a report stating that e-cigarettes contain a lower number of toxic substances than conventional cigarettes, but their long-term health effects are not yet clear.<sup>22</sup> The report, commissioned by the FDA at the direction of Congress, is the result of a comprehensive review of over 800

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<sup>18</sup> *Id.*

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

<sup>20</sup> WORLD HEALTH ORG., *supra* note 12.

<sup>21</sup> *New Report One of the Most Comprehensive Studies on Health Effects of E-Cigarettes; Finds That Using E-Cigarettes May Lead Youth to Start Smoking, Adults to Stop Smoking*, THE NAT'L ACADEMIES OF SCIENCE, ENGINEERING AND MEDICINE (Jan. 23, 2018), <http://www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=24952>.

<sup>22</sup> COMMITTEE ON THE REVIEW OF HEALTH EFFECTS OF ELECTRONIC NICOTINE DELIVERY SYSTEMS, THE NATIONAL ACADEMIES OF SCIENCES, ENGINEERING, MEDICINE, PUBLIC HEALTH CONSEQUENCES OF E-CIGARETTES (2018) [hereinafter NASEM Report].

peer-reviewed studies on e-cigarettes. Although the research is limited due to the relatively short time e-cigarettes have been available, the NASEM committee concluded that e-cigarettes—“although not devoid of health risks—are likely to be far less harmful than conventional cigarettes.”<sup>23</sup> However, the report also found that e-cigarette use was considerably higher than use of any other tobacco product, including cigarette smoking, for people aged 12-years-old to 17-years-old in 2016.<sup>24</sup> The use of these tobacco products varies across sociodemographic groups such as race, ethnicity, age, and gender. The report also found that use is typically greater among males than females in both youths and adults.<sup>25</sup> Additionally, literature suggests that e-cigarette use increases the uptake and transition to conventional cigarette use among youths.<sup>26</sup>

Alternatively, the NASEM report also highlights evidence that suggests transitioning from conventional cigarettes to e-cigarettes decreases exposure to the thousands of carcinogens and toxins found in traditional cigarettes along with reduced risk of short-term health outcomes.<sup>27</sup> The chair of the committee that wrote the NASEM report, David Eaton, opined that “e-cigarettes cannot be simply categorized as either beneficial or harmful.”<sup>28</sup>

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<sup>23</sup> *Id.* at 26.

<sup>24</sup> *Id.* at 497.

<sup>25</sup> *Id.* at 395-99.

<sup>26</sup> *Id.* at 464.

<sup>27</sup> Steven Reinberg, *E-Cigarettes: Both Good and Bad, Expert Panel Says*, HEALTH DAY, January 23, 2018, <https://consumer.healthday.com/cancer-information-5/electronic-cigarettes-970/e-cigarettes-both-good-and-bad-expert-panel-says-730424.html>.

<sup>28</sup> Patti Neighmond, *E-Cigarettes Likely Encourage Kids to Try Tobacco But May Help Adults Quit*, NATIONAL PUBLIC RADIO, Jan. 23, 2018,

Adding that “in some circumstances, such as their use by non-smoking adolescents and young adults, their adverse effects clearly warrant concern”<sup>29</sup> and “in other cases, such as when adult smokers use them to quit smoking, they offer an opportunity to reduce smoking-related illness.”<sup>30</sup>

Eaton and his colleagues found conclusive evidence that exposure to nicotine from e-cigarettes is highly dependent on multiple factors such as properties of the e-liquid, characteristics of the e-cigarette device, and functionality of the device.<sup>31</sup> Likewise, research literature suggests that the amount of nicotine exposure and intake from the use of e-cigarettes among experienced adult e-cigarette users is similar to the amount of nicotine intake from conventional cigarettes.<sup>32</sup>

There is conclusive evidence that most e-cigarettes contain and release harmful toxic substances along with nicotine.<sup>33</sup> However, substantial evidence suggests that exposure to these toxic substances (except for nicotine), under typical conditions of use, is significantly lower from e-cigarettes than exposure to harmful and

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<https://www.npr.org/sections/health-shots/2018/01/23/579973659/e-cigarettes-likely-encourage-kids-to-try-tobacco-but-may-help-adults-quit>.

<sup>29</sup> *Id.*

<sup>30</sup> *Id.*

<sup>31</sup> Sheila Kaplan, *Vaping Can Be Addictive and May Lure Teenagers to Smoking, Science Panel Concludes*, NY TIMES, Jan. 23, 2018, <https://www.nytimes.com/2018/01/23/health/e-cigarettes-smoking-fda-tobacco.html>.

<sup>32</sup> *Id.*

<sup>33</sup> AAFP Staff, *Comprehensive E-cigarettes Study Offers Mixed Findings*, AMERICAN ACADEMY OF FAMILY PHYSICIANS (Jan 26, 2018), <https://www.aafp.org/news/health-of-the-public/20180126e-cigreport.html>.



toxic substances from conventional cigarette use.<sup>34</sup> Nevertheless, no available evidence suggests immediate cancer endpoints in humans as a result of e-cigarette use.<sup>35</sup> According to NASEM, “an intermediate cancer endpoint is a precursor to the possible development of cancer. For example, polyps are lesions that are intermediate cancer endpoints for colon cancer.”<sup>36</sup> Lastly, there is limited evidence from in vivo animal studies using intermediate biomarkers of cancer that support the hypothesis that long-term e-cigarette use could increase the risk of cancer.”<sup>37</sup> The NASEM report recognizes the limitations the variance within ENDS or e-cigarettes places for research. The wide diversity of ENDS introduces many challenges for research in the public health field as well as the public health impact.<sup>38</sup>

#### **D. Response to the NASEM Report**

While the impacts of the NASEM Report on e-cigarette use still remains uncertain, several high-ranking public health experts have expressed their opinions on the results of the study. Matthew Meyer, president of the Campaign for Tobacco-Free Kids, said in a statement, “it is deeply troubling that there are still so many unanswered questions about the impact of e-cigarettes on public health despite the fact they have been on the market for a decade and are being used by millions of kids and adults.”<sup>39</sup> Meyer added that “this report shows what happens when a new product is

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

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

<sup>36</sup> *Id.*

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

<sup>38</sup> NASEM Report, *supra* note 22, at 384.

<sup>39</sup> Neighmond, *supra* note 28.

introduced without meaningful government oversight. It demonstrates why the FDA should fully and aggressively implement the overdue e-cigarette regulations that took effect in August 2016.”<sup>40</sup>

E-cigarettes are “an addictive product that require closer scrutiny by FDA”, said Harold Wimmer, President and CEO of the American Lung Association.<sup>41</sup> “The Academies’ thorough and comprehensive review of the science shows clear and convincing evidence that FDA must use its full oversight authority over e-cigarettes to protect the public health,” Wimmer said in an official statement through his office. He went further in lambasting the FDA’s delay in regulating e-cigarettes:

This report underscores the grave mistake FDA made in July when it announced it would postpone by five years the legal requirement that e-cigarette manufacturers submit their products for FDA review in order to determine whether they should stay on the marketplace. E-cigarettes have become the most popular tobacco product among youth, continuing to attract and addict our kids to nicotine while exposing them to potentially dangerous toxins and carcinogens. FDA must enforce the Tobacco Control Act in order to protect the public health from e-cigarettes.<sup>42</sup>

“E-cigarettes may help adult smokers move away from conventional cigarettes, but it does not achieve ending an

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

<sup>41</sup> Press Release, Harold P. Wimmer, President and CEO, Am. Lung Ass’n, *National Academy Report Makes Clear: FDA Must Use Its Full Authority to Protect the Public Health from E-Cigarettes* (Jan. 23, 2018) <http://www.lung.org/about-us/media/press-releases/national-academies-report-fda.html?referrer=https://www.google.com/>.

