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### Puff Puff Pass the Legislation: A Comparison of E-Cigarette Regulations Across Borders

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# Puff Puff Pass the Legislation: A Comparison of E-Cigarette Regulations Across Borders

By Rachel E. Zarrabi\*

I.	INTRODUCTION .....	129
II.	TYPES OF E-CIGARETTE LEGISLATION .....	131
A.	<i>Policy Domains</i> .....	131
B.	<i>Product Classifications</i> .....	134
C.	<i>Regulatory Mechanisms</i> .....	134
D.	<i>Canada</i> .....	135
III.	REGULATION OF E-CIGARETTES IN THE UNITED STATES .....	136
A.	<i>Regulation History of E-Cigarettes</i> .....	136
B.	<i>Prevalence of Vaping, Health Risks, and Recent Outbreaks</i> .....	137
1.	Prevalence of Vaping .....	137
2.	Health Risks of Vaping .....	141
3.	Recent Outbreaks and Deaths .....	143
C.	<i>The FDA's Current Approach</i> .....	145
1.	Plan for Tobacco and Nicotine Regulation .....	145
a.	Regulatory Policies .....	145
b.	Science-Based Review .....	145
c.	Youth Tobacco Prevention Plan .....	146
2.	"Real Cost Campaign" .....	146
a.	Reaction to the "Real Cost Campaign" .....	147
3.	Current Federal Rules for Tobacco Manufacturers .....	148
4.	Action Against E-Cigarette Manufacturers .....	149
D.	<i>Future Plans for the FDA</i> .....	151
IV.	THE EUROPEAN UNION .....	154
A.	<i>Current Regulations</i> .....	154
1.	Safety and Quality Requirements .....	154
2.	Packaging and Labeling .....	154
3.	Monitoring and Reporting .....	155
4.	Implementing Legislation .....	155
a.	EU's Stance on the Health Risks .....	155
b.	United Kingdom's Stance on the Health Risks .....	156
V.	CHINA .....	157
VI.	THE WORLD HEALTH ORGANIZATION .....	160
VII.	OTHER CONSIDERATIONS .....	162
VIII.	CONCLUSION .....	164

## I. INTRODUCTION

Electronic cigarettes (e-cigarettes) are a world phenomenon.<sup>1</sup> Overnight it appeared and became a prevalent part of society.<sup>2</sup> When traditional cigarette smoking decreased due to anti-smoking campaigns and common knowledge of the health-risks, e-cigarette smoking sprang up to fill the gap.<sup>3</sup> What began as an alternative to traditional cigarettes and a nicotine-quitting-aid became a cultural phenomenon for youths.<sup>4</sup> Considering this epidemic, the Food and Drug Administration (FDA) announced its campaign to combat the high prevalence of youth e-cigarette smoking or “juuling.”<sup>5</sup>

However the United States is not the only country struggling to combat the epidemic.<sup>6</sup> Across the globe, countries are taking different regulatory stances to help curb and control who can smoke

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\* Rachel E. Zarrabi is a third-year law student at Pepperdine University School of Law. She is an avid animal lover and believes that her three-pound sable-colored Chihuahua, Phoebe, is the greatest companion known to man. Rachel thanks her parents for understanding her absence when writing this article. She dedicates this comment to all of the youths who are addicted to nicotine and hopes that soon they will realize vaping does not make them cool.

<sup>1</sup> Pasquale Caponnetto, Davide Campagna, Gabriella Papale & Cristina Russo, *The Emerging Phenomenon of Electronic Cigarettes*, 6 EXPERT REV. OF RESPIRATORY MED. 63 (2012).

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

<sup>3</sup> Sarah Bennet, *Is Vaping Really a Safe Alternative to Smoking?*, ACADIA INSURANCE, <https://www.acadiainsurance.com/vaping-really-safe-alternative-smoking/> (last visited Sept. 25, 2019).

<sup>4</sup> *FDA launches new, comprehensive campaign to warn kids about the dangers of e-cigarette use*, FOOD & DRUG ADMIN., <https://www.fda.gov/news-events/press-announcements/fda-launches-new-comprehensive-campaign-warn-kids-about-dangers-e-cigarette-use-part-agencys-youth> (last visited Sept. 25, 2019).

<sup>5</sup> U.S. FDA (@US\_FDA), TWITTER (Sept. 19, 2018, 8:08 AM), [https://twitter.com/US\\_FDA/status/1042430111713316864](https://twitter.com/US_FDA/status/1042430111713316864); Scott Gilbert, *The Medical Minute: Hazards of juuling or vaping*, PENN ST. NEWS <https://news.psu.edu/story/527326/2018/07/03/impact/medical-minute-hazards-juuling-or-vaping> (last updated July 3, 2018).

<sup>6</sup> Lora Jones, *Vaping: How popular are e-cigarettes?*, BBC NEWS (Sept. 15, 2019), <https://www.bbc.com/news/business-44295336>.

and for what purpose.<sup>7</sup> This comment explores the types of legislation, approaches to regulating e-cigarettes, and analyzes whether the FDA's campaign and current regulations are effective. So far, it appears that the United States is ahead of the game with its new, aggressive proposal for regulating e-cigarettes.<sup>8</sup> The FDA is standing against the companies and products that target youthful consumers.<sup>9</sup> Most countries acknowledge the gaps in current scientific research regarding the long-term health risks of vaping, and some are waiting to take a legislative stance until it is clearer which side of the health line e-cigarettes fall.<sup>10</sup>

Section II of this comment discusses the types of regulations that countries enact.<sup>11</sup> Section III examines the potential health risks of e-cigarettes, and how the United States is changing its approach to combat the growing youth e-cigarette epidemic.<sup>12</sup> Section IV details the European Union's stance on e-cigarettes.<sup>13</sup> Section V outlines how China has yet to take any real legislative stance on e-cigarette products.<sup>14</sup> Section VI details the harm e-cigarettes can do to the human body and details the World Health Organization's recommendation for countries.<sup>15</sup> Section VII briefly discusses the

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<sup>7</sup> *Country Laws Regulation E-cigarettes: A Policy Scan*, GLOBAL TOBACCO CONTROL, <https://www.globaltobaccocontrol.org/e-cigarette/country-laws/view> (last visited Sept. 29, 2019).

<sup>8</sup> *Family Smoking Prevention and Tobacco Control Act – An Overview*, FOOD & DRUG ADMIN., <https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/family-smoking-prevention-and-tobacco-control-act-overview> (last updated Jan. 17, 2018).

<sup>9</sup> Press Release, FOOD & DRUG ADMIN., *FDA warns JUUL Labs for marketing unauthorized modified risk tobacco products, including in outreach to youth* (Sept. 9, 2019), <https://www.fda.gov/news-events/press-announcements/fda-warns-juul-labs-marketing-unauthorized-modified-risk-tobacco-products-including-outreach-youth>.

<sup>10</sup> *See generally Country Laws Regulation E-cigarettes: A Policy Scan*, *supra* note 7.

<sup>11</sup> *See infra* Section II.

<sup>12</sup> *See infra* Section III.

<sup>13</sup> *See infra* Section IV.

<sup>14</sup> *See infra* Section V.

<sup>15</sup> *See infra* Section VI.

argument that the value of e-cigarettes as a nicotine replacement therapy outweighs the dangers of youth vaping.<sup>16</sup>

At the end of this comment, it will be clear that the United States is taking a firm stance to combat youth e-cigarette use. Nicotine and other harmful chemicals in e-cigarettes are at the forefront of the FDA's mind, and its hard-hitting approach is yielding results.<sup>17</sup> Compared to other countries, the United States combats youth e-cigarette use head-on and has the tools to successfully quash it.<sup>18</sup>

## II. TYPES OF E-CIGARETTE REGULATIONS

A country's e-cigarette regulatory scheme looks to effectively target e-cigarette use at the business and consumer levels.<sup>19</sup> In the regulation of e-cigarettes, there are policy domains, product classifications, and regulatory mechanisms.<sup>20</sup>

### A. Policy Domains

E-cigarette legislation covers a wide-area of topics.<sup>21</sup> Legislators make decisions on the minimum age for purchase, sale of e-cigarettes, advertising of e-cigarettes, allowable packaging, product ingredients, mandatory reporting and notification, taxation, and locations where vaping is allowed.<sup>22</sup>

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<sup>16</sup> See *infra* Section VII.

<sup>17</sup> See generally *Country Laws Regulation E-cigarettes: A Policy Scan*, *supra* note 7.

<sup>18</sup> See generally *id.*

<sup>19</sup> *Country Laws Regulating E-Cigarettes*, JOHNS HOPKINS BLOOMBERG SCH. OF PUB. HEALTH INST. FOR GLOBAL TOBACCO CONTROL (last visited Feb. 4, 2019, 10:58 AM), <https://globaltobaccocontrol.org/e-cigarette/regulatory-mechanisms-0>.

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

<sup>21</sup> *Policy Domains*, JOHNS HOPKINS BLOOMBERG SCH. OF PUB. HEALTH INST. FOR GLOBAL TOBACCO CONTROL (last visited Mar. 8, 2019, 3:29 PM), <https://globaltobaccocontrol.org/e-cigarette/policy-domains>.

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

Many countries have the same age requirement for purchasing both e-cigarettes and traditional cigarettes.<sup>23</sup> However, many countries have a lower age requirement for e-cigarettes, while some countries have a higher minimum age of purchase.<sup>24</sup> Countries either choose to ban e-cigarette sales, permit sale but restrict advertising or imported products, prohibit sale if the product contains nicotine, or permit the sale for those who meet the minimum age.<sup>25</sup>

For advertisement regulation, the majority of countries either outright prohibit advertising and promotion of e-cigarettes or regulate advertising and promotion.<sup>26</sup> A small minority of countries only restrict advertising when the product contains nicotine.<sup>27</sup> Further, some countries control packaging to ensure it is child-safe, while others require packaging to contain health warnings.<sup>28</sup> One country prohibits brands and patents for e-cigarettes.<sup>29</sup>

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<sup>23</sup> *Minimum Age*, JOHNS HOPKINS BLOOMBERG SCH. OF PUB. HEALTH INST. FOR GLOBAL TOBACCO CONTROL (last visited Mar. 8, 2019, 3:33 PM), <https://globaltobaccocontrol.org/e-cigarette/minimum-age>.

