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## The Deceiving Pocket-Sized Device that has Fueled a New Age of Tobacco Smokers

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## Introduction

The electronic cigarette (“e-cigarette”) industry has created a new generation of adolescents<sup>1</sup> addicted to nicotine. E-cigarettes have largely been marketed as cessation devices; however, the 2020 Surgeon General's Report observed that no study looking at the potential for e-cigarettes to be cessation devices has produced sufficient evidence to conclude that they are. Notably, in the six years that the Food and Drug Administration (“FDA” or “Agency”) has executed its authority over the e-cigarette products, the agency has never approved of a device as a quit smoking aid due to the inadequacy in evidence to show the products’ effectiveness in quitting cigarette smoking.<sup>2</sup> Meanwhile, adolescents have dominated the e-cigarette scene, as we have seen a relentless surge in use amongst them throughout the years.<sup>3</sup> Further, researchers have discovered a link between e-cigarette use and eventual combustible cigarette smoking among adolescents.<sup>4</sup> And while e-cigarettes have also been marketed as safer alternatives to traditional

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<sup>1</sup> “Adolescence” refers to young people under the age of eighteen and will be used interchangeably with “teenager” and “youth,” unless otherwise indicated.

<sup>2</sup> *Adult Smoking Cessation – The Use of E-Cigarettes*, C.D.C. (Jan 23, 2020), [https://www.cdc.gov/tobacco/data\\_statistics/sgr/2020-smoking-cessation/fact-sheets/adult-smoking-cessation-e-cigarettes-use/index.html](https://www.cdc.gov/tobacco/data_statistics/sgr/2020-smoking-cessation/fact-sheets/adult-smoking-cessation-e-cigarettes-use/index.html).

<sup>3</sup> *See Youth E-cigarette Use Remains Serious Public Health Concern Amid COVID-19 Pandemic*, F.D.A. (Sep. 30, 2021), <https://www.fda.gov/news-events/press-announcements/youth-e-cigarette-use-remains-serious-public-health-concern-amid-covid-19-pandemic> (In 2021, an estimated two million middle and high school students in the United States reported using e-cigarettes).

<sup>4</sup> *Talking to Youth and Young Adults to Prevent E-Cigarette Use*, C.D.C. (Aug. 20, 2021), <https://www.cdc.gov/tobacco/features/back-to-school/index.html> (“young people who use e-cigarettes may be more likely to smoke regular cigarettes later in life.”); *see* Kaitlyn M. Berry et al., *Association of Electronic Cigarette Use With Subsequent Initiation of Tobacco Cigarettes in US Youths*, [J]AMA NETWORK OPEN (Feb. 1, 2019), <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2723425> (adolescents between the ages of twelve and fifteen, whose first tobacco product use was an e-cigarette, were more than four times as likely to transition into smoking traditional cigarettes); *see also* Jessica L. Barrington-Trimis et al., *E-Cigarettes and Future Cigarette Use*, PEDIATRICS (July 2016), <https://pubmed.ncbi.nlm.nih.gov/27296866/> (researchers found that e-cigarette users were approximately six times more likely to transition into using traditional cigarettes than their non-e-cigarette counterparts in a sample of eleventh and twelfth graders).

tobacco smoking, these devices pose a great number of different risks and many that have yet to be realized.

Adolescents are a particularly vulnerable population for a number of reasons, one of which is that the “majority of tobacco use begins before adulthood,” putting youth at an increased “risk of tobacco initiation.”<sup>5</sup> Nicotine dependence has been shown to be higher among youth who begin using e-cigarettes at an earlier age.<sup>6</sup> E-cigarette devices have been designed to look sleek and modern, appealing most to the youth who, up until recently, remained the tobacco industry’s direct target customer for these products.<sup>7</sup> This feature allows youth to disguise their use from parents and school officials with ease. Adolescents have also been told that these products are safe and have been denied access to information regarding the contents of the devices.<sup>8</sup> Devices have been manufactured to include high levels of nicotine to ensure that adolescents become addicted to the product,<sup>9</sup> guaranteeing the industry's own success. As of 2016, sixty percent of e-cigarette users who were not previously smokers of traditional cigarettes

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<sup>5</sup> Megan Schroeder, *Technical Project Lead (TPL) Review of PMTAs: PM0000529.PD1-PM0000531.PD1, PM0000535.PD1-PM0000537.PD1, PM0000540.PD1-PM0000541.PD1*, F.D.A. (Mar. 23, 2022), <https://www.fda.gov/media/157144/download>.