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

addiction to nicotine,” said American Heart Association CEO Nancy Brown.<sup>43</sup> Brown added, “we agree with the National Academies that the jury is still out on the benefits and harmful effects of e-cigarettes, especially in the long-term. Until we have sufficient scientific data, we must have strong FDA regulation of these products and any new versions that come on the market.”<sup>44</sup> FDA Commissioner Scott Gottlieb lauded the report, stating that “the comprehensive report not only adds to our knowledge base but also raises some important questions about the net effect of e-cigarettes. One finding that’s particularly troubling is that kids who experiment with e-cigarettes are more likely to try smoking. At the same time, the report finds that current smokers who completely switch to e-cigarettes may see improved short-term health outcomes.”<sup>45</sup>

While the report will undoubtedly color public health policy with regards to e-cigarettes, law makers and experts will require time to fully cultivate policies from the report’s findings. The lasting effect of the report on public health policy remains to be seen. There are already laws and court decisions at the federal level regarding e-cigarettes which will be explored in Part II of this Note.

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<sup>43</sup> Press Release, Nancy Brown, CEO, Am. Heart Ass’n, *New National Academies report welcome contribution to e-cigarette debate, says the American Heart Association* (Jan. 23, 2018), <https://newsroom.heart.org/news/new-national-academies-report-welcome-contribution-to-e-cigarette-debate-says-the-american-heart-association>.

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

<sup>45</sup> Food and Drug Admin., *National Academies of Sciences, Engineering, and Medicine releases FDA-commissioned report on the potential public health consequences of e-cigarettes*, (Jan. 23, 2018), <https://www.fda.gov/NewsEvents/Newsroom/FDAInBrief/ucm593407.htm>.

## II. Federal Response to E-Cigarette Regulation

### A. Administrative and Judicial Action at the Federal Level

Beginning in 2008, the FDA made efforts to regulate e-cigarettes as unapproved drug/device combination products under the Federal Food, Drug & Cosmetic Act (“FDCA”) due to the promotion of e-cigarettes as tobacco cessation aids.<sup>46</sup> If the FDA had properly asserted its authority, manufacturers would be subject to standards showing that their products were safe and effective as advertised.<sup>47</sup> This would likely have cost hundreds of millions of dollars in research, studies, and clinical trials to comply. Under the FDCA, the FDA has the authority to regulate, among other items, “drugs” and “devices”.<sup>48</sup> The agency had attempted to rely on the existing FDCA statute and other regulatory tools at its disposal to prohibit adulterated and misbranded products from entering interstate commerce.<sup>49</sup>

The attempted application of the FDCA over e-cigarettes was fraught, however, based on the Supreme Court holding in *FDA v. Brown & Williamson Tobacco Corp.*, which stated that the FDCA did not have jurisdiction over tobacco products as drugs because allowing so would shirk congressional intent.<sup>50</sup> In coming to its conclusion, the Court stated the main purpose of the FDCA was to “ensure that any product regulated by the FDA is ‘safe’ and

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<sup>46</sup> Jonathan H. Adler et al., *Baptists, Bootleggers, & Electronic Cigarettes*, 33 Yale J. ON REG. 313, 333 (2016).

<sup>47</sup> *Id.*

<sup>48</sup> Neelam Gill, *Planning for the FDA’s deeming rule for e-cigarettes*, Law360 Expert Analysis, Sep 21, 2015.

<sup>49</sup> *Id.*

<sup>50</sup> *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 125 (2000).

‘effective’ for its intended use.”<sup>51</sup> Under the *Brown & Williamson* analysis, FDA would be required to ban tobacco from commerce altogether under the FDCA because tobacco is undisputedly unsafe. Because of these potentially far reaching implications, tobacco products cannot be considered drugs or devices under the FDCA. Later cases would extend this principle to e-cigarettes, which contain liquid nicotine made from tobacco, and would also not be categorized under the FDCA.

In 2010, after a long-fought legal battle with e-cigarette manufacturers, it was decided that the FDA was unable to assert control over e-cigarettes under the FDCA, and block shipments of e-cigarettes into the U.S.<sup>52</sup> In 2009, the FDA directed U.S. Customs and Border Protection to deny import of e-cigarettes made by Smoking Everywhere and Sottera (NJOY). The FDA asserted that electronic cigarettes were an unapproved drug/device combination which required pre-approval, registration, and listing with the FDA under FDCA, leading to the court case *Sottera Inc. v. U.S. Food and Drug Administration*.<sup>53</sup>

In *Sottera*, e-cigarette manufacturers sought an injunction to allow the entry of their products into the U.S. and sued the federal government for attempting to regulate e-cigarettes under the FDCA.<sup>54</sup> The U.S. Court of Appeals for the D.C. Circuit held that e-cigarettes were not subject to FDA regulation under the FDCA of 2009.<sup>55</sup> This analysis was based in part on the Supreme Court’s

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<sup>51</sup> *Id.* at 133.

<sup>52</sup> *Sottera Inc. v. U.S. Food and Drug Administration*, 627 F. 3d 891, 899 (D.C. Cir. 2010).

<sup>53</sup> Gill, *supra* note 48.

<sup>54</sup> *Sottera*, 627 F.3d at 892.

<sup>55</sup> *Id.* at 899.

ruling in *Brown & Williamson*,<sup>56</sup> holding that tobacco products which are clearly not safe when used as intended, cannot fit under the regulatory scheme set forth in the FDCA.<sup>57</sup> Therefore, so long as “the plaintiff’s e-cigarette products were not marketed for therapeutic use”, attempts to extend its authority over e-cigarettes were statutorily prohibited.<sup>58</sup>

In response to the regulatory gap exposed in *Brown & Williamson*, Congress expanded the Family Smoking Prevention and Tobacco Control Act of 2009 (“TCA”) to include e-cigarettes.<sup>59</sup> The expansion of the TCA allowed the FDA to gain jurisdiction over e-cigarettes and regulate their marketing, manufacturing, warning labels, and sales to minors.<sup>60</sup> The TCA also gave the FDA the authority to oversee the manufacture, distribution, and marketing of certain products, such as “cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco, and any other tobacco products” the FDA deems to be subject to the law.<sup>61</sup> Under the TCA, the FDA can exert authority over tobacco products by 1) imposing restrictions on their sale; 2) imposing restrictions on advertising and promotion; 3) regulating the mode of manufacture; and 4) requiring ingredient listing.<sup>62</sup>

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<sup>56</sup> *Brown & Williamson*, 529 U.S. at 134.

<sup>57</sup> *Id.* at 134.

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

<sup>59</sup> 21 U.S.C. §§ 321(g)-(h) (2009).

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

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

<sup>62</sup> Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco

Pursuant to this authority, in April 2014, the FDA proposed the "Deeming Rule," which would statutorily define electronic cigarettes containing nicotine as "tobacco product," thereby extending the FDA's regulatory authority to these products.<sup>63</sup> Among other things, the Deeming Rule required e-cigarette companies to register with the FDA, report product and ingredient listings, and obtain FDA premarket approval of new tobacco products.<sup>64</sup>

In May 2016, the FDA finalized the Deeming Rule, extending its authority to all tobacco products, including e-cigarettes introduced after February 15, 2007. Under the expanded regulations, restrictions are placed on sales to minors and advertising and promotional efforts.<sup>65</sup> Specifically, the new regulations require:

Registration of all products and reporting of all product and ingredient listings. FDA review for marketing of all new tobacco products. FDA confirmation of all direct and implied claims of reduced risk and that marketing the product will

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Products and Required Warning Statements for Tobacco Products; Final Rule, 21 C.F.R. Parts 1100, 1140, and 1143 (2016).

<sup>63</sup> Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 21 C.F.R. Parts 1100, 1140, and 1143 (2014).