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

<sup>25</sup> *Sale*, JOHNS HOPKINS BLOOMBERG SCH. OF PUB. HEALTH INST. FOR GLOB. TOBACCO CONTROL (last visited Mar. 8, 2019, 3:34 PM), <https://globaltobaccocontrol.org/e-cigarette/sale>. For example, India chose to ban e-cigarettes. G.S. Mudur, *E-cigarettes effective but carry risks*, TELEGRAPH INDIA (April 2, 2019), <https://www.telegraphindia.com/health/e-cigarettes-effective-but-carry-risks/cid/1683672>. India's Health Ministry informed all states to seek a ban on "the manufacture, trade and sale of e-cigarettes . . ." *Id.* In 2016 and 2017, seven states — Bihar, Uttar Pradesh, Jammu and Kashmir, Karnataka, Kerala, Mizoram and Punjab — implemented the ban. *Id.* The Association of Vapers of India was not pleased, because they believe e-cigarettes are less harmful than traditional cigarettes. *Id.*

<sup>26</sup> *Advertising, promotion and sponsorship*, JOHNS HOPKINS BLOOMBERG SCH. OF PUB. HEALTH INST. FOR GLOBAL TOBACCO CONTROL (last visited Mar. 8, 2019, 3:35 PM), <https://globaltobaccocontrol.org/e-cigarette/advertising-promotion-and-sponsorship>.

<sup>27</sup> *Id.*

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

<sup>29</sup> *Packaging (child safety packaging, health warnings and trademark)*, JOHNS HOPKINS BLOOMBERG SCH. OF PUB. HEALTH INST. FOR GLOBAL TOBACCO CONTROL (last visited Mar. 8, 2019, 3:37 PM), <https://globaltobaccocontrol.org/e-cigarette/packaging-child-safety-packaging-health-warnings-and-trademark>.

Product regulation concerns nicotine volume and concentration; safety and hygiene; and ingredients and flavors.<sup>30</sup> Some countries regulate the concentration and volume of nicotine.<sup>31</sup> For example, the European Union (EU) has a “threshold concentration of 20 [milligrams per milliliter].”<sup>32</sup> Others ban ingredients other than nicotine, which are unsafe in e-liquid.<sup>33</sup> Further, countries also control the nicotine quality, and the flavors e-liquids may have.<sup>34</sup>

Governments now regulate the business side of vaping.<sup>35</sup> They require manufacturers and retailers to notify their regulating authority before new product launches and submit reports of sales.<sup>36</sup> Furthermore, countries now prohibit or restrict vaping in public.<sup>37</sup> Lastly, as with any product, taxes are levied both on e-cigarettes and e-liquid.<sup>38</sup> The taxes vary based on the classification that the country in question gave the product.<sup>39</sup>

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<sup>30</sup> *Product regulation (nicotine volume/concentration, safety/hygiene, ingredients/flavors)*, JOHNS HOPKINS BLOOMBERG SCH. OF PUB. HEALTH INST. FOR GLOBAL TOBACCO CONTROL (last visited Mar. 8, 2019, 3:35 PM), <https://globaltobaccocontrol.org/e-cigarette/product-regulation-nicotine-volumeconcentration-safetyhygiene-ingredientsflavors>.

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

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

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

<sup>34</sup> *Id.* “While cigarettes produce smoke, e-liquids help to produce vapor in e-cigarettes. *E-liquid*, MAXIMUM YIELD, <https://www.maximumyield.com/definition/4621/e-liquid> (last visited Sept. 25, 2019).

<sup>35</sup> *Reporting/notification*, JOHNS HOPKINS BLOOMBERG SCH. OF PUB. HEALTH INST. FOR GLOBAL TOBACCO CONTROL (last visited Mar. 8, 2019, 3:40 PM), <https://globaltobaccocontrol.org/e-cigarette/reportingnotification>; *Vape-free public places*, JOHNS HOPKINS BLOOMBERG SCH. OF PUB. HEALTH INST. FOR GLOBAL TOBACCO CONTROL (last visited Mar. 8, 2019, 3:41 PM), <https://globaltobaccocontrol.org/e-cigarette/vape-free-public-places>; *Tax*, JOHNS HOPKINS BLOOMBERG SCH. OF PUB. HEALTH INST. FOR GLOBAL TOBACCO CONTROL (last visited Mar. 8, 2019, 3:42 PM), <https://globaltobaccocontrol.org/e-cigarette/tax>.

<sup>36</sup> *Reporting/notification*, *supra* note 35.

<sup>37</sup> *Vape-free public places*, *supra* note 35

<sup>38</sup> *Tax*, *supra* note 35.

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

### B. Product Classifications

Countries have different approaches on how they classify e-cigarettes as a product.<sup>40</sup> A small number of countries, such as England, France, Canada, and Germany, classify e-cigarettes as consumer products.<sup>41</sup> Another subset of countries, like Norway, Austria, and Belgium, regulate e-cigarettes with a specific nicotine threshold as medicinal devices.<sup>42</sup> A small number of countries classify nicotine as poison or a hazardous substance.<sup>43</sup> However, most countries fall into two other categories.<sup>44</sup> One category is regulating e-cigarettes as tobacco products or products like tobacco.<sup>45</sup> The other category, which contains the majority of countries, is regulating e-cigarettes as “electronic nicotine delivery systems” (ENDS).<sup>46</sup> These categories are not exclusive because countries can classify products in more than one category and take different regulatory approaches for different classifications of e-cigarettes.<sup>47</sup>

### C. Regulatory Mechanisms

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<sup>40</sup> *Product Classification*, JOHNS HOPKINS BLOOMBERG SCH. OF PUB. HEALTH INST. FOR GLOBAL TOBACCO CONTROL (last visited Feb. 4, 2019, 11:20 AM), <https://globaltobaccocontrol.org/e-cigarette/product-classifications>.

<sup>41</sup> *Consumer Product*, JOHNS HOPKINS BLOOMBERG SCH. OF PUB. HEALTH INST. FOR GLOBAL TOBACCO CONTROL (last visited Mar. 8, 2019, 3:47 PM), <https://globaltobaccocontrol.org/category/product-classifications/consumer-product>.

<sup>42</sup> *Medicinal*, JOHNS HOPKINS BLOOMBERG SCH. OF PUB. HEALTH INST. FOR GLOBAL TOBACCO CONTROL (last visited Mar. 8, 2019, 3:49 PM), <https://globaltobaccocontrol.org/category/product-classifications/medicinal>.

<sup>43</sup> *Tobacco related product*, JOHNS HOPKINS BLOOMBERG SCH. OF PUB. HEALTH INST. FOR GLOBAL TOBACCO CONTROL (last visited Mar. 8, 2019, 3:50 PM), <https://globaltobaccocontrol.org/category/product-classifications/tobacco-related-product>.

<sup>44</sup> *Product Classification*, *supra* note 40.

<sup>45</sup> *Id.*

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

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



Countries also use different mechanisms to control e-cigarettes.<sup>48</sup> The majority of countries take a legislative approach and enact a law, decree, resolution, circular, or notification.<sup>49</sup> This includes the United States, England, Germany, Italy, the UAE, Belgium, and Brazil.<sup>50</sup> A small number of countries regulate e-cigarettes under legislation or bans which previously existed.<sup>51</sup> This includes countries like Austria, Norway, and Vietnam.<sup>52</sup> A smaller number of countries, like Greece, Hungary, and Spain, chose to amend current legislation.<sup>53</sup> Another subset use a combination of new legislation and current legislation.<sup>54</sup> This includes Argentina, Denmark, Ireland, Japan, Netherlands, and Thailand.<sup>55</sup> A very small minority of countries combine tobacco legislation with existing legislation.<sup>56</sup> France, for example, combined new, amended, and existing legislation.<sup>57</sup>

#### *D. Canada*

To demonstrate a regulatory scheme, we will now examine Canada as an example. Canada's Tobacco and Vaping Products Act (TVPA) exhibits forthcoming legislation.<sup>58</sup> Regarding advertisement, the Act strictly prohibits any advertisement and promotion of vaping products, or vaping brands, that could reasonably appeal "to young persons."<sup>59</sup> The Act prohibits testimonials and endorsements on packaging and using "the depiction of a person, character or animal" as an endorsement.<sup>60</sup> TVPA

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<sup>48</sup> *Regulatory Mechanisms*, JOHNS HOPKINS BLOOMBERG SCH. OF PUB. HEALTH INST. FOR GLOBAL TOBACCO CONTROL (last visited Feb. 4, 2019, 11:21 AM), <https://globaltobaccocontrol.org/e-cigarette/regulatory-mechanisms-0>.

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

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

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

<sup>52</sup> *Id.*

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

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

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

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

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

<sup>58</sup> Tobacco and Vaping Products Act, S.C. 2018, c 20 (Can.).

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

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

additionally prohibits sponsorship promotion which associates a brand with persons, entities, events, and activities, including sports and cultural events.<sup>61</sup>

TVPA also addresses prohibiting deceptive product promotions that would lead someone to believe that e-cigarettes have health benefits.<sup>62</sup> The Act also prohibits vaping promotion that discourages quitting tobacco smoking or encourages smoking resumption.<sup>63</sup> TVPA prohibits illustrations or branding that make flavored products appealing to young persons.<sup>64</sup> TVPA illustrates how legislative acts can attack e-cigarettes promotion to combat e-cigarette usage among youths.<sup>65</sup>

### III. REGULATION OF E-CIGARETTES IN THE UNITED STATES

#### A. Regulation History of E-Cigarettes

In 2009, President Barack Obama signed into law the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act).<sup>66</sup> The Act restricted marketing tobacco products to children and provided the FDA the authority to act to protect the children.<sup>67</sup> The Act banned “sales to minors, vending machine sales, package sales of fewer than twenty cigarettes, tobacco-brand sponsorships of sports and entertainment events or other social or cultural events, and free giveaways of sample cigarettes and brand-name non-tobacco promotional items.”<sup>68</sup> The Act exempts adult-only facilities, which indicates it aimed to protect children.<sup>69</sup>

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

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

<sup>63</sup> *Id.*

<sup>64</sup> *Id.*

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

<sup>66</sup> *Family Smoking Prevention and Tobacco Control Act – An Overview*, *supra* note 8.