<sup>6</sup> Meghan E. Morean; Schitra Krishnan-Sarin, & Stephanie S. O'Malley, *Assessing Nicotine Dependence in Adolescent E-cigarette Users: The 4-item Patient-Reported Outcomes Measurement Information System (PROMIS) Nicotine Dependence Item Bank for Electronic Cigarettes*, DRUG ALCOHOL DEPENDENCY (Jan. 26, 2020), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6983293/>.

<sup>7</sup> See *infra* Part V.B.; see also *FDA Warns Manufacturers and Retailers to Remove Certain E-Cigarette Products Targeted to Youth from the Market*, F.D.A. (Apr. 27, 2020), <https://www.fda.gov/news-events/press-announcements/fda-warns-manufacturers-and-retailers-remove-certain-e-cigarette-products-targeted-youth-market> (FDA issued ten warning letters to businesses that marketed items “such as a backpack and sweatshirt designed with stealth pockets to hold and conceal an e-cigarette” and devices that resemble small, harmless items).

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

<sup>9</sup> Cf. Kristin Jones & Gary A. Salzman, *The Vaping Epidemic in Adolescents*, MO. MED (2020), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7023954/> (“nicotine addiction often originates in adolescence with studies showing that close to ninety percent of adult daily smokers started before the age of eighteen.”).

were younger than twenty-five years.<sup>10</sup> In order to curb the nicotine addiction in the adolescent population, increased efforts to more effectively regulate the e-cigarette industry must be taken. Additionally, youth must be educated on the contents of the devices and the real and alarming health harms they pose.

This paper is structured as follows: Part I of this article provides an introduction to electronic cigarettes, explaining what they are, how they work and how the modern e-cigarette came to exist. Next, Part II introduces the laws regulating these devices with a specific focus on laws geared towards adolescents. Part III explores the health effects of the device's components. Part IV analyzes e-cigarette usage trends during the coronavirus pandemic. Lastly, Part V provides recommendations to strengthen restrictions in place to limit e-cigarette use amongst youth.

## **I. The Electronic Cigarette<sup>11</sup>**

Electronic nicotine delivery systems (“ENDS”), which encompasses e-cigarettes, are devices that “through an aerosolized solution, delivers nicotine, flavor, or any other substance to the user inhaling from the device.”<sup>12</sup> Although there are many variations of e-cigarettes, in both shape and size, the main components are the battery, atomizer, mouthpiece, and cartridge.<sup>13</sup> The battery serves as a power source for the atomizer, which heats the liquid stored within the cartridge, which contains nicotine.<sup>14</sup> The nicotine contained within these devices may be derived

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<sup>10</sup> Albert D. Osei et al., *The Association Between E-Cigarette Use and Asthma Among Never Combustible Cigarette Smokers: Behavioral Risk Factor Surveillance System (BRFSS) 2016 & 2017*, BMC PULMONARY MED. (Oct. 16, 2019), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6796489/>.

<sup>11</sup> This paper will focus only on devices that contain nicotine.

<sup>12</sup> 15 U.S.C. § 375(7) (2022).

<sup>13</sup> NAT'L ACAD. OF SCIENCES, ENGINEERING, AND MED. ET AL., PUBLIC HEALTH CONSEQUENCES OF E-CIGARETTES 55 (David Eaton eds., 2018).

<sup>14</sup> See generally *Know the Risks: E-Cigarettes & Young People*, H.H.S (2022), <https://e-cigarettes.surgeongeneral.gov/getthefacts.html>.

from either tobacco leaf or synthetically made in the lab.<sup>15</sup> When a user inhales from the e-cigarette, the heated liquid turns into an aerosol released from the mouthpiece.<sup>16</sup> The nicotine levels within these devices vary and can contain up to fifty milligrams of nicotine.<sup>17</sup> To compare, a traditional cigarette user will typically inhale between twenty-two to thirty-six milligram of nicotine per pack.<sup>18</sup>

The earliest device that bears a resemblance to the contemporary e-cigarette was created by inventor Herbert A. Gilbert.<sup>19</sup> He applied for a patent in 1963 and characterized his device as a “smokeless non-tobacco cigarette . . . [comprising of a] harmless flavoring material.”<sup>20</sup> Notably, Gilbert’s prototypes are believed to have “never” contained any nicotine.<sup>21</sup> Although the patent was granted, the device was never commercialized,<sup>22</sup> likely attributable to the fact that

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<sup>15</sup> *What is Synthetic Nicotine and What Does it Mean for the Youth Vaping Epidemic?* TRUTH INITIATIVE (Mar. 15, 2022), <https://truthinitiative.org/research-resources/emerging-tobacco-products/what-synthetic-nicotine-and-what-does-it-mean-youth>.