<sup>64</sup> Tim Agajanian & Thomas McNamara, *Vapor Smoke and Mirrors: The Future of E-Cigarettes*, LAW360, June 5, 2017, <https://www.law360.com/articles/931179/vapor-smoke-and-mirrors-the-future-of-e-cigarettes>.

<sup>65</sup> Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, 81 Fed. Reg. 28973 (May 10, 2016).

benefit public health as a whole. Inclusion of health warnings.<sup>66</sup>

The Deeming Rule also requires manufacturers of all newly-regulated products to show that the products introduced on the market after February 15, 2007, meet the applicable public health standards set forth in the law, and receive marketing authorization from the FDA.<sup>67</sup> The May 2016 Deeming Rule expansion was in response to *Sottera*, and as a consequence, e-cigarette manufacturers and retailers are prohibited from informing consumers that e-cigarettes are less dangerous than combustible cigarettes. Such claims may only be made with the FDA's approval, after submitting to a lengthy and costly approval process.<sup>68</sup>

The TCA places sweeping prohibitions on e-cigarette producers on making any claims about cigarette alternatives. Under the Act's provisions concerning "Modified Risk Tobacco Products" (MRTP), producers of deemed products may not make commercial statements that "explicitly or implicitly" indicate the product or its smoke "presents a lower risk of tobacco-related disease or is less harmful than one or more other commercially marketed tobacco products ... contains a reduced level of a substance or presents a reduced exposure to a substance," or "does not contain or is free of a substance."<sup>69</sup>

The FDA's position appears to be that e-cigarette manufacturers must be barred from making statements that mislead

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

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

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

<sup>69</sup> Agajanian & McNamara, *supra* note 64.



consumers.<sup>70</sup> For example, an e-cigarette maker cannot proclaim that vaping is less dangerous than smoking, because consumers might mistakenly believe e-cigarettes are completely safe. Broader analysis on whether this violates the First Amendment remains unsettled in the legal community.<sup>71</sup> The government claims a significant interest in ensuring that producers do not misrepresent their products or make unsubstantiated claims. Opponents state that if the FDA is concerned that e-cigarette manufacturers might oversell their products' benefits or mislead consumers, it can require disclaimers and qualifications, similar to nutritional supplements. Otherwise, a complete ban violates the First Amendment.<sup>72</sup>

In June of 2017, an e-cigarette manufacturer took further issue with the ruling that deemed e-cigarettes tobacco products. Nicopure Labs, LLC sued the FDA, claiming the agency had exceeded its authority by designating e-cigarettes as tobacco products, and the provisions of the TCA violated the company's First Amendment Rights.<sup>73</sup> The U.S. District Court for the District of Columbia adamantly affirmed that the TCA does not ban the manufacture or sale of e-cigarettes; it merely regulates warning labels and ensures that manufacturers take measures to truthfully advertise their

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<sup>70</sup> Deeming Tobacco Products to Be Subject to the Federal Food Drug and Cosmetic Act, 81 Fed. Reg. 28973 (May 10, 2016).

<sup>71</sup> Jonathan Adler, *Why FDA regulations limiting e-cigarette marketing may cost lives and violate the Constitution*, VOLOKH CONSPIRACY, Dec. 12, 2017, [https://www.washingtonpost.com/news/volokh-conspiracy/wp/2017/12/12/why-fda-regulations-limiting-e-cigarette-marketing-may-cost-lives-and-violate-the-constitution/?noredirect=on&utm\\_term=.7760345bd7bd](https://www.washingtonpost.com/news/volokh-conspiracy/wp/2017/12/12/why-fda-regulations-limiting-e-cigarette-marketing-may-cost-lives-and-violate-the-constitution/?noredirect=on&utm_term=.7760345bd7bd).

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

<sup>73</sup> Nicopure Labs, LLC v. Food & Drug Admin., 266 F. Supp. 3d 360, 366 (D.D.C. 2017).

products.<sup>74</sup> The court also found that nicotine contained in e-liquid is adequately labeled a “component” of a tobacco product and therefore jurisdiction over it is warranted under the TCA. Nicopure filed an appeal of the ruling to the D.C. Circuit Court on August 31, 2017, although the appeal was dismissed by the Circuit Court in September 2017.<sup>75</sup>

## **B. The Trump Administration**

In May 2017, the Trump Administration nominated an e-cigarette company board member, Scott Gottlieb, to be the new commissioner of the FDA.<sup>76</sup> In July 2017, the New York Times reported the FDA was more open to “e-cigarettes than many other federal public health officials, who have opposed the devices as a gateway to nicotine addiction and eventually to the smoking of tobacco cigarettes.”<sup>77</sup> The article cited Commissioner Gottlieb, saying that while he was concerned about the use of e-cigarettes by children, and could consider regulating flavors designed to appeal to them, there were also “potential benefits to addicted cigarette smokers of products capable of delivering nicotine without having to burn tobacco.”<sup>78</sup> Under Commissioner Gottlieb, the FDA delayed the regulation requiring e-cigarettes entering the market after Feb 15, 2007 to undergo premarket review, allowing such products to stay

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<sup>74</sup> *Id.* at 420.

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

<sup>76</sup> U.S. Food and Drug Admin., *Meet Scott Gottlieb, M.D., Commissioner of Food and Drugs*, March 27, 2018, <https://www.fda.gov/aboutfda/centersoffices/ucm557569.htm>.

<sup>77</sup> Sheila Kaplan, *F.D.A. Delays Rules That Would Have Limited E-Cigarettes on Market*, NY TIMES, July 28, 2017, <https://www.nytimes.com/2017/07/28/health/electronic-cigarette-tobacco-nicotine-fda.html>.

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

on the market until 2022.<sup>79</sup> Greg Conley, president of the American Vaping Association, explained that “without this delay, over 99 percent of vapor products available on the market today would be banned next year.”<sup>80</sup>

The FDA also stated that traditional cigarettes require increased regulation to lower nicotine levels to non-addictive amounts.<sup>81</sup> Per the new administration’s policy, an increased focus on reducing combustible cigarettes may have increased federal implications for e-cigarettes. If the FDA finds that e-cigarettes are a viable cessation instrument, it could expand access to both manufacturers as well as distributors of e-cigarettes.

Several aspects of the FDA’s regulation on e-cigarettes went into effect on August 8, 2016. However, under Commissioner Gottlieb, the provisions within this regulation were delayed.<sup>82</sup> In May 2017, the Trump administration, through the U.S. Department of Justice, delayed enforcement of the May 2016 FDA Deeming Rule. As a result of the delay, e-cigarette manufacturers were not required to submit plans for placing addictiveness warnings on their products.<sup>83</sup> Moreover, e-cigarette manufacturers did not need to submit ingredient information contained in e-cigarettes by August 2017, which otherwise would have been required pursuant to the May 2016 Deeming Rule. In addition, the Department of Justice’s

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<sup>79</sup> U.S. Food and Drug Admin., *Statement from F.D.A. Commissioner Scott Gottlieb, M.D., on new steps to address epidemic of youth e-cigarette use* (Sept. 12, 2018), <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm620185.htm>.

<sup>80</sup> Kaplan, *supra* note 77.

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

<sup>82</sup> Agajanian & McNamara, *supra* note 64.