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

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

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

The Tobacco Control Act requires that the advertisements for smokeless tobacco packages have large and visible warnings.<sup>70</sup> It also ensured that scientific evidence supported products labeled as “modified risk” make sure it actually is a “modified risk.”<sup>71</sup> Also, the Act required tobacco companies to disclose the ingredients in its products.<sup>72</sup> In addition, the Act required tobacco companies to register annually and submit to FDA inspection every two years.<sup>73</sup> Further, it allowed the FDA to have standards for products, which meant it could regulate nicotine and other ingredient levels.<sup>74</sup> Moreover, the Act banned flavored cigarettes because of its appeal to children.<sup>75</sup> However, the Tobacco Control Act neither requires the reduction of nicotine levels to zero nor bans certain classes of tobacco products.<sup>76</sup>

### *B. Prevalence of Vaping, Health Risks, and Recent Outbreaks*

#### 1. Prevalence of Vaping

The FDA addresses the argument that people should have access to e-cigarettes as an alternative to cigarettes because it’s potentially less harmful than cigarettes.<sup>77</sup> The FDA holds that while e-cigarettes may help adult smokers switch over to an alternative, the overall public health impact would be negative if the products cause young people to become addicted to nicotine.<sup>78</sup> The FDA continuously

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<sup>70</sup> *Smokeless Tobacco Labeling and Warning Statement Requirements*, FOOD & DRUG ADMIN. (last updated Aug. 13, 2018), <https://www.fda.gov/TobaccoProducts/Labeling/Labeling/ucm2023662.htm>.

<sup>71</sup> *Family Smoking Prevention and Tobacco Control Act – An Overview*, *supra* note 8.

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

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

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

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

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

<sup>77</sup> *The Facts on the FDA’s New Tobacco Rule*, FOOD & DRUG ADMIN. (last updated Nov. 9, 2017), <https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm506676.htm>.

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

updates its view on whether or not e-cigarettes are harmful by considering the most recent scientific evidence.<sup>79</sup>

In his article discussing vaping hazards, Scott Gilbert explains how vape products are prompting young consumers to become addicted to nicotine.<sup>80</sup> In 2009, the FDA outlawed flavored cigarettes, but the FDA has not banned flavored e-cigarettes.<sup>81</sup> E-liquid often comes in different flavors and colors, which is intended to attract young consumers.<sup>82</sup> Gilbert addresses a few different arguments regarding e-cigarettes as an alternative to cigarettes.<sup>83</sup> First, Gilbert considers whether nicotine is addictive and can negatively impact brain development.<sup>84</sup> Second, he addresses whether one “pod” of e-liquid contains the same amount of nicotine as a pack of cigarettes.<sup>85</sup> Third, he examines “nicotine-free” e-cigarettes that still contain nicotine.<sup>86</sup> There are other toxic chemicals in e-cigarettes like formaldehyde and antifreeze.<sup>87</sup> Gilbert then discusses the Center for Disease Control (CDC) report that 60% of people who vape also smoke traditional cigarettes, and that vapor contains harmful carcinogens, making second-hand vaping harmful.<sup>88</sup>

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

<sup>80</sup> Scott Gilbert, *The Medical Minute: Hazards of juuling or vaping*, PENN ST. NEWS, (last updated July 3, 2018), <https://news.psu.edu/story/527326/2018/07/03/impact/medical-minute-hazards-juuling-or-vaping>.

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

<sup>82</sup> *Id.*

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

<sup>84</sup> *Id.* The National Institute on Drug Abuse detailed the health risks of nicotine for teens. *Electronic Cigarettes (E-cigarettes)*, NAT'L INST. ON DRUG ABUSE, <https://www.drugabuse.gov/publications/drugfacts/electronic-cigarettes-e-cigarettes#ref> (revised June 2018). Because the teen years are formative in development, nicotine use can cause long-lasting effects. *Id.* The Institute explains that nicotine affects the brain's reward system and teen e-cigarette use can make other drugs, like cocaine and methamphetamine, more pleasurable and affects the “brain circuits that control attention and learning.” *Id.* This can cause mood disorders and impulse control problems. *Id.*

<sup>85</sup> Gilbert, *supra* note 80.

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

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

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

E-cigarettes are the most popular tobacco product among teenagers, so Gilbert stresses discussing risks of vaping with teenagers.<sup>89</sup>

In December 2018, the Surgeon General of the United States, Jerome Adams, issued an advisory opinion urging local restrictions to prevent minor e-cigarette use.<sup>90</sup> He specifically mentioned the harm nicotine causes a developing brain.<sup>91</sup> According to Surgeon General Adams, nicotine addiction impairs learning and memory in young people, paves the way to substance abuse, and causes youths to turn to traditional cigarettes.<sup>92</sup> E-cigarettes may spike traditional cigarette smoking.<sup>93</sup>

Surgeon General Adams cited a study on the prevalence of youth e-cigarette consumption.<sup>94</sup> The University of Michigan studied adolescent drug trends in 2018 – specifically, the surges in vaping, marijuana vaping, and use of mind-altering substances.<sup>95</sup> The study found the increase in vaping among minors from 2017 to 2018 was the “largest ever recorded in the past [forty-three] years for any adolescent substance use outcome in the [United States].”<sup>96</sup> The use of nicotine in e-cigarettes has gone from 11% to 21% among twelfth-grade students.<sup>97</sup> For tenth-grade students, nicotine vaping has gone from 8% to 16%, and for eighth-grade students, vaping has gone from 3.5% to 6.1%.<sup>98</sup> Overall, for ninth to twelfth-grade, there has been at least a 1.3 million increase students who vape from 2017 to

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

<sup>90</sup> Jayne O’Donnell, *Surgeon General issues rare advisory calling for price-changes, indoor vape-free policies*, USA TODAY (Dec. 18, 2018), <https://www.usatoday.com/story/news/health/2018/12/18/surgeon-general-advisory-teen-vaping-indoor-vaping-state-local-taxes/2338781002/>.

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

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

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

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

<sup>95</sup> Nicholas Prieur, *National Adolescent Drug Trends in 2018*, U. OF MICHIGAN INST. FOR SOC. RES. 1, 1 (Dec. 17, 2018), <http://monitoringthefuture.org/pressreleases/18drugpr.pdf>.

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

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

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

2018.<sup>99</sup> The study suggested that the current policies on vaping are ineffective and a new approach is necessary.<sup>100</sup> The study praises the FDA's announcement to curb juuling and suggests that the rapidly growing e-cigarette industry needs a new approach tailored to the problem.<sup>101</sup>

The study concludes that the increase in addiction was attributable to vaping because the use of other tobacco products did not increase while e-cigarette usage was high.<sup>102</sup> Thus, e-cigarettes are leading youths into nicotine addiction, rather than leading them away from it.<sup>103</sup> The study also mentioned that marijuana vaping has doubled in every grade studied, particularly twelfth-grade.<sup>104</sup> However, it seems that the adolescent use of other controlled substances has not significantly changed.<sup>105</sup>

Because of recent evidence of increased youth vaping, the Surgeon General asked state and local governments to enforce regulations.<sup>106</sup> He suggested specifically for officials to ban vaping in indoor public venues, to increase vaping taxation, and limit flavored products.<sup>107</sup> However, some criticize the Surgeon General for not

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<sup>99</sup> *Id.* It is interesting to note whether youths had knowledge of what was inside the e-liquid they had been using - one study tracked whether or not youths knew nicotine was in vaping liquid, or whether they believed it only contained "flavoring". *Monitoring the Future Survey: High School and Youth Trends*, NAT'L INST. ON DRUG ABUSE, <https://www.drugabuse.gov/publications/drugfacts/monitoring-future-survey-high-school-youth-trends> (last updated Dec. 2018). For eighth-graders, 15.1% reported they were vaping "just flavoring," while 10.9% reported nicotine. *Id.* In tenth-graders, it was an identical percentage of "just flavoring," with 24.7% reporting nicotine as an ingredient. *Id.* For twelfth-graders, 29.7% reported nicotine, with 25.7% reporting "just flavoring." *Id.* This lack of knowledge of e-liquid content falls in line with the inconsistent e-liquid labelling problem, as well as youths vaping with other people's devices with no knowledge of what is contained inside. *Id.*

<sup>100</sup> Prieur, *supra* note 95, at 2.

<sup>101</sup> *Id.*

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

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

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

<sup>105</sup> *Id.*

<sup>106</sup> O'Donnell, *supra* note 90.

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

going further.<sup>108</sup> Nicotine addiction has not been widely studied and youths are not the only people affected.<sup>109</sup> Parents, teachers, and health care officials are also in the fold and encouraged to recognize a JUUL, a smaller e-cigarette device.<sup>110</sup> At-home solutions are also proposed, such as banning vaping in the home and encouraging parents to discuss the health risks with their children.<sup>111</sup> Social media also plays a role because JUUL has a large online presence.<sup>112</sup>

## 2. Health Risks of Vaping

While vaping prevalence seems to have exploded, the corresponding research into the health risks has not.<sup>113</sup> Because vaping has recently become such a large presence, there has not been enough time to study the long-term effects vaping has on one's body.<sup>114</sup> However, researchers have taken steps to rectify the knowledge gap.<sup>115</sup>

One article designed to inform the public about vaping mentioned that the flavoring in e-liquid does not come without its own risks.<sup>116</sup> The chemicals found in e-liquid include diacetyl and 2,3-pentanedione.<sup>117</sup> Diacetyl and 2,3-pentanedione are used to create a buttery flavor and both are linked to potential lung damage.<sup>118</sup> Studies suggest that the aerosol delivery system in vaping allows the toxins to reach further into the lungs.<sup>119</sup> The article cites another

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

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

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

<sup>111</sup> *Id.*

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

<sup>113</sup> Raquel Rutledge, *Q&A: What teens – and many adults – don't know about e-cigarettes and vaping*, USA TODAY (Nov. 15, 2018), <https://www.usatoday.com/story/news/investigations/2018/11/15/q-hidden-dangers-vaping/1983334002/>.