<sup>16</sup> Nat’l Acad. of Sciences, Engineering, and Med. et al., *supra* note 13.

<sup>17</sup> Danny Prosser, *Understanding Vape Juice Nicotine Strengths*, VERDICT BRANDS (Dec. 14, 2020), <https://www.verdictvapors.com/blogs/news/understanding-vape-juice-nicotine-strengths>.

<sup>18</sup> Tim Jewell, *How Much Nicotine is in a Cigarette and Other Tobacco Products?* Healthline (Nov. 28, 2019), <https://www.healthline.com/health/how-much-nicotine-is-in-a-cigarette#nicotine-in-cigarettes>.

<sup>19</sup> *Historical Timeline of Vaping & Electronic Cigarettes*, CONSUMER ADVO. FOR SMOKE-FREE ALT, <https://casaa.org/education/vaping/historical-timeline-of-electronic-cigarettes/> (last visited, April 3, 2022).

<sup>20</sup> Smokeless Non-Tobacco Cigarette, U.S. Patent No. 3,200,819A (filed Apr. 4, 1963) (issued Aug. 17, 1985).

<sup>21</sup> *Supra* note 18.

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

concerns for health risks associated with combustible cigarettes were less prevalent<sup>23</sup> and there was a positive public sentiment towards cigarettes.<sup>24</sup>

Forty years later, in 2003, the first commercially successful e-cigarette was developed by Chinese pharmacist Hon Lik.<sup>25</sup> Lik created the device with the intent to use the product as a cessation device, such that current adult smokers would be able to quit smoking tobacco products.<sup>26</sup> This device was introduced into the United States market in 2007, and has aggressively been advertised as an alternative to tobacco products with potentially less harmful effects.<sup>27</sup>

## II. Major Legislation Affecting E-Cigarette Use Among Adolescents

### A. Tobacco Control Act

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<sup>23</sup> See *History of the Surgeon General's Reports on Smoking and Health: A Brief History*, C.D.C. (Dec. 2006), [https://www.cdc.gov/tobacco/data\\_statistics/sgf/history/index.htm](https://www.cdc.gov/tobacco/data_statistics/sgf/history/index.htm) (the first report of a linkage between cigarettes and lung was released in 1964); see generally K. Michael Cummings & Robert N. Proctor, *The Changing Public Image of Smoking in the United States: 1964-2014*, CANCER EPIDEMIOLOGY BIOMARKERS & PREVENTION (Jan. 2014), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3894634/>.

<sup>24</sup> *Smoking and Health (1962)*, ROYAL COLLEGE OF PHYSICIANS, <https://www.rcplondon.ac.uk/projects/outputs/smoking-and-health-1962> (report was met by "ambivalent, even hostile response."); see INSTITUTE OF MEDICINE, ENDING THE TOBACCO PROBLEM: A BLUEPRINT FOR THE NATION 41 (Richard J. Bonnie et al. eds., 2007) (cigarette use was at its peak in the 1960s); see also *Not All Americans Are Smoking Less*, POPULATION REFERENCE BUREAU (Feb. 1, 2011), <https://www.prb.org/resources/not-all-americans-are-smoking-less/> (approximately forty-two percent of the American population were smokers in the 1960s); see generally *History of the Surgeon General's Reports on Smoking and Health: A Brief History*, *supra* note 23 (the tobacco industry launched an advertising campaign consisting of medical doctor and celebrity endorsements in efforts to dispel concern over the linkage of adverse medical evidence to cigarette use and to increase cigarette sales).

<sup>25</sup> *Supra* note 19.

<sup>26</sup> Sarah Boseley, *Hon Lik Invented the E-Cigarette to Quit Smoking – But Now He's a Dual User*, THE GUARDIAN (June 9, 2015), <https://www.theguardian.com/society/2015/jun/09/hon-lik-e-cigarette-inventor-quit-smoking-dual-user>.

<sup>27</sup> H.H.S., E-CIGARETTE USE AMONG YOUTH AND YOUNG ADULTS: A REPORT OF THE SURGEON GENERAL 10 (2016), [https://e-cigarettes.surgeongeneral.gov/documents/2016\\_SGR\\_Full\\_Report\\_508.pdf](https://e-cigarettes.surgeongeneral.gov/documents/2016_SGR_Full_Report_508.pdf).