<sup>83</sup> *Id.*

move to delay FDA enforcement of e-cigarettes lifted the ban on e-cigarette interstate commerce, including the labeling of “light”, “low” or “mild” to identify the types of e-cigarettes for consumers.<sup>84</sup>

With several Trump administration officials’ ties to the tobacco and e-cigarette industries, the May 2016 Deeming Rule is appearing destined for overhaul. FDA Commissioner Gottlieb served on the board of the e-cigarette firm, Kure, until May 2016.<sup>85</sup> Although he retained stock in the company after his nomination, Gottlieb pledged to sell it. Additionally, Chad A. Readler, acting Assistant Attorney General for the Civil Division, represented Big Tobacco company R.J. Reynolds prior to joining the Justice Department.<sup>86</sup>

In addition to agency heads having industry ties, the Deeming Rule may have had an adverse impact on e-cigarette business. For example, major e-cigarette company, NJOY, filed for bankruptcy after the rule became effective.<sup>87</sup> Opponents also argue the May 2016 Deeming Rule requires e-cigarette firms to conduct health based and behavioral research on the psychological effects their products have on consumers.<sup>88</sup> Opponents claim the cost associated with such research aggravates the industry.<sup>89</sup>

Those in favor of the May 2016 Deeming Rule cite the rapid rise in e-cigarette consumption by teenagers as a need for increased

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

<sup>85</sup> *Id.*

<sup>86</sup> *Id.*

<sup>87</sup> Lisa Fickensher, *E-Cigarette Maker files for bankruptcy*, NY POST, Sept. 19, 2016, <https://nypost.com/2016/09/19/e-cigarette-maker-files-for-bankruptcy/>.

<sup>88</sup> *Id.*

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

regulation. On May 19, 2017, eleven Democratic U.S. senators, including Elizabeth Warren (D-MA) and Richard J. Durbin (D-IL), penned a letter to Commissioner Gottlieb expressing concerns about the recent delay in fully implementing the May 2016 Deeming Rule.<sup>90</sup> The eleven Democratic senators maintained that the two-year window, provided by the rule, is sufficient to comply with the proposed regulations.

The FDA and the U.S. Department of Health and Human Services have considerable discretion when implementing tobacco policy reform. The future of the FDA's regulation of e-cigarettes is currently in flux, but there is a growing possibility that e-cigarettes may no longer be classified as tobacco products. In April 2017, U.S. Rep. Duncan Hunter (R-CA) introduced a bill that would change the current FDA classification of e-cigarettes as tobacco products.<sup>91</sup>

On March 8, 2018, U.S. Rep. Frank Pallone (D-NJ), the Ranking Member on the House Committee on Energy and Commerce, wrote to Commissioner Gottlieb, urging him to undo the delays to the May 2016 Deeming Rule.<sup>92</sup> Reiterating that the FDA's decision to delay the provisions of the Deeming Rule would allow products to stay on the market without premarket review until 2022, Rep. Pallone asked the FDA to regulate e-cigarettes and other ENDS products.<sup>93</sup> Rep. Pallone's letter also singled out one specific brand

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<sup>90</sup> Agajanian & McNamara, *supra* note 64.

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

<sup>92</sup> Letter from Frank Pallone, Jr., Ranking Member, Comm. on Energy and Commerce, to Scott Gottlieb, Commissioner, FDA, Mar. 8, 2018, [https://democratsenergycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/FDA.2018.03.08.%20Letter%20re%20Juul%20Products%20and%20deeming%20rule.%20HE\\_o.pdf](https://democratsenergycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/FDA.2018.03.08.%20Letter%20re%20Juul%20Products%20and%20deeming%20rule.%20HE_o.pdf).

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

of e-cigarette found to be targeting minors called JUUL.<sup>94</sup> Rep. Pallone's letter states "[t]he need for FDA oversight has become all the more critical as press reports note that JUUL has become widely available to minors and its usage among teens is rampant."<sup>95</sup> Rep. Pallone was deeply concerned that the "FDA's delay of the final deeming rule will lead to more kids and teens using these harmful products and getting addicted to nicotine," and he cited the NASEM report for support that e-cigarette use increases the risk of using combustible cigarettes among youth and young adult.<sup>96</sup>

On March 6, 2019 Commissioner Gottlieb announced he would resign from the FDA effective March 31, 2019.<sup>97</sup> Commissioner Gottlieb had been under increasing pressure from Republicans in Congress to drop his tough stance against youth e-cigarette use, specifically by targeting e-liquid flavors.<sup>98</sup> A new FDA Commissioner was not immediately announced and the Trump Administration's stance regarding e-cigarettes has not been made clear.

Outside of the TCA's provisions, the FDA has left regulation of e-cigarettes to state and local governments. As a result, states have employed varying policy approaches to regulate e-cigarettes ranging from no additional regulations to the moderate employment of their police powers.

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<sup>94</sup> *Id.*

<sup>95</sup> *Id.*

<sup>96</sup> *Id.*

<sup>97</sup> Sheila Kaplan & Jan Hoffman, *F.D.A. Commissioner Scott Gottlieb, Who Fought Teenage Vaping, Resigns* NY TIMES, March 6, 2019, <https://www.nytimes.com/2019/03/05/health/scott-gottlieb-resigns-fda.html>.

<sup>98</sup> *Id.*

### III. State Responses to E-Cigarette Regulation

State economies often dictate growth and regulation within certain industries. When e-cigarettes first entered the U.S. market, they were imported from China.<sup>99</sup> Since that time, U.S. companies, notably traditional Big Tobacco companies such as R.J. Reynolds and Phillip Morris, have joined the e-cigarette manufacturing business. The expansion and overhaul of Big Tobacco's involvement in the e-cigarette manufacturing industry has changed the landscape of many U.S. state regulations.<sup>100</sup>

#### A. The Taxers

Eight jurisdictions currently have taxes on e-cigarettes—California, the District of Columbia, Kansas, Louisiana, Minnesota, North Carolina, Pennsylvania, and West Virginia.<sup>101</sup> These jurisdictions tax either a percentage of the whole sale price or by milliliter of e-liquid. The tax rates by state show the disparity in regulatory philosophy, with Minnesota charging a tax of 95% of the wholesale price, while North Carolina charges a \$0.05 tax for every milliliter of e-liquid sold.

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<sup>99</sup> CENTERS FOR DISEASE CONTROL AND PREVENTION, 2016 SURGEON GENERAL'S REPORT: E-CIGARETTE USE AMONG YOUTH AND YOUNG ADULTS (2016), [https://www.cdc.gov/tobacco/data\\_statistics/sgr/e-cigarettes/pdfs/2016\\_SGR\\_Chap\\_1\\_508.pdf](https://www.cdc.gov/tobacco/data_statistics/sgr/e-cigarettes/pdfs/2016_SGR_Chap_1_508.pdf).

<sup>100</sup> Caroline Abate, *Tobacco Companies Taking Over the E-Cigarette Industry*, HUFFINGTON POST, Feb. 27, 2017, [https://www.huffingtonpost.com/entry/tobacco-companies-taking-over-the-e-cigarette-industry\\_us\\_58b48e02e4b0658fc20f98do](https://www.huffingtonpost.com/entry/tobacco-companies-taking-over-the-e-cigarette-industry_us_58b48e02e4b0658fc20f98do).

<sup>101</sup> Audryana Camacho, *Extras on Excise: While States Start Taxing E-Cigarettes, Proposed Federal Restrictions Go Up in Vapor*, BLOOMBERG BNA, Jan. 18 2017, <https://www.bna.com/extras-excise-states-b73014449960/>.

## 1. Minnesota

Minnesota was the first state in the country to pass a tax on e-cigarettes. In 2010, the Minnesota legislature amended its tobacco tax statutes, adding e-cigarettes into the scope of its tobacco laws. In 2013, the legislature passed a series of laws increasing the tax on e-cigarettes to 95% of the wholesale value.<sup>102</sup> The revenue collected from the tobacco excise tax was \$5.7 million in 2016, an estimated 50% of that from taxes collected on e-cigarette sales.<sup>103</sup> In 2017, the Minnesota Senate proposed SF 1052, which would further amend the tax and move away from the wholesale tax to a 30% tax on every milliliter of e-liquid sold.<sup>92</sup> The State's department of health website prominently states that e-cigarettes are not proven to help reduce smoking and that e-cigarettes pose a health risk to children.<sup>104</sup>

## 2. North Carolina

Perhaps noting the action taking place in Minnesota, in 2014, North Carolina Governor Pat McCrory signed a law adding a \$0.05 tax to every milliliter of nicotine e-liquid sold.<sup>105</sup> The organization leading the charge for this tax was Big Tobacco company R.J.