<sup>114</sup> *Id.*

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

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

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

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

<sup>119</sup> Raquel Rutledge, *Gasping for Action: Lab tests reveal popular e-cigarette liquids contain harmful chemicals*, USA TODAY (Nov. 14, 2018),

study where the e-liquid chemicals cause lung inflammation in mice.<sup>120</sup> The chemicals remain unregulated because there are no requirements for manufacturers to test e-liquid.<sup>121</sup> Therefore, it is difficult to determine which e-liquids contain harmful chemicals, and not all companies are truthful when reporting the contents of their e-liquids.<sup>122</sup> Further, nicotine is not an FDA regulated chemical, nor is it a controlled substance.<sup>123</sup>

One scientist in Greece proposed that vaping is a calculated risk, because there is a certain acceptable amount of the aforementioned chemicals that one can inhale in a day.<sup>124</sup> However, the acceptable amount is below the average most users inhale daily and scientists agree that currently it is impossible to know the real exposure to these chemicals.<sup>125</sup> The consumers of e-liquids are guinea pigs, unknowingly causing future detriment to their lungs.<sup>126</sup>

A further concern is that e-cigarettes are linked to heart attacks and strokes.<sup>127</sup> One study analyzed 400,000 Americans in a 2016 health survey.<sup>128</sup> The study compared people who reported regular use of e-cigarettes with those who do not use e-cigarettes.<sup>129</sup> People who regularly used e-cigarettes had about a 70% higher risk of stroke, a 60% higher risk of heart attack or angina, and a 40% higher risk of coronary heart disease.<sup>130</sup> The study considered whether such people also smoked traditional cigarettes.<sup>131</sup> While the findings are concerning, it should not be accepted blindly because the study did

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<https://www.usatoday.com/story/news/investigations/2018/11/14/lab-tests-reveal-popular-e-cigarette-liquids-contain-harmful-chemicals/2006540002/>.

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

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

<sup>122</sup> *Id.*

<sup>123</sup> *Id.*

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

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

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

<sup>127</sup> Rachael Rettner, *E-Cigarettes Linked to Heart Attacks, Strokes*, LIVE SCIENCE (Jan. 30, 2019), <https://www.livescience.com/64629-e-cigarettes-heart-attacks-strokes.html>.

<sup>128</sup> *Id.*

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

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

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



not account for individual's health and lifestyle and did not study over a long time period.<sup>132</sup> However, the findings cannot be dismissed and further research is needed.

### 3. Recent Outbreaks and Deaths

While the research into the health risks of vaping is not solid, recent hospitalizations and deaths linked to vaping cannot be ignored.<sup>133</sup> On August 23, 2019, the first death from vaping-related lung illness occurred in Illinois.<sup>134</sup> In response to the vast amounts people reporting respiratory illness from e-cigarettes, Illinois requested help from the CDC.<sup>135</sup> A week later, United States health officials reported on their investigation into 215 cases of severe lung disease across twenty-five states.<sup>136</sup> The CDC and the FDA were unable to link the lung disease to a specific cause or particular product.<sup>137</sup> However, both urged consumers to not buy products off the street and to regulate their health.<sup>138</sup> It might be possible to trace the disease to counterfeit pods designed for JUUL devices.<sup>139</sup> Commissioner Gottlieb warned against counterfeit fruit-flavored pods because they are made with unknown ingredients.<sup>140</sup>

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

<sup>133</sup> Emma Newburger, *First death reported from vaping-related lung illness, officials say*, CNBC (Aug. 23, 2019), <https://www.cnbc.com/2019/08/23/first-death-reported-in-illinois-from-vaping-related-lung-illness-officials-say.html>.

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

<sup>135</sup> *Id.*

<sup>136</sup> Angelica LaVito, *US health officials investigating 215 possible cases of severe lung disease associated with vaping*, CNBC (Aug. 30, 2019), <https://www.cnbc.com/2019/08/30/cdc-investigating-215-possible-cases-of-vaping-related-severe-lung-disease.html?recirc=taboolainternal>.

<sup>137</sup> *Id.*

<sup>138</sup> *Id.* It is also important to note that at least half of the cases reported involved THC, although there has been no causal link established. *Id.*

<sup>139</sup> Angelica LaVito, *Fake Juul pods line store shelves, worrying users and posing another threat to the embattled company*, CNBC (Aug. 26, 2019), <https://www.cnbc.com/2019/08/26/fake-juul-pods-fill-shelves-after-vaping-giant-pulled-fruity-flavors.html>.

<sup>140</sup> *Id.* JUUL's investigations into these counterfeit pods led back to Chinese factories with dirty and unsanitary conditions. *Id.* Law enforcement has conducted

The CDC said in a statement that it was “saddened to hear about the first death related to the outbreak of severe lung disease in those who use e-cigarette or ‘vaping’ devices” and that its investigation is ongoing.<sup>141</sup> It reiterated the risk associated with vaping (considering how little is known about the health risks) and warned young people, pregnant women, and non-tobacco users that e-cigarettes are not safe.<sup>142</sup>

Further, it appears that the death in Illinois was not an isolated incident.<sup>143</sup> A second person died in Oregon after becoming sick from vaping with a tetrahydrocannabinol (THC)<sup>144</sup> product purchased at a marijuana shop.<sup>145</sup> The legal purchase raises questions about the counterfeit theory but further investigations are necessary into the origins of such products.<sup>146</sup>

State agencies can also respond to the vaping epidemic. Michigan was the first state to ban flavored e-cigarettes.<sup>147</sup> Michigan’s Governor, Gretchen Whitmer, stated that the ban was a result of the State Department of Health and Human Services declaration that youth vaping is a public health emergency.<sup>148</sup>

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fifteen raids this year and have found “hundreds of thousands of counterfeit products.” *Id.*

<sup>141</sup> *CDC Director’s Statement on the first death related to the outbreak of severe lung disease in people who use e-cigarette or “vaping” devices*, CDC NEWSROOM (Aug. 23, 2019), <https://www.cdc.gov/media/releases/2019/s0823-vaping-related-death.html>.

<sup>142</sup> *Id.*

<sup>143</sup> Matt Richtel, *Another Patient Has Died From Lung Disease After Vaping*, N.Y. TIMES (Sept. 7, 2019), <https://www.nytimes.com/2019/09/04/health/vaping-death-lung.html>.

<sup>144</sup> THC is a psychoactive compound found in cannabis. Kimberly Holland, *CBD vs. THC: What’s the Difference*, HEALTHLINE (May 20, 2019), <https://www.healthline.com/health/cbd-vs-thc>.

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

<sup>146</sup> *Id.* Reported patients are mostly teens or adults in their twenties or thirties. *Id.* Symptoms include “severe shortness of breath, vomiting, fever, and fatigue.” *Id.*

<sup>147</sup> Laurie McGinley, *Michigan becomes first state to ban flavored e-cigarettes*, WASH. POST (Sept. 4, 2019), [https://www.washingtonpost.com/health/michigan-becomes-first-state-to-ban-flavored-e-cigarettes/2019/09/03/34f234c6-ce4c-11e9-8c1c-7c8ee785b855\\_story.html?noredirect=on](https://www.washingtonpost.com/health/michigan-becomes-first-state-to-ban-flavored-e-cigarettes/2019/09/03/34f234c6-ce4c-11e9-8c1c-7c8ee785b855_story.html?noredirect=on).

<sup>148</sup> *Id.* The ban will be in effect for six months and can be renewed for another six months. *Id.* This is meant as a stopgap until a permanent ban is placed. *Id.* The ban will be on retail and online sales. *Id.*

### C. *The FDA's Current Approach*

#### 1. Plan for Tobacco and Nicotine Regulation

The FDA announced a comprehensive plan for tobacco and nicotine regulation.<sup>149</sup> The plan is designed to take place over multiple years and aims to protect youths from nicotine addiction and help addicted adult smokers quit.<sup>150</sup> The plan has three components: (1) regulatory policies on addiction, appeal, and cessation; (2) science-based review of tobacco products; and (3) the youth tobacco prevention plan.<sup>151</sup>

##### a. Regulatory Policies

One of the focal points of the plan is to lower the nicotine levels in cigarettes to a minimal or non-addictive level by creating a standard for nicotine levels.<sup>152</sup> This policy aims to decrease future addiction, as well as to help current addicts.<sup>153</sup> The plan also introduces a proposal on the regulation of flavors in tobacco products, although no decisions have been made and it is currently under review.<sup>154</sup>

The plan aims to increase access to medicinal nicotine products (such as evaluating the safety of nicotine replacement therapy), as well as to educate the public about nicotine and to correct common misconceptions.<sup>155</sup>

##### b. Science-Based Review

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<sup>149</sup> *FDA's Comprehensive Plan for Tobacco and Nicotine Regulation*, FOOD & DRUG ADMIN., <https://www.fda.gov/TobaccoProducts/NewsEvents/ucm568425.htm> (last updated Sept. 12, 2018).

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

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

<sup>152</sup> *Id.*

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

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

<sup>155</sup> *Id.*

The FDA gave tobacco companies additional time to submit reports detailing their products for review to ensure that the reports will be more accurate and detailed.<sup>156</sup> The FDA is also seeking feedback from the industry regarding whether or not it will be able to comply with the new rules.<sup>157</sup>

The most important part of the plan involves the exploration of additional product standards that could prevent injuries from known risks.<sup>158</sup> This includes a potential product standard to prevent the batteries in vapes from exploding and another to address concerns about children’s exposure to liquid nicotine.<sup>159</sup> The FDA will explore a product standard for e-cigarettes, which will consider levels of toxicants and impurities in propylene glycol, glycerin, and nicotine in e-liquids.<sup>160</sup>

### c. Youth Tobacco Prevention Plan

The FDA is launching regulatory and research efforts into the access youth have to e-cigarettes, the marketing that targets youths, and the education of youths.<sup>161</sup> This includes the “Real Cost Campaign,” detailed below.<sup>162</sup>

## 2. “Real Cost Campaign”

In September 2018, Scott Gottlieb, the commissioner of the FDA, announced on Twitter the “Real Cost Campaign” aimed at educating

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<sup>156</sup> *Id.*

<sup>157</sup> *Id.*

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

<sup>159</sup> *Id.* Nicotine is not the only concern – there is also a practice called *dripping*, where teens are placing e-liquids directly onto the heated atomizer coils. *Electronic Cigarettes (E-cigarettes)*, NAT’L INST. ON DRUG ABUSE, <https://www.drugabuse.gov/publications/drugfacts/electronic-cigarettes-e-cigarettes#ref>, (revised June 2018). It is unknown whether or not this has negative health effects. *Id.* It has been reported that teens engage in dripping to (1) create thicker vapor, (2) improve flavors, and (3) to “produce a stronger throat hit – a pleasurable feeling that the vapor creates when it causes the throat to contract.” *Id.*

<sup>160</sup> *FDA’s Comprehensive Plan for Tobacco and Nicotine Regulation*, *supra* note 149.