The enactment of the Family Smoking Prevention and Tobacco Control Act (“Tobacco Control Act”) in 2009 paved the way for FDA oversight over manufacturing, distribution, and marketing of tobacco products,<sup>28</sup> recognizing it as the “primary federal regulatory authority.”<sup>29</sup> One of the many reasons for the Tobacco Act's creation was for fear of the rise in a new generation of teenagers dependent on tobacco products and the absence of regulation of these new devices.<sup>30</sup> Paramount were the health concerns the devices were believed to cause and the evidence showing that “all new users of tobacco products are under the minimum legal age to purchase such products.”<sup>31</sup>

The Tobacco Control Act ensured that the FDA would have the authority to address concerns regarding tobacco product use by adolescents.<sup>32</sup> It restricted tobacco products from being marketed and sold to children and required that warnings on smokeless tobacco packages and advertisements be more pronounced in size and visibility.<sup>33</sup> Additionally, retailers are encouraged to implement employee training programs that focus on raising awareness of, and compliance with, federal laws and regulations surrounding the promotion of, sale and distribution of, and youth access to, tobacco products.<sup>34</sup> Retailers whose programs comply with

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<sup>28</sup> *Family Smoking Prevention and Tobacco Control Act – An Overview*, F.D.A. (June 3, 2020), <https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/family-smoking-prevention-and-tobacco-control-act-overview>.

<sup>29</sup> Family Smoking Prevention and Tobacco Control Act, H.R. 1256, 111th Cong. (2009) (enacted).

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

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

<sup>32</sup> *Section 3 of the Tobacco Control Act - Purpose*, F.D.A. (Jan. 7, 2018), <https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/section-3-tobacco-control-act-purpose>.

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

<sup>34</sup> *Tobacco Retailer Training Programs*, F.D.A. (Aug. 2018), <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/tobacco-retailer-training-programs> (training programs are not required).

FDA standards<sup>35</sup> may face lower monetary penalties for violations under the Tobacco Control Act.<sup>36</sup>

### **B. 2016 Deeming Rule**

Seven years passed before the FDA would bring ENDS products containing nicotine derived from tobacco leaf under its jurisdiction by way of the so-called “Deeming Rule.”<sup>37</sup>

During the time e-cigarette sales went unregulated, usage of these products amongst adolescents spiked astronomically.<sup>38</sup>

The Deeming Rule compels retailers to not sell any tobacco product to persons under the age of eighteen years, applying to both in-person and online transactions, and to verify the purchaser’s age using photographic identification.<sup>39</sup> Additionally, ENDS manufacturer became required to apply for and obtain marketing authorization through the Premarket Tobacco Product Application (PMTA) pathway<sup>40</sup> from the FDA before introducing their products into interstate

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<sup>35</sup> See *Tobacco Retailer Training Programs*, F.D.A. (Aug. 2018), <https://www.fda.gov/media/79013/download> (FDA guidance document that sets forth the elements that should be included in a retailer training program).

<sup>36</sup> H.R. 1256.

<sup>37</sup> See *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*, 81 Fed. Reg. 28,974 (May 10, 2016), <https://www.federalregister.gov/documents/2016/05/10/2016-10685/deeming-tobacco-products-to-be-subject-to-the-federal-food-drug-and-cosmetic-act-as-amended-by-the> (21 U.S.C. § 387a(b) grants the FDA authority to deem other types of tobacco products subject to the Federal Food, Drug, and Cosmetic Act).

<sup>38</sup> See Arielle Duhaim-Ross, *Three Million American Teens Used E-cigarettes in 2015*, THE VERGE (Apr. 14, 2016, 1:00 PM), <https://www.theverge.com/2016/4/14/11429736/e-cigarettes-teenagers-cdc-youth-rates-increase-vape> (e-cigarette use among high school students increased from 1.5 percent in 2011 to 16 percent in 2015).

<sup>39</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*, 81 Fed. Reg. 28,974.

<sup>40</sup> see *infra* part II,E.

commerce for commercial distribution.<sup>41</sup> The original submission deadline for products that were already on the market as of August 2016 was extended from August 2018 to August 2022.<sup>42</sup> E-cigarette device brands that had successfully submitted a PMTA were permitted to stay on the market indefinitely, as no deadline was set for when the Agency's review needed to be completed.<sup>43</sup>

In response to the indefinite extended application review deadlines, public health organizations challenged the FDA's guidance and sought to compel the FDA's compliance with the Tobacco Control Act.<sup>44</sup> The organizations argued that the FDA's decision to postpone the deadline presented harm to the public health and to adolescents in light of the fact that the delay would allow e-cigarettes to remain on