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<sup>102</sup> Minnesota Department of Revenue, Analysis of S.F. 1052 (Senjem)/H.F. 1346 (Davids), Mar. 7, 2017, [http://www.revenue.state.mn.us/research\\_stats/revenue\\_analyses/2017\\_2018/sf1052\(hf1346\)\\_1.pdf](http://www.revenue.state.mn.us/research_stats/revenue_analyses/2017_2018/sf1052(hf1346)_1.pdf).

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

<sup>104</sup> S.F. 1052, 90<sup>th</sup> Leg., (Minn. 2017), [https://www.revisor.mn.gov/bills/text.php?number=SF1052&session=ls90&version=latest&session\\_number=0&session\\_year=2017](https://www.revisor.mn.gov/bills/text.php?number=SF1052&session=ls90&version=latest&session_number=0&session_year=2017).

<sup>105</sup> Marti Maguire, *North Carolina lawmakers adopt tax on electronic cigarettes*, REUTERS, May 29, 2014, <https://www.reuters.com/article/us-usa-cigarettes-north-carolina/north-carolina-lawmakers-adopt-tax-on-electronic-cigarettes-idUSKBN0E92C020140529>.



Reynolds, which has its headquarters in the state.<sup>106</sup> While this revelation may come as a surprise to some, this sort of proactive lobbying for beneficial legislation is standard operating procedure for the company.<sup>107</sup> R.J. Reynolds, which entered into the e-cigarette market with its brands VUSE and Reynolds Vapor,<sup>108</sup> sought to gain a favorable tax-rate for its new product, currying favor with lawmakers in the North Carolina legislature.<sup>109</sup> The tax is significantly lower than the one charged on traditional cigarettes, taxed at \$0.45 per pack.<sup>110</sup>

### 3. Pennsylvania

In 2016, lawmakers in Pennsylvania, seeking to reduce the state's revenue gaps, implemented a 40% wholesale tax on e-cigarettes.<sup>111</sup> The Pennsylvania Department of Revenue estimated

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<sup>106</sup> Jim Morrill, *NC Debates tax on e-cigarettes*, THE CHARLOTTE OBSERVER, May 15, 2014, <http://www.charlotteobserver.com/news/politics-government/article9122030.html>.

<sup>107</sup> *Id.*

<sup>108</sup> CENTERS FOR DISEASE CONTROL AND PREVENTION, 2016 SURGEON GENERAL'S REPORT: E-CIGARETTE USE AMONG YOUTH AND YOUNG ADULTS (2016), [https://www.cdc.gov/tobacco/data\\_statistics/sgr/e-cigarettes/pdfs/2016\\_SGR\\_App\\_4-1\\_508.pdf](https://www.cdc.gov/tobacco/data_statistics/sgr/e-cigarettes/pdfs/2016_SGR_App_4-1_508.pdf).

<sup>109</sup> Mark Binker, *Reynolds gave \$50,000 to House GOP group*, WRAL.COM, Apr. 8, 2015, <http://www.wral.com/reynolds-gave-50-000-to-house-gop-group/14568933/>.

<sup>110</sup> *Id.*

<sup>111</sup> Justine McDaniel, *Vape Tax Brings In Millions - and Is Said to Close Over 100 Pa. Businesses*, THE PHILADELPHIA INQUIRER, Sept. 5, 2017, <http://www.philly.com/philly/news/pennsylvania/vape-tax-brings-in-millions-and-closes-over-100-pa-businesses-20170905.html>.

the tax would increase revenues by \$11.2 million in the first year.<sup>112</sup> The law, however, has met considerable backlash by retailers who claim the tax is untenable and has caused more than 100 businesses to close as a result.<sup>113</sup> In 2017, the Pennsylvania Senate introduced S.B. 508, which would mirror North Carolina's \$0.05 per milliliter tax.<sup>114</sup>

#### 4. New York

E-cigarettes were the subject of various proposed bills in the 2017-18 session of the New York State Legislature. Pending legislation could affect excise taxation, discounts, and warning labels and possible prohibitions over certain types of vapor products. Three bills on an excise tax are currently pending in the state legislature. S07335 would impose upon e-liquids an excise tax of \$0.25 per fluid milliliter,<sup>115</sup> and A01138/S0189 would treat e-liquid cartridges as "tobacco products" subject to a tax of 75% of the wholesale price.<sup>116</sup> The Memorandum in Support of A01138 states that, "[a]s the State continues to fight to lessen the smoking population as a public health measure, allowing an addictive drug like nicotine to be sold without tax is simply counter intuitive."<sup>117</sup> The bill's sponsor, Assemblyman Jeffrey Dinowitz (D-Bronx), disputes the view that e-cigarettes are "a

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<sup>112</sup> INDEP. FISCAL OFFICE, QUARTERLY REVENUE ESTIMATES: FISCAL YEAR 2016-2017 11 (Aug. 24, 2016), [http://www.ifo.state.pa.us/download.cfm?file=/Resources/Documents/QRE\\_FY16-17.pdf](http://www.ifo.state.pa.us/download.cfm?file=/Resources/Documents/QRE_FY16-17.pdf).

<sup>113</sup> McDaniel, *supra* note 111.

<sup>114</sup> S.B. 508, 201st Gen. Assemb., Reg. Sess. (Pa. 2017).

<sup>115</sup> S.B. 7335, 241st Leg. Sess. (N.Y. 2017).

<sup>116</sup> A.B. 1138, 241st Gen. Assemb., Reg. Sess. (N.Y. 2017), (Memorandum in Support of Legislation).

<sup>117</sup> A.B. 1138, 241st Gen. Assemb., Reg. Sess. (N.Y. 2017).

safe alternative to traditional forms of smoking, i.e. cigarettes, cigarillos and many other smoking related ways of inhaling nicotine,” and he further asserted that “the FDA is unaware of what is in the majority of these devices.”<sup>118</sup>

Two additional bills proposed in the legislature aim to prohibit certain types of vapor products. A08688 would prohibit the sale of flavored e-liquids and flavored e-cigarettes.<sup>119</sup> According to the Memorandum in Support, “This bill would eliminate the temptation for young people in New York State to try flavored electronic cigarettes and in turn reduce the number of people who become regular users of tobacco products.”<sup>120</sup>

A00325 would prohibit refill sales of e-liquid, and each violation would be punishable by a civil penalty of up to \$500.<sup>121</sup> According to the Memorandum in Support, “This legislation brings an awareness of the extreme dangers of these products by banning them from store shelves with the goal of saving people’s lives.”<sup>122</sup> New York legislators have clearly made e-cigarettes a priority in the current legislative session and could serve as a guide for other states around the country.

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

<sup>119</sup> A.B. 8688, 241st Gen. Assemb., Reg. Sess. (N.Y. 2017), (Memorandum in Support of Legislation).

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

<sup>121</sup> A.B. 325, 241st Gen. Assemb., Reg. Sess. (N.Y. 2017).

<sup>122</sup> A.B. 325, 241st Gen. Assemb., Reg. Sess. (N.Y. 2017), (Memorandum in Support of Legislation).