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

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

youths about the potential dangers e-cigarettes pose.<sup>163</sup> The campaign launched in 2014 as an effort to educate teens on the harmful effects of traditional cigarettes and expanded in 2016 to reach rural boys on the harmful effects of smokeless tobacco.<sup>164</sup> However, the Real Cost Campaign has now turned its eye to e-cigarettes.<sup>165</sup>

In 2014, e-cigarettes became the most common tobacco product among youths.<sup>166</sup> To combat 80% of youth's belief that e-cigarettes are not harmless, the Real Cost Campaign targets youths through social media.<sup>167</sup> The Campaign consists of online video ads, a website, digital media content, and materials in high schools nationwide.<sup>168</sup>

#### a. Reaction to the "Real Cost Campaign"

In 2015, a group of researchers published a study on the effectiveness of the Real Cost Campaign a year after it launched, when it was aimed at stopping youths from smoking conventional cigarettes.<sup>169</sup>

The study showed that awareness of the Real Cost brand was at 49.9% among youths, and awareness of the Real Cost advertisements was 89.0%.<sup>170</sup> Overall, researchers concluded that the education campaign was successful.<sup>171</sup>

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<sup>163</sup> U.S. FDA, *supra* note 5.

<sup>164</sup> *The Real Cost Campaign*, FOOD & DRUG ADMIN., <https://www.fda.gov/TobaccoProducts/PublicHealthEducation/PublicEducationCampaigns/TheRealCostCampaign/default.htm>, (last updated Sept. 18, 2018).

<sup>165</sup> *Id.*

<sup>166</sup> *Id.*

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

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

<sup>169</sup> Jennifer C. Duke, Tesfa N. Alexander, Xiaoquan Zhao, Janine C. Delahanty, Jane A. Allen, Anna J. MacMonegle & Matthew C. Farrelly, *Youth's Awareness of and Reactions to The Real Cost National Tobacco Public Education Campaign*, 55 AM. J. PREV. MED. 319, 319 (2015).

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

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

Researchers conducted another study in 2017 after the second wave of the Real Cost campaign in 2016.<sup>172</sup> The study measured the efficiency of the campaign by “(1) estimating the cost per quality-adjusted life year saved and (2) estimating the total monetary return on investment by comparing the cost savings associated with the campaign to campaign expenditures.”<sup>173</sup> The study concluded that the campaign was cost effective because the amount it spent per individual to divert the person from becoming a lifelong smoker was significantly less than the “financial burden to individuals, their families, and society” when someone is a lifelong smoker.<sup>174</sup> The reduction in health problems and death from tobacco makes the Real Cost campaign a worthwhile investment.<sup>175</sup>

### 3. Current Federal Rules for Tobacco Manufacturers

The FDA is currently regulating all tobacco retailers, including e-cigarette retailers, under the Federal Food, Drug, and Cosmetic Act (FD&C Act).<sup>176</sup> Tobacco retailers must follow a set of rules in order to comply with the Act.<sup>177</sup> These rules include: identification checks of anyone buying tobacco products under twenty-seven, restricting tobacco products sales to people eighteen and over, no sale of tobacco products in vending machines except in adult-only facilities, and no free samples of tobacco products to consumers.<sup>178</sup>

Furthermore, the FDA implemented the “This is Our Watch” program.<sup>179</sup> The FDA designed the program to aid retailers to comply

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<sup>172</sup> Jennifer C. Duke et. al., *supra* note 169.

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

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

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

<sup>176</sup> *Selling Tobacco Products in Retail Stores*, FOOD & DRUG ADMIN. (last updated June 4, 2019), <https://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Retail/ucm205021.htm>.

<sup>177</sup> *Id.*

<sup>178</sup> *Id.*

<sup>179</sup> *This Is Our Watch*, FOOD & DRUG ADMIN. (last updated Aug. 1, 2018), <https://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Retail/ucm237741.htm>.

with federal laws.<sup>180</sup> It is also helping retailers protect minors from tobacco use.<sup>181</sup> Participation in the program is voluntary, but retailers are encouraged to put the materials on display in stores.<sup>182</sup> The program educates owners, managers, and clerks, as well as targeting the education of the consumer.<sup>183</sup> “This is Our Watch” provides point-of-purchase tools—posters, register stickers, regulation flyers, age verification calendars, register signage, and instruction booklets—to help retailers comply with the federal tobacco regulation.<sup>184</sup>

E-cigarettes are regulated the same as tobacco products. On August 10, 2018, the tobacco rules applied to “covered tobacco products.”<sup>185</sup> “Covered tobacco products” are defined as “any tobacco product deemed to be subject to the FD&C Act under §1100.2 . . . but exclud[ing] any component or part that is not made or derived from tobacco.”<sup>186</sup> Further rules for e-cigarettes, or ENDS, include no sales or distribution without a health warning on packages, and no advertising displays without health warnings.<sup>187</sup>

#### 4. Action Against E-Cigarette Manufacturers

In May 2018, the FDA and Federal Trade Commission (FTC) acted against companies that targeted youths through its advertisement of e-cigarette-related products.<sup>188</sup> Together, the agencies issued thirteen warning letters to manufacturers,

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<sup>180</sup> *Id.*

<sup>181</sup> *Id.*

<sup>182</sup> *Id.*

<sup>183</sup> *Id.*

<sup>184</sup> *Id.*

<sup>185</sup> *Selling Tobacco Products in Retail Stores*, *supra* note 176.

<sup>186</sup> *CTP Glossary*, FOOD & DRUG ADMIN. (last updated Oct. 17, 2017), <https://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm514344.htm#C>.

<sup>187</sup> *Selling Tobacco Products in Retail Stores*, *supra* note 176.

<sup>188</sup> *FTC Takes Action Against Companies Misleading Kids With E-Liquids That Resemble Children’s Juice Boxes, Candies and Cookies*, FOOD & DRUG ADMIN. (last updated May 2, 2018), <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm605507.htm>.

distributors, and retailers for “selling e-liquids used in e-cigarettes with labeling [and] advertising that cause them to resemble kid-friendly food products, such as juice boxes, candy or cookies, some of them with cartoon-like imagery.”<sup>189</sup>

Furthermore, the FDA and FTC warned companies for their sale of products to minors.<sup>190</sup> In September 2018, the FDA issued over 1,300 warning letters and fines to retailers who illegally sold JUUL and other e-cigarette products to minors during a “nationwide, undercover blitz of brick-and-mortar and online stores this summer.”<sup>191</sup> This occurred alongside FDA Commissioner Gottlieb’s announcement of the Youth Tobacco Prevention Plan.<sup>192</sup> The sting targeted the five brands of e-cigarette products, which comprised over 97% of the American market for e-cigarettes.<sup>193</sup>

The FDA held a public meeting for Tobacco Product Application Review on October 22–23, 2018, where it intended to “improve public understanding and to seek feedback on the policies and processes for the submission and review of tobacco product marketing applications, including the general scientific principles relevant to various application pathways, in order to assist persons considering submitting marketing applications for tobacco products” which fall under the FD&C Act.<sup>194</sup> Tobacco product manufacturers, distributors, medical experts, government agencies, and researchers attended the meeting.<sup>195</sup> The FDA educated the relevant parties on the application process.<sup>196</sup>

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<sup>189</sup> *Id.*

<sup>190</sup> *Id.*

<sup>191</sup> *FDA Takes New Steps to Address Epidemic of Youth E-Cigarette Use, Including a Historic Action Against More Than 1,300 Retailers and 5 Major Manufacturers for Their Roles Perpetuating Youth Access*, FOOD & DRUG ADMIN. (last updated Sept. 11, 2018), <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm620184.htm>.

<sup>192</sup> *Id.*

<sup>193</sup> *Id.*

<sup>194</sup> *Tobacco Product Application Review – A Public Meeting*, FOOD & DRUG ADMIN. (last updated May 30, 2019), <https://www.fda.gov/tobacco-products/ctp-newsroom/tobacco-product-application-review-public-meeting>.

<sup>195</sup> *Id.*

<sup>196</sup> *Id.*



#### *D. Future Plans for the FDA*

In November 2018, FDA Commissioner Scott Gottlieb took a further step in the war against vaping when he proposed new steps for the FDA to prevent youth access to flavored tobacco products.<sup>197</sup> He intends to save the next generation from nicotine dependence.<sup>198</sup> Specifically, Commissioner Gottlieb directed the Center for Tobacco Products (CTP) in the FDA to “revisit [their] compliance policy as it applies to deemed ENDS products that are flavored, including all flavors other than tobacco, mint and menthol.”<sup>199</sup> He seeks to stop youth access by limiting sales to “age-restricted, in-person locations,” and curtailing online sales through “heightened practices for age verification.”<sup>200</sup>

Commissioner Gottlieb explains the lack of regulation of mint and menthol-flavored ENDS. The flavors are geared towards adult users of ENDS and Gottlieb does not wish to stop adult users seeking e-cigarettes as nicotine replacements for traditional cigarettes.<sup>201</sup> Furthermore, Commissioner Gottlieb clarified that he does not wish to completely cut off the positive features of ENDS, and as a result causing traditional cigarettes to appeal more.<sup>202</sup> However, he will revisit the policy if trends suggest the mint and menthol flavors are becoming more popular among youths.<sup>203</sup> The Commissioner notes the possible popularity of menthol among youths and minority communities and wishes to strike a balance between youth access and adult smokers.<sup>204</sup>

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<sup>197</sup> Scott Gottlieb, *Statement from FDA Commissioner Scott Gottlieb, M.D., on Proposed New Steps to Protect Youth by Preventing Access to Flavored Tobacco Products and Banning Menthol in Cigarettes*, FOOD & DRUG ADMIN. (Nov. 15, 2018), <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm625884.htm>.

<sup>198</sup> *Id.*

<sup>199</sup> *Id.*

<sup>200</sup> *Id.*

<sup>201</sup> *Id.*

<sup>202</sup> *Id.*

<sup>203</sup> *Id.*

<sup>204</sup> *Id.*

In addition to this proposed ban on flavored ENDS, the Commissioner is directing CTP to “publish additional information regarding [the] best practices for online sales.”<sup>205</sup> The goal is timeliness; to have this information available as soon as possible so that online sellers can adopt these practices and stop youth access to tobacco products.<sup>206</sup> The Commissioner intends to closely monitor the online sales of mint and menthol e-cigarettes to ensure minors are not purchasing it.<sup>207</sup> Commissioner Gottlieb reiterated the elasticity of his approach and explained to the public his willingness to revisit the policies upon receipt of further relevant data.<sup>208</sup> The Commissioner seeks to expand and develop reviews of the products in the hopes of developing methods to prevent ENDS from falling into young hands.<sup>209</sup> He appealed to the manufacturers to not wait for federal action prompting but to stop sales and marketing practices that target youths on their own.<sup>210</sup>

It seems the FDA’s new approach is making headway, as it already produced positive results.<sup>211</sup> In response to the Commissioner’s first announcement in September and prior to the Commissioner’s announcement in November, JUUL has taken a step of its own in the fight against youth vaping.<sup>212</sup> In early November 2018, JUUL announced its decision to stop selling its flavored products in stores and to decrease its presence on social media.<sup>213</sup> This is an encouraging step because JUUL is one of the largest e-cigarette companies, selling at over 90,000 retail stores with multiple fruit-flavored e-liquids.<sup>214</sup> JUUL will verify age when it comes to

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<sup>205</sup> *Id.*

<sup>206</sup> *Id.*

<sup>207</sup> *Id.*

<sup>208</sup> *Id.*

<sup>209</sup> *Id.*

<sup>210</sup> *Id.*

<sup>211</sup> Ryan W. Miller, *JUUL to Halt Sale of Flavored E-Cigarette Products In Stores After FDA Crackdown*, USA TODAY (Nov. 14, 2018), <https://www.usatoday.com/story/news/health/2018/11/13/juul-flavored-e-cigarette-products-social-media-fda-crackdown/1990688002/>.

<sup>212</sup> *Id.*

<sup>213</sup> *Id.*

<sup>214</sup> *Id.*

online sales.<sup>215</sup> JUUL's CEO stated its original purpose was not to involve youths in vaping, and though youth vaping was an outcome of their sales, it intends to be part of the solution.<sup>216</sup> This may seem like a preemptive strike of its own accord but the FDA's part cannot be overlooked.<sup>217</sup> In September, the FDA gave JUUL and other e-cigarette companies a chance to submit plans to combat youth e-cigarette usage.<sup>218</sup> JUUL intends to align themselves with the FDA's approach on mint and menthol-flavored products in retail stores, and it has made plans to enact "secret shopper" programs to make sure the retailers comply with its directive.<sup>219</sup>

JUUL is not completely in compliance with the FDA's current process because the company stated that fruit-flavored e-liquids could be back on retail shelves if it appears retailers are practicing age-verification techniques and limiting the available supply.<sup>220</sup> JUUL's actions received criticism, considering that it only attempted to help youth addiction after it controlled 75% of the e-cigarette

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<sup>215</sup> *Id.* It seems that the legislature will trust e-cigarette manufacturers to do the right thing on their own. Lynn Evans, *E-Cigarettes Threaten Adolescent Health*, CLARION LEDGER, (Feb. 2, 2019), <https://www.clarionledger.com/story/opinion/columnists/2019/02/02/e-cigarettes-threaten-adolescent-health/2730745002/>. Three Mississippi congressmen introduced different bills to ban vaping in schools, punish purchasing e-cigarettes with fake identification cards, allow youths to aid law enforcement in sting operations against vendors who sell to minors, and tax products like JUULs as much as cigarettes and cigars. *Id.*

<sup>216</sup> Miller, *supra* note 211.

<sup>217</sup> *Id.*

<sup>218</sup> *Id.*

<sup>219</sup> *Id.*

<sup>220</sup> *Id.* While it is discouraging to think that JUUL may place harmful products back on the market, it may not get the opportunity. Rachel Siegel, *San Francisco Becomes First Major U.S. City to Ban*

*E-Cigarette Sales to Combat Teen Vaping*, WASH. POST (June 26, 2019), <https://www.washingtonpost.com/business/2019/06/26/san-francisco-bans-e-cigarette-sales-curb-teenage-vaping/>. San Francisco has now banned e-cigarette sales inside the city, which is remarkable considering that JUUL Labs is based in San Francisco. *Id.* The city has banned sales to brick-and-mortar stores as well as online sales that ship to San Francisco addresses in an effort to reduce teen vaping. *Id.* JUUL argues that the ban could create a black market for products, but legislators believe nicotine addiction is a more pressing concern. *Id.*

market and was the most popular brand among youths.<sup>221</sup> Its social media revocation is insignificant when its branding is so synonymous with young users that the users themselves promote JUUL on their own social media platforms.<sup>222</sup> While the company promised only to endorse posters who are vaping as an alternative to smoking traditional cigarettes, it begs the question if such actions are now too little, too late?<sup>223</sup>

#### IV. THE EUROPEAN UNION

##### A. *Current Regulations*

The EU regulates e-cigarettes as consumer products through Article 20 of the Tobacco Products Directive.<sup>224</sup> It has safety requirements, packaging requirements, labeling rules, monitoring and reporting rules, and implemented legislation.<sup>225</sup>

##### 1. Safety and Quality Requirements

The EU has a maximum nicotine concentration and volume for e-liquid.<sup>226</sup> E-cigarettes must be child-resistant, tamper-proof, and prevent spillage from full containers.<sup>227</sup> The ingredients must meet purity requirements and should evenly deliver nicotine in every puff.<sup>228</sup>

##### 2. Packaging and Labelling

The EU requires health warnings on products, which inform consumers the product contains nicotine and is not for non-smoking

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<sup>221</sup> Miller, *supra* note 211.

<sup>222</sup> *Id.*

<sup>223</sup> *Id.*

<sup>224</sup> *Electronic Cigarettes*, EUR. COMM'N (last visited Feb. 4, 2019), [https://ec.europa.eu/health/tobacco/ecigarettes\\_en](https://ec.europa.eu/health/tobacco/ecigarettes_en).

<sup>225</sup> *Id.*

<sup>226</sup> *Id.*

<sup>227</sup> *Id.*

<sup>228</sup> *Id.*

use.<sup>229</sup> Furthermore, packaging must list of all product ingredients.<sup>230</sup> There must also be instructions for use and “information on adverse effects, risk groups, addictiveness and toxicity.”<sup>231</sup> Packaging cannot contain promotions or advertising.<sup>232</sup>

### 3. Monitoring and Reporting

The Directive requires monitoring and reporting for manufacturers and importers.<sup>233</sup> Manufacturers and importers must notify all products they place on the EU market to the Commission through a Commission-provided standardized electronic form.<sup>234</sup>

### 4. Implementing Legislation

To implement the Directive, the Commission enacted the Commission Implementing Decisions 2015/2183 and 2016/586 and published the Commission Report COM(2016) 269 final.<sup>235</sup> The first Decision established a common format for the notification of electronic cigarettes and refill containers.<sup>236</sup> The second Decision addressed technical standards for the refill mechanisms of electronic cigarettes.<sup>237</sup> Report 269 was from the Commission to Parliament and Council regarding the “potential risks to public health associated with the use of refillable electronic cigarettes.”<sup>238</sup> While it seems that the EU is proactively approaching e-cigarette legislation, it remains unclear whether it is as concerned as the United States with youth e-cigarette usage.

#### a. EU’s Stance on the Health Risks

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<sup>229</sup> *Id.*

<sup>230</sup> *Id.*

<sup>231</sup> *Id.*

<sup>232</sup> *Id.*

<sup>233</sup> *Id.*

<sup>234</sup> *Product Regulation*, EUR. COMM’N (last visited Mar. 8, 2019), [https://ec.europa.eu/health/tobacco/products\\_en](https://ec.europa.eu/health/tobacco/products_en).

<sup>235</sup> *Electronic Cigarettes*, *supra* note 224.

<sup>236</sup> *Id.*

<sup>237</sup> *Id.*

<sup>238</sup> *Id.*

Similar to the regulatory bodies in the United States, officials in the EU are questioning whether e-cigarettes are a viable alternative to traditional cigarettes.<sup>239</sup> Traditional smoking is still a prevalent problem in the EU, considering there are almost 700,000 cigarette-related deaths every year.<sup>240</sup> Vytenis Andriukaitis, the EU Commissioner for Health and Food Safety, acknowledges that e-cigarettes cause less damage than traditional cigarettes.<sup>241</sup> However, he did stress that data on e-cigarette usage is still being collected and under scientific scrutiny.<sup>242</sup> The Commissioner stated that the best way to stop smoking would be to seek medical doctors and psychologists care for appropriate medicine, rather than attempting to quit by oneself.<sup>243</sup>

#### b. United Kingdom's Stance on the Health Risks

In 2015, Public Health England (PHE) published a report on the health risks of e-cigarettes, claiming that e-cigarettes were at least 95% less harmful than traditional cigarettes.<sup>244</sup> In 2018, PHE revisited their earlier findings, only to reaffirm their conclusion that vaping posed a smaller health risk than traditional cigarettes.<sup>245</sup> Further, vaping led to over 20,000 people successfully quitting smoking each year.<sup>246</sup> PHE promoted e-cigarette use as nicotine replacement therapy and encouraged users to make the switch in

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<sup>239</sup> Sarantis Michalopoulos, *Andriukaitis: E-cigarettes Under Thorough Scrutiny, and Not the Way to Stop Smoking*, EURACTIV (May 3, 2018), <https://www.euractiv.com/section/healthconsumers/news/andriukaitis-e-cigarettes-under-thorough-scrutiny-and-not-the-way-to-stop-smoking/>.