## B. The Banners

In 2013, New York City passed Local Law 152, which banned the use of e-cigarettes in parks, restaurants, and public places.<sup>123</sup> In doing so, New York City banned e-cigarette use in the same venues where traditional cigarette smoking is banned under the Smoke-Free Air Act. This ban was met with legal action by an interest group named Citizens Lobbying Against Smoker Harassment (CLASH).<sup>124</sup> CLASH argued the New York Constitution's "One-Subject Rule" contained in article III, §15, prohibited lumping two disparate subjects into the same law.<sup>125</sup> The court unanimously found the assertion was a misreading of the rule, because Local Law 152 only pertained to e-cigarettes and was not passed at the state level. Therefore, Local Law 152 was enforceable and did not violate the New York Constitution or any statutory law.<sup>126</sup> As of October, 2017, 688 local laws throughout the United States explicitly restricted the use of e-cigarettes in public venues.<sup>127</sup>

## C. The Acquiescent

Many states have taken no action to regulate e-cigarettes beyond what is mandated by the federal government. Nebraska, Nevada, Rhode Island, and Tennessee do not regulate e-cigarettes at all, permitting indoor vaping at bars and restaurants. Oklahoma,

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<sup>123</sup> NYC DEPARTMENT OF HEALTH AND MENTAL HYGIENE, SMOKING AND THE USE OF ELECTRONIC CIGARETTES UNDER THE NEW YORK CITY SMOKE-FREE AIR ACT Chapter 10 (Sept. 15, 2014).

<sup>124</sup> *See, e.g.*, NYC C.L.A.S.H. v. City of New York, 147 A.D.3d 97 (N.Y. App. Div. Jan. 3, 2017).

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

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

<sup>127</sup> AMERICAN NONSMOKERS' RIGHTS FOUNDATION, STATES AND MUNICIPALITIES WITH LAWS REGULATING USE OF ELECTRONIC CIGARETTES (Oct. 2, 2017), [www.no-smoke.org/pdf/ecigslaws.pdf](http://www.no-smoke.org/pdf/ecigslaws.pdf).

New Hampshire, Tennessee, and Nevada also prohibit municipalities from regulating e-cigarettes more stringently than the State does.<sup>128</sup>

Under the New Hampshire Indoor Smoking Act, business owners have the authority to create policies prohibiting the use of e-cigarettes in their establishments, but are not obligated to do so.<sup>129</sup> Lagging regulations in New Hampshire and other states that have not implemented additional measures to curb the usage of e-cigarettes can be ascribed to the lack of understanding of what e-cigarettes are.

In 2015, Rhode Island lawmakers considered an indoor vaping ban, however legislators appeared to question the product or how widespread its usage was.<sup>130</sup> Some testimony from users attested to the notion that e-cigarette vapor is merely water vapor with food grade flavoring. The general consensus from state legislators was that more information and research was required before they could be certain that e-cigarettes are harmless.<sup>131</sup> The growing number of e-cigarette business owners in Rhode Island developed an increasingly powerful voice, disputing the need for additional

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<sup>128</sup> Wikipedia, List of vaping bans in the United States, [https://en.wikipedia.org/wiki/List\\_of\\_vaping\\_bans\\_in\\_the\\_United\\_States](https://en.wikipedia.org/wiki/List_of_vaping_bans_in_the_United_States) (last visited March 27, 2019).

<sup>129</sup> New Hampshire Department of Health and Human Services, E-Cigarettes and Electronic Smoking Devices, <https://www.dhhs.nh.gov/dphs/tobacco/e-cigarettes.html> (last visited March 27, 2019).

<sup>130</sup> Tim Faulkner, *R.I. Bill Would Ban Indoor Smoking of E-Cigarettes*, ECORI NEWS, Mar. 21, 2015, [https://www.ecori.org/government/2015/3/21/ri-bill-would-ban-indoor-smoking-of-e-cigarettes\\_](https://www.ecori.org/government/2015/3/21/ri-bill-would-ban-indoor-smoking-of-e-cigarettes_)

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

legislation placing limits on e-cigarettes.<sup>132</sup> As the methods adopted in different states show, e-cigarette regulation has had wide and varying implementation due to the lack of data and information regarding the potential health impacts of e-cigarette smoking.

#### IV. New Jersey's E-Cigarette Ban Proposal

In early 2016, a New Jersey State Senator began making national headlines. "State senator proposes ban on flavored e-cigarettes" read the title of a Politico story.<sup>133</sup> The article quoted Sen. Joseph Vitale (D-Middlesex).<sup>134</sup> "Big tobacco is getting into this business because they see their tobacco revenue declining and this [e-cigarettes] is a way they can make up for it."<sup>135</sup> With that, Senator Vitale who serves as the chair of the Health, Human Services, and Senior Citizens committee, introduced S298 in the 217th legislature; a bill that would prohibit the sale or distribution of flavored electronic smoking devices.<sup>136</sup>

By May 2016, another national Politico headline ran: "Senate health panel to take up flavored e-cigarette ban."<sup>137</sup> The committee

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<sup>132</sup> *Id.*

<sup>133</sup> Matt Freidman, *State Senator Proposes Ban on Flavored E-cigarettes*, POLITICO, Feb. 1, 2016, <https://www.politico.com/states/new-jersey/story/2016/02/state-senator-proposes-ban-on-flavored-e-cigarettes-097998>.

<sup>134</sup> New Jersey Legislature, *Senator Joseph F. Vitale (D)*, <http://www.njleg.state.nj.us/members/BIO.asp?Leg=175>.

<sup>135</sup> Freidman, *supra* note 133.

<sup>136</sup> S.298, 217th Leg., 2016 Sess. (N.J. 2016), <http://www.njleg.state.nj.us/2016/Bills/S0500/298I1.HTM>.

<sup>137</sup> Katie Jennings, *Senate Health Panel to Take up Flavored E-cigarette Ban*, POLITICO, May 16, 2016, <https://www.politico.com/states/new-jersey/story/2016/05/senate-health-panel-to-take-up-flavored-e-cigarette-ban>.

hearings, led by Senator Vitale, inspired hours of emotional testimony from advocates who believed e-cigarettes lured children and teenagers into smoking.<sup>138</sup> Opponents of the ban passionately argued that e-cigarettes help traditional cigarette smokers quit.<sup>139</sup> Support for the bill was hardly unanimous amongst legislators. Although the Senate health committee approved the measure, the proposal engendered bi-partisan criticism, with two Republican senators on the committee voting against it and Democrat Robert Gordon abstaining, stating that “[t]his legislation may be taking us down the wrong road.”<sup>140</sup> Asked about his support for the bill, Sen. Ronald Rice (D-Essex) summarized the competing notions regarding bans on e-cigarettes: “if you’re talking about kids, we can have that debate and I deal with it ... But the adult piece, we keep infringing upon, and decision-making is starting to reach a point where even as a Democrat, as liberal as I am, you’re starting to choke me.”<sup>141</sup>

New Jersey led all other state governments and the federal government in regulating e-cigarette use. In 2010, New Jersey expanded its Smoke Free Air Act to include e-cigarettes, prohibiting their use in public indoor spaces and workplaces.<sup>142</sup> Many other states soon followed. New Jersey also banned the sale of e-cigarettes

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[jersey/story/2016/05/senate-health-panel-to-take-up-flavored-e-cigarette-ban-101740](http://jersey/story/2016/05/senate-health-panel-to-take-up-flavored-e-cigarette-ban-101740).

<sup>138</sup> Michael Symons, *NJ Considers Banning Vape Flavors, No Cigarette Sales at Pharmacies*, NJ 101.5, May 17, 2016, <http://nj1015.com/nj-considers-banning-vape-flavors-no-cigarette-sales-at-pharmacies/>.

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

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

<sup>141</sup> *Id.*

<sup>142</sup> Staff Reporter, *E-Cigarette Restrictions Signed Into Law*, NJ TODAY, Jan. 14 2010, <http://njtoday.net/2010/01/14/e-cigarette-restrictions-signed-into-law/>.

to minors, outpacing the federal restriction regarding the same by more than six years.<sup>143</sup>

The first words of Senate Bill 298 read: “There has been a proliferation of flavored cigarettes and flavored electronic smoking devices in recent years, and many of these products have fruit, chocolate, or other flavors that are particularly attractive to children.”<sup>144</sup> Section 2 of the bill goes on to declare the prohibition:

No person, either directly or indirectly by an agent or employee, or by a vending machine owned by the person or located in the person's establishment, shall sell, offer for sale, distribute for commercial purpose at no cost or minimal cost or with coupons or rebate offers, give or furnish, to a person (1) a cigarette, or any component part thereof, which contains a natural or artificial constituent or additive that causes the cigarette or any smoke emanating from that product to have a characterizing flavor other than tobacco, clove, or menthol; or (2) any electronic smoking device or any cartridge or other component of the device or other related product, including a liquid refill, that has a characterizing flavor other than tobacco, clove, or menthol.<sup>145</sup>

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<sup>143</sup> Deeming Tobacco Products to Be Subject to The Federal Food Drug and Cosmetic Act, *supra* note 65.

<sup>144</sup> S298, 217th Leg., 2016 Sess. (N.J. 2016), [https://www.njleg.state.nj.us/2016/Bills/S0500/298\\_R1.HTM](https://www.njleg.state.nj.us/2016/Bills/S0500/298_R1.HTM).

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



The bill is an amendment to P.L.2008, c.91 (C.2A:170-51.5 et seq.), the 2008 prohibition of flavored traditional cigarette sales, which was also sponsored by Sen. Vitale.<sup>146</sup>

In 2008, then New Jersey Governor Jon Corzine signed An Act Banning the Sale of Certain Flavored Cigarettes, codified at N.J.S.A. 2A: 170-51.5.<sup>147</sup> The legislative history of that bill reveals studies showing that tobacco companies like Philip Morris mixed cocoa beans to create chocolate flavoring in its cigarettes, increasing the carcinogenicity of smoke condensate, and creating a more dangerous product.<sup>148</sup> It also showed that adding sugar or saccharine, an artificial sweetener, to cigarette flavoring, increased the likelihood of young smokers becoming addicted.<sup>149</sup> Cities and states were quick to follow New Jersey, adopting similar measures.<sup>112</sup> In late 2009, the FDA enacted a ban on cigarettes containing certain characterizing flavors.<sup>150</sup>

However, lawmakers in New Jersey continued to pass legislation regulating the delivery of nicotine. In 2009, the Senate

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<sup>146</sup> S.613, 213<sup>th</sup> Leg., 2008 Sess. (N.J. 2008), [ftp://www.njleg.state.nj.us/20082009/S1000/613\\_I1.DOC](ftp://www.njleg.state.nj.us/20082009/S1000/613_I1.DOC).

<sup>147</sup> SNUS NEWS & OTHER TOBACCO PRODUCTS, *New Jersey Bans Flavored Cigarettes*, Dec. 5, 2008, <http://snus-news.blogspot.com/2009/05/on-october-1-2008-new-jersey-governor.html>.

<sup>148</sup> Purcell Consulting, *The Effects of Cigarette Activates on the Palpability of Cigarettes* (Mar. 26, 2013), <http://www.smokefreetasmania.com/wp-content/uploads/2017/01/Palatability-Purcell.pdf>.

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

<sup>150</sup> U.S. Food and Drug Admin., *Menthol and Other Flavors in Tobacco Products* (July 7, 2018), <https://www.fda.gov/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm2019416.htm>.

unanimously voted to pass Sen. Vitale's bill S-3053 to restrict e-cigarette smoking in indoor public areas and workplaces.<sup>140</sup> This was codified in N.J. Stat. § 26:3D-57 through 26:3D-60.<sup>151</sup> In 2014, Sen. Vitale's winning streak against tobacco took a hit when his proposal, S.B.-1867, a measure to impose the same tax rate on e-cigarettes as traditional cigarettes, died in the Senate Budget and Appropriations Committee.<sup>152</sup> By this point, e-cigarettes were popular and the coalition of vapor retailers in New Jersey had grown.<sup>153</sup>

While New Jersey has done well to protect the health of its citizens by forging ahead on e-cigarette regulation, the most recent public health policy, proposing an outright ban of flavored e-cigarette sales in the State, is controversial and has been criticized as unnecessary. By the time the 2018 legislative session had begun, S298 was dead due to inaction by the legislature.<sup>154</sup> The proposals laid out in S298 were reintroduced verbatim by Assemblyman Herb Conaway (D-Burlington) as A3178 in the 2018 legislative session of the 218<sup>th</sup> Legislature.<sup>155</sup> As e-cigarette use continues to grow, states are increasingly seeking innovative approaches to their regulation.

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<sup>151</sup> Staff Reporter, *NJ Senate Approves 'E-Cigarette' Restrictions*, NJ TODAY (Dec. 11, 2009), <http://njtoday.net/2009/12/11/nj-senate-approves-%E2%80%98e-cigarette%E2%80%99-restrictions/>.

<sup>152</sup> S.B. 1867, 216th Leg., 2014 Sess. (N.J. 2014), <https://legiscan.com/NJ/bill/S1867/2014>.

<sup>153</sup> Caren Chesler, *Hanging with the Vapers*, NEW JERSEY MONTHLY (Apr. 17, 2015), <https://njmonthly.com/articles/arts-entertainment/hanging-with-the-vapers/>.

<sup>154</sup> S.B. 1867, 216th Leg., 2014 Sess. (N.J. 2014), <https://legiscan.com/NJ/bill/S1867/2014>.

<sup>155</sup> A3178, 218th Leg., 2018 Sess. (N.J. 2018), <https://legiscan.com/NJ/bill/A3178/2018>.

## V. A Prescriptive New Jersey Framework for E-Cigarette Regulation

With uncertainty surrounding the potential health risks of e-cigarettes, narrow analysis on the implications of e-cigarette legislation, and limited guidance by the federal government, New Jersey must wade into the nebulous realm of e-cigarette regulation while balancing multiple factors. Although time and research will yield more concrete results on the best course of action to take for regulators at all levels, New Jersey can create forward-looking policy now, that could best serve its citizens in the future.

The NASEM report, while highly comprehensive, states there is no available evidence that e-cigarette use is associated with intermediate cancer endpoints in humans,<sup>156</sup> causes respiratory diseases,<sup>157</sup> effects pregnancy outcomes,<sup>158</sup> or whether there are any long-term changes in mortality compared with smokers who only smoke combustible tobacco cigarettes.<sup>159</sup> Accordingly, New Jersey lawmakers should not move forward with the current proposal to ban all flavored e-cigarette sales and should instead i) enforce the FDA's regulations regarding e-cigarette sales to minors and advertising; ii) follow a taxation approach that will be effective but not overly burden retailers and buyers; iii) mandate e-cigarette packaging contain warning labels; and iv) use revenue from an e-cigarette tax to help fund smoking cessation programs state-wide.

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<sup>156</sup> NASEM Report, *supra* note 22, at 297-98.

<sup>157</sup> *Id.* at 328-29.

<sup>158</sup> *Id.* at 364.

<sup>159</sup> *Id.* at 507.

### **A. Enforce the FDA's Regulations Regarding E-Cigarette Sales to Minors and Advertising**

In *Nicopure*, the District Court for the District of Columbia explained that the FDA's regulation of e-cigarettes was not an attempt to ban sales or affect manufacturing of e-cigarettes.<sup>160</sup> The court stated it wished "to reassure the many worried vapers who followed these proceedings closely that this case is not about banning the manufacture or sale of the devices."<sup>161</sup> The court found that the TCA had a rational basis to ensure consumers were informed about the products and to regulate sales to minors.<sup>162</sup> Additionally, the court found the TCA did not violate the Fifth Amendment's substantive due process rights of manufacturers of e-cigarettes.<sup>163</sup> The federal government has provided a legal backing and rational basis for regulating e-cigarettes in this capacity. New Jersey should not overreach its police power and ban sales of all flavored e-cigarettes. Providing consumers with warnings and ensuring they are aware of potential health risks better serves the state's purpose of tobacco mitigation.

The argument made by Sen. Vitale, that such flavors are targeted towards minors, is also not a viable rationale for a ban. Flavors in e-liquids consist of a different chemical makeup<sup>164</sup> than the flavored combustible cigarettes that were previously banned in

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<sup>160</sup> *Nicopure Labs, LLC v. Food & Drug Admin.*, 266 F. Supp. 3d 360, 367 (D.D.C. 2017).

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

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

<sup>163</sup> *Id.* at 366.

<sup>164</sup> Cheng, *supra* note 13.

New Jersey in 2008 and 2009.<sup>165</sup> Even if studies show that certain additives increase the carcinogenicity of flavored cigarettes, no such evidence has been conclusive regarding e-liquid. New Jersey should instead enforce the FDA's existing ban of e-cigarette sales to minors, to the fullest extent of the law.

The NASEM report concludes that “among youth and young adult e-cigarette users, there is moderate evidence” to support the proposition that “e-cigarette use increases the frequency and intensity of subsequent combustible cigarette smoking.”<sup>166</sup> This evidence should be incorporated into the legislative proposal regarding e-cigarettes and should be used to impose harsh penalties on any manufacturers, distributors, or commercial ventures that provide e-cigarettes or related products to youths and young adults. Imposition of criminality for such offenses can be policed at a state and local level to ensure that school aged children are not targeted or supplied with e-cigarettes.

### **B. Follow a Taxation Approach That Will Be Effective but Will Not Overly Burden Retailers and Buyers**

Like the other eight jurisdictions that impose a tax on e-cigarette sales, New Jersey should re-introduce legislation that would tax e-cigarettes. In doing so, New Jersey should apply an approach that moderates between what North Carolina and Minnesota have done. The North Carolina tax on e-cigarettes appears to be overly passive, providing friendly terms for the Big Tobacco industry that looks to acquire a larger market share in the e-cigarette space. On the other hand, the Minnesota tax of 95% appears to be economically prohibitive for consumers, and regressive to those who believe e-cigarettes can help decrease the use of combustible tobacco. New Jersey policy makers should observe

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<sup>165</sup> S.B. 1947, 216th Leg., 2018 Sess. (N.J. 2018), [https://www.njleg.state.nj.us/2018/Bills/S2000/1947\\_I1.HTM](https://www.njleg.state.nj.us/2018/Bills/S2000/1947_I1.HTM).

<sup>166</sup> NASEM Report, *supra* note 22, at 418.

Pennsylvania closely, because although tax revenues have increased, businesses claim to have been harmed in the process, and this can lead to adverse economic impacts throughout the state. Unlike the flat tax per pack imposed on traditional cigarettes, New Jersey should apply a tax of 20-25% per milliliter of e-liquid sold. This does not overly burden consumers who are looking for smoking substitutes but does establish barriers and potentially limits consumption.

### **C. Mandate That E-Cigarette Packaging Have Warning Labels**

While the long-term effects of e-cigarette smoking are still unknown, the health risks of nicotine are known and available. New Jersey should mandate warning labels on e-cigarette packaging, alerting consumers to the possible health risks and also noting the nicotine content of each bottle of e-liquid. The NASEM report states there is “moderate evidence that e-cigarettes with nicotine are more effective than e-cigarettes without nicotine for smoking” cessation<sup>167</sup> and that “frequent use of e-cigarettes is associated with an increased likelihood of cessation.”<sup>168</sup> The report also presents substantial evidence that “nicotine intake from e-cigarette devices among adults can be comparable to that of combustible cigarettes.”<sup>169</sup> Warning labels are essential if there is to be a promulgation of e-cigarettes as smoking cessation devices. While adults may find e-cigarettes to be an effective form of smoking cessation, the dangers associated with the nicotine content in e-liquid must be transparently reported.

A 2018 study at the NYU Langone School of Medicine, in collaboration with the NYU College of Global Public Health, examined the association between state level tobacco control policies

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<sup>167</sup> *Id.* at 440.

<sup>168</sup> *Id.*

<sup>169</sup> *Id.* at 113.

and the prevalence of e-cigarette use.<sup>170</sup> The study indicated that states with strict regulations on tobacco had fewer e-cigarette users, and that increased cigarette taxation and smoke-free air acts resulted in fewer cigarette and e-cigarette users.<sup>171</sup> As tobacco control regulations vary by state and southern states have fewer regulations, e-cigarette use is also varied by region and state.<sup>172</sup> Western and southern states had the highest rates of e-cigarette use, whereas eastern and northeastern states had lower rates of e-cigarette use.<sup>173</sup> Current e-cigarette use was “highest in Oklahoma (10.3%) and lowest in Delaware (2.7%), and current cigarette use was highest in West Virginia (26.1%) and lowest in Utah (10.7%).”<sup>174</sup> The study also noted “states with stronger implementation of tobacco control measures, including state-level funding for tobacco prevention and control programs that are recommended by the Centers of Disease Control and Prevention (CDC), had lower rates of both current cigarette and e-cigarette use.”<sup>175</sup>

New Jersey already has some of the strictest tobacco laws in the nation.<sup>176</sup> As the study notes, strong policies against tobacco such

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<sup>170</sup> Omar El-Shahawy et al., *Evaluating State-Level Differences in E-cigarette and Cigarette Use Among Adults in the United States Between 2012 and 2014: Findings from the National Adult Tobacco Survey*, NICOTINE & TOBACCO RESEARCH, Feb. 27, 2018, at 1.

<sup>171</sup> *Id.*

<sup>172</sup> *Id.*

<sup>173</sup> *Id.*

<sup>174</sup> *Id.*

<sup>175</sup> *Id.*

<sup>176</sup> State of New Jersey Department of Health, Tobacco Control: Regulations and Enforcement, <http://www.nj.gov/health/fhs/tobacco/regulations/> (last visited March 27, 2019).

as smoke-free air, tobacco signage for retailers, age sales enforcement, warning labels, and cigarette taxes, naturally help to reduce e-cigarette consumption. Each of these policies has already been instituted by New Jersey. As a result, New Jersey should not seek to individually cease e-cigarette sales in the state, but should harden its enforcement on existing laws and ensure that resources are expended on limiting access to youths.

#### **D. Use Revenue from an E-Cigarette Tax to Help Fund Smoking Cessation Programs State-Wide**

Using new revenue from e-cigarette taxes, New Jersey should help fund smoking cessation programs, if state leaders are truly dedicated to eliminating smoking in the state. These programs can include counseling sessions, reduction plan management, and medical support. If e-cigarettes are deemed to provide a viable alternative for smoking reduction, e-cigarette manufacturers and retailers should be asked to contribute to this program to ensure that smokers who want to quit are given the tools and opportunity to do so.

The NASEM report states there is limited evidence that e-cigarettes may be effective aids to promote smoking cessation.<sup>177</sup> While this may be the case, New Jersey could require revenue earned from e-cigarette excise to be spent on programs and other state funded aids that are more established in funding smoking cessation.

## **VI. Conclusion**

E-cigarettes are undoubtedly a disruptive product that will usher in a new era of smoking policy throughout the world. It is still uncertain if the products will be a positive force to help eradicate traditional cigarette smoking, or will create a new wave of smokers unlike any seen before. While public health experts continue to argue about the merits of e-cigarettes, the federal government seeks to

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<sup>177</sup> NASEM Report, *supra* note 22, at 439.



assert new control over the products, and courts continue to determine the constitutionality of regulations at each step, it will be up to individual states to create policy that is lasting and effective. New Jersey has the opportunity to implement policy that will best suit the needs of the people and also ensure the state is able to protect its citizens. It should once again lead the country in public health and progressive policy.