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

<sup>241</sup> *Id.*

<sup>242</sup> *Id.*

<sup>243</sup> *Id.*

<sup>244</sup> *PHE publishes independent expert e-cigarettes evidence review*, PUB. HEALTH ENGLAND (Feb. 6, 2018), <https://www.gov.uk/government/news/phe-publishes-independent-expert-e-cigarettes-evidence-review>.

<sup>245</sup> *Id.*

<sup>246</sup> *Id.*

addition to seeking help from a quitting-smoking service.<sup>247</sup> Nicotine addiction does not appear to concern the United Kingdom (UK), considering Ann McNeill, a Professor of Tobacco Addiction at King's College London, argues that the health risks from smoking come from cancer-causing chemicals in cigarettes, not nicotine, which "causes little if any of the harm."<sup>248</sup> Youth smoking may not be as concerning because e-cigarette usage among non-cigarette-smoking youth is less than one percent in the UK.<sup>249</sup>

## V. CHINA

Because China invented the e-cigarette in 2003 as a traditional cigarette alternative, it is worth looking at China's vaping regulation.<sup>250</sup> China has a smoking culture, and it currently has 300 million known smokers.<sup>251</sup> Similarly, vaping is extremely prevalent.<sup>252</sup> However, there may be potential conflict of interest when it comes to vaping legislation because China's government is one of the leading producers of tobacco products and many Chinese citizens are turning to vaping as an aid to quit smoking.<sup>253</sup>

It appears the government might begin regulating.<sup>254</sup> Despite China being the first to have e-cigarettes on the market in 2003,<sup>255</sup>

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<sup>247</sup> *Id.* The UK differs from Greece on whether e-cigarettes are harmful. Where the UK believes e-cigarettes are a viable alternative, Greece has been treating e-cigarettes the same as traditional cigarettes, including bans on smoking in public and on advertising, in an effort to reduce "cultural degradation." Sarantis Michalopoulos, *Greek court says e-cigarettes do not differ from traditional smoking*, EURACTIV (Mar. 9, 2018), <https://www.euractiv.com/section/health-consumers/news/greek-court-says-e-cigarettes-do-not-differ-from-traditional-smoking/>.

<sup>248</sup> *Id.*

<sup>249</sup> *Id.*

<sup>250</sup> Diane Caruana, *China's bold smoking ban*, VAPINGPOST (Dec. 13, 2016), <https://www.vapingpost.com/2016/12/13/chinas-bold-smoking-ban/>.

<sup>251</sup> *Id.* This amounts to one third of the world's total smokers. *Id.*

<sup>252</sup> *Id.*

<sup>253</sup> *Id.*

<sup>254</sup> *Id.*

<sup>255</sup> *Id.* 2003 was three years before e-cigarettes hit the world-wide market. *Id.*

China does not have any vaping regulations in place.<sup>256</sup> The President of the Beijing Tobacco Control Association called for involved government departments to consider regulating e-cigarettes, as well as a possible ban on public e-cigarette use.<sup>257</sup> Chinese authorities, which includes the State Tobacco Monopoly Administration, have banned e-cigarette sales to minors.<sup>258</sup> Although this seems positive, the document is not legally binding.<sup>259</sup>

China appears to have a youth vaping epidemic similar to the United States'.<sup>260</sup> E-cigarette sales are popular among younger consumers and children easily obtain devices from shops near their schools.<sup>261</sup> Children as young as ten are able to obtain the devices and imitate "cool" smoking adults.<sup>262</sup> Websites in China where someone can purchase e-cigarettes do not require age or identification verification.<sup>263</sup> Currently, 6.9% of Chinese teenagers smoke, while at least 19.9% have tried smoking at least once.<sup>264</sup> Because China is currently the world's largest e-cigarette manufacturer, it is not hard for these kids to get an e-cigarette device if they desire to do so.<sup>265</sup>

Even though the national government may be slow on regulating, that does not preclude local governments from legislating.<sup>266</sup> In fact,

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<sup>256</sup> Diane Caruana, *China: Tobacco Regulators Ask for Vaping Laws*, VAPING POST (Aug. 6, 2018), <https://www.vapingpost.com/2018/08/06/china-tobacco-regulators-ask-for-vaping-laws/>.

<sup>257</sup> *Id.*

<sup>258</sup> Diane Caruana, *Chinese Cities Consider E-Cigarette Ban*, VAPINGPOST (Nov. 9, 2018), <https://www.vapingpost.com/2018/11/09/chinese-cities-consider-e-cigarette-bans/>.

<sup>259</sup> *Id.*

<sup>260</sup> Zhang Yu, *Cities mull ban on e-cigarettes in public even though China is the biggest producer*, GLOBAL TIMES (Nov. 7, 2018), <http://www.globaltimes.cn/content/1126288.shtml>.

<sup>261</sup> *Id.*

<sup>262</sup> *Id.*

<sup>263</sup> *Id.*

<sup>264</sup> *Id.*

<sup>265</sup> *Id.* China is responsible for 90% of the world's e-cigarette product volume. *Id.*

<sup>266</sup> Bryan Grogan, *Hangzhou Becomes 1<sup>st</sup> City in China to Ban Public Vaping*, THAT'S MAGS (Jan. 7, 2019),



the Chinese city Hangzhou was the first city to ban e-cigarettes and vaping in public.<sup>267</sup> The ban applies to “public places, indoor workplaces and on public transportation, as well as outdoor areas including schools, kindergartens and hospitals.”<sup>268</sup> It allowed entertainment venues a time period to comply with the regulations and to construct smoking rooms if they wished to do so.<sup>269</sup> Those who violate regulations are subject to fines, which will increase if they persist despite verbal warnings.<sup>270</sup> Hangzhou is further requiring identification if it appears the consumer is underage.<sup>271</sup> Vendors who violate the policies are also subject to a fine.<sup>272</sup>

In 2018, Carrie Lam Cheng Yuet-ngor, a Hong Kong legislative leader, announced a complete ban on e-cigarettes and other new tobacco products.<sup>273</sup> It contradicted what was earlier thought to be Hong Kong’s legislative approach, which would regulate e-cigarettes instead of ban them.<sup>274</sup> The ban received criticism because it unfairly characterizes e-cigarettes.<sup>275</sup> People have criticized e-cigarettes bans for being based on unsubstantiated scientific claims, while traditional cigarettes sales remain legal despite the copious known health risks posed.<sup>276</sup>

Bans in China, the largest producer of e-cigarettes, could impact availability of the devices in America—currently there are proposed

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<http://www.thatsmags.com/shanghai/post/26463/hangzhou-becomes-the-first-city-in-china-to-ban-public-vaping>.

<sup>267</sup> *Id.*

<sup>268</sup> *Id.*

<sup>269</sup> *Id.*

<sup>270</sup> *Id.*

<sup>271</sup> *Id.*

<sup>272</sup> *Id.*

<sup>273</sup> Emily Tsang, *Carrie Lam’s policy address 2018: land development to maternity leave, five key takeaways from city leader’s blueprint for Hong Kong*, SOUTH CHINA MORNING POST (Oct. 10, 2018), <https://www.scmp.com/news/hong-kong/politics/article/2167795/carrie-lams-policy-address-2018-land-development-maternity>.

<sup>274</sup> *Id.*

<sup>275</sup> Stephen Vines, *Hong Kong’s ban on e-cigarettes is absurd. If vaping is as bad as smoking, why hasn’t tobacco been outlawed?*, SOUTH CHINA MORNING POST (Oct. 17, 2018), <https://www.scmp.com/comment/insight-opinion/hong-kong/article/2168894/hong-kongs-ban-e-cigarettes-absurd-if-vaping-bad>.

<sup>276</sup> *Id.*

tariffs on Chinese e-cigarettes in America.<sup>277</sup> Perhaps a possible solution to the growing problem in America is an imported e-cigarettes ban, coupled with national use-restrictions.<sup>278</sup> China produces 91% of the United States' imported e-cigarette products.<sup>279</sup> Some see e-cigarettes not only as a healthier option to traditional cigarette smoking, but as a cheaper option.<sup>280</sup> If tariffs against China were put into place, it could increase the average e-cigarette user's vaping cost by 15%.<sup>281</sup> It is possible that even a 10% price increase in e-cigarette prices could reduce sales by 12% to 19%.<sup>282</sup> JUUL in particular has the potential to suffer extreme economic loss, because China is the only place that can support its manufacturing volume.<sup>283</sup>

## VI. THE WORLD HEALTH ORGANIZATION

In 2014, the World Health Organization (WHO) released a bulletin which addressed increased e-cigarette use.<sup>284</sup> WHO recognized three areas with scientific evidence to support possible negative effects of e-cigarette use: nicotine health risks, inhalation of toxic chemicals in e-products, and inhalation of second-hand emissions.<sup>285</sup> In 2014, WHO held a meeting with countries that signed the Framework Convention on Tobacco Control (FCTC).<sup>286</sup> During the meeting, countries agreed to regulate or ban ENDS to prevent non-smokers and youths from vaping, protect bystanders from second-hand e-cigarette emissions, and minimize potential

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<sup>277</sup> Kara Carlson, *Tariffs on Chinese goods could batter the US vaping industry*, REUTERS (Aug. 8, 2018), <https://www.reuters.com/article/us-usa-trade-china-vaping/tariffs-on-chinese-goods-could-batter-the-u-s-vaping-industry-idUSKBN1KT2AV>.

<sup>278</sup> *Id.*

<sup>279</sup> *Id.*

<sup>280</sup> *Id.*

<sup>281</sup> *Id.*

<sup>282</sup> *Id.*

<sup>283</sup> *Id.*

<sup>284</sup> *Countries vindicate cautious stance on e-cigarettes*, WORLD HEALTH ORG. (Dec. 2014), <https://www.who.int/bulletin/volumes/92/12/14-031214/en/>.

<sup>285</sup> *Id.*

<sup>286</sup> *Id.*

health risks and challenge health claims of e-cigarettes.<sup>287</sup> WHO has recognized the lack of available research, acknowledged the need to fill the gaps, but argues that despite the lack of research, some risks are easily foreseeable.<sup>288</sup> Particularly foreseeable is the fact that the nicotine amount in each ‘hit’ is not regulated because it is the user establishes the amount of nicotine.<sup>289</sup>

In 2016, WHO readdressed the e-cigarette issue when it considered whether indoor smoking bans should include e-cigarettes.<sup>290</sup> It considered that sanctioned indoor vaping, where traditional cigarette smoking is not allowed, would encourage smokers to switch.<sup>291</sup> WHO dismissed the argument because of the lack of evidence and stated that the ban could normalize vaping for non-smokers.<sup>292</sup> WHO also dismissed the argument that banned indoor use would cause discomfort for people experiencing withdrawal, because there is evidence that the discomfort is modest.<sup>293</sup>

Further, WHO examined the arguments in favor of banning indoor vaping.<sup>294</sup> One argument was that the visual similarity between vaping and traditional smoking might cause renormalization of smoking indoors, leading to the return of traditional smoking indoors.<sup>295</sup> Another argument was that exposure to vaping might cause relapses in people who quit smoking.<sup>296</sup> For example,

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<sup>287</sup> *Id.*

<sup>288</sup> *Id.*

<sup>289</sup> *Id.* WHO also discussed the possibility of e-liquid contacting a person’s skin and causing nicotine poisoning. *Id.* There was also the possibility of children drinking the liquid. *Id.* Both America and the U.K. have seen an increase in nicotine poisoning, many reports involving children. *Id.*

<sup>290</sup> *Id.*

<sup>291</sup> *Id.*

<sup>292</sup> *Id.*

<sup>293</sup> *Id.*

<sup>294</sup> *Id.*

<sup>295</sup> *Id.*

<sup>296</sup> *Id.* WHO is spending time combatting e-cigarettes, but it has not abandoned the crusade against traditional smoking. *Tobacco Free Initiative (TFI)*, WORLD HEALTH ORG., <https://www.who.int/tobacco/control/background/en/> (last visited Mar. 8, 2019, 4:09 PM). WHO has a Tobacco Free Initiative (TFI) to “help reduce the heavy burden of disease and death that is attributable to tobacco use or

researchers showed young tobacco smokers a video of someone vaping and the smokers reported an increased desire to smoke traditional cigarettes and vape.<sup>297</sup> Evidence suggests that smoke-free areas aid in helping people quit.<sup>298</sup>

WHO also examined whether exposure to vapor causes adverse health effects.<sup>299</sup> WHO reported that “second-hand aerosols from e-cigarettes are a new air contamination source for hazardous particulate matter.”<sup>300</sup> Increased concentration of the toxicants are found in second-hand aerosols and pose an increased health risk for bystanders, especially those with respiratory conditions.<sup>301</sup> WHO also noted that people find vapor clouds to be a nuisance, especially in indoor locations.<sup>302</sup> Finally, WHO demonstrated the value in an outright indoor vaping ban because it prevents public confusion if there is a blanket ban on indoor vaping.<sup>303</sup>

In conclusion, WHO encourages policy makers to ban indoor vaping and to consider whether vaping is an acceptable recreational activity or a nicotine replacement.<sup>304</sup>

## VII. OTHER CONSIDERATIONS

When discussing e-cigarette legislation, it would be unfair to dismiss the potential benefits e-cigarettes have. E-cigarettes are considered a potential quitting aid for people who smoke traditional

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exposure.” *Id.* WHO introduced MPOWER, “a package of technical measures and resources,” to help implement FCTC provisions. *Id.*

<sup>297</sup> *Countries vindicate cautious stance on e-cigarettes, supra* note 284.

<sup>298</sup> *Id.*

<sup>299</sup> *Id.*

<sup>300</sup> *Id.* The concern is the level of metals, such as nickel and chromium. *Id.* In aerosols from e-cigarettes, the metals are higher than the background air. *Id.* This also is true in second-hand smoke. *Id.* Further, increased levels of nicotine, acetaldehyde, and formaldehyde are found in second-hand aerosol. *Id.*

<sup>301</sup> *Id.*

<sup>302</sup> *Id.*

<sup>303</sup> *Id.* WHO argues that exemptions in certain workplaces or restaurants would cause unnecessary confusion and that simplicity will help the public and law enforcement to successfully implement the law. *Id.*

<sup>304</sup> *Id.*

cigarettes.<sup>305</sup> Many people use e-cigarettes to successfully quit smoking.<sup>306</sup> A study published in the *New England Journal of Medicine*, found e-cigarettes are a more effective quitting aid than nicotine-replacement therapies already in place.<sup>307</sup> However, not everyone agrees with that argument because there are plenty of aids to quit smoking, which have been researched extensively and for which the health risks are certain.<sup>308</sup> Some researchers suggest that e-cigarettes should be a last resort, used after extensively researched methods fail.<sup>309</sup>

Vaping in the United States is also a political issue, not just a health issue.<sup>310</sup> Not everyone appreciates the FDA's restrictions, calling it an "aggressive regulatory assault."<sup>311</sup> Through a letter to the White House, conservative groups demand President Trump halt Commissioner Gottlieb's new policies.<sup>312</sup> The groups argue that the

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<sup>305</sup> *What We Know About Electronic Cigarettes*, SMOKEFREE.GOV, <https://smokefree.gov/quit-smoking/ecigs-menthol-dip/ecigs> (last visited Oct. 1, 2019).

<sup>306</sup> Laurie McGinley, *E-cigarettes more effective than nicotine replacement to help smokers quit, study finds*, WASH. POST (Jan. 30, 2019), [https://www.washingtonpost.com/health/2019/01/30/e-cigarettes-more-effective-than-nicotine-replacement-help-smokers-quit-study-finds/?utm\\_term=.138856541f53](https://www.washingtonpost.com/health/2019/01/30/e-cigarettes-more-effective-than-nicotine-replacement-help-smokers-quit-study-finds/?utm_term=.138856541f53).

<sup>307</sup> Peter Hajek, et. al., *A Randomized Trial of E-Cigarettes versus Nicotine-Replacement Therapy*, THE NEW ENGLAND JOURNAL OF MEDICINE (Jan. 30, 2019), <https://www.nejm.org/doi/full/10.1056/NEJMoa1808779>. In this study, participants were placed in either an e-cigarette group, or a nicotine-replacement group. *Id.* In a one-year period, 80% of the members of the e-cigarette group were still using their assigned product, as opposed to the 9% of the group using nicotine-replacement therapy. *Id.* Although it is interesting to note that a higher percentage of the e-cigarette users experienced throat or mouth irritation (65% in the e-cigarette group as opposed to 51% in the nicotine-replacement group). *Id.* However, the e-cigarette group has lesser incidences of cough and phlegm production. *Id.* The study concluded e-cigarettes were the more effective quitting aid. *Id.*

<sup>308</sup> McGinley, *supra* note 306.

<sup>309</sup> *Id.*

<sup>310</sup> Laurie McGinley, *Conservatives bash FDA for 'regulatory panic' on e-cigarettes*, WASH. POST (Feb. 4, 2019), [https://www.washingtonpost.com/national/health-science/conservatives-bash-fda-for-regulatory-panic-on-e-cigarettes/2019/02/03/b1e8d326-27c7-11e9-8eef-0d74f4bf0295\\_story.html?noredirect=on&utm\\_term=.327ae5b7acfa](https://www.washingtonpost.com/national/health-science/conservatives-bash-fda-for-regulatory-panic-on-e-cigarettes/2019/02/03/b1e8d326-27c7-11e9-8eef-0d74f4bf0295_story.html?noredirect=on&utm_term=.327ae5b7acfa).

<sup>311</sup> *Id.*

<sup>312</sup> *Id.*

policies are going to hurt adults using e-cigarettes as a quitting aid.<sup>313</sup> Although they acknowledge the concerns over youth vaping, they still believe the regulations are a “government overreach.”<sup>314</sup> However, Gottleib has not backed down and his democratic counterparts praise him for standing his ground.<sup>315</sup> As research develops on both sides of the argument, it’s unclear who will triumph in the coming years.<sup>316</sup>

### VIII. CONCLUSION

It is clear from the varying approaches and multiple research studies on e-cigarettes that it is a topic that will be debated over the years to come. However, while doctors and researchers argue over the chemicals contained in e-cigarettes and its potential long-term health risks, policy makers are deciding how to regulate e-cigarettes.<sup>317</sup> Clearly, from the varying approaches across the globe, policy makers do not agree despite research about the looming health threats the devices pose.<sup>318</sup> Most legislatures are attempting to balance e-cigarettes as an alternative to cigarettes and the skyrocketing youth nicotine addiction.<sup>319</sup>

It seems that countries are split on whether e-cigarettes are harmful, and whether it should implement legislation.<sup>320</sup> China has not acknowledged the health risks, nor have they implemented legislation, apart from a few local governments taking matters into their own hands.<sup>321</sup> The EU acknowledges the risks and implemented guidelines through a directive, but has a limited regulatory stance, rather than a direct ban or confrontational approach.<sup>322</sup> The UK has decided that the risks are negligible and encouraged citizens to use e-

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<sup>313</sup> *Id.*

<sup>314</sup> *Id.*

<sup>315</sup> *Id.*

<sup>316</sup> *Id.*

<sup>317</sup> *See generally supra* Section III–V.

<sup>318</sup> *Id.*

<sup>319</sup> *See supra* Section III–V.

<sup>320</sup> *See supra* Section III–V.

<sup>321</sup> *See supra* Section V.

<sup>322</sup> *See supra* Section IV.

cigarettes as nicotine replacement therapy.<sup>323</sup> Finally, the United States, which acknowledges e-cigarette risks, focuses specifically on the popularity the devices have among youths.<sup>324</sup> The FDA is taking a hands-on approach and singling out the problem children of the e-cigarette industry.<sup>325</sup> It is facing down the titan e-cigarette companies, crushing the fruity e-liquids that appeal to children, and campaigning to youths through their domain: social media.<sup>326</sup> Most importantly, the multi-front attack appears to be working.<sup>327</sup> While some criticize Commissioner Gottlieb for going too far or for not going far enough, it appears that his mission to keep youths from nicotine addiction and other unknown health risks will be worthwhile.<sup>328</sup> Will the world follow suit? Or will e-cigarettes rival the traditional cigarette epidemic which has plagued our world for generations?

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<sup>323</sup> *See supra* Section IV.

<sup>324</sup> *See supra* Section III.

<sup>325</sup> *See id.*

<sup>326</sup> *See id.*

<sup>327</sup> *See id.*

<sup>328</sup> *See id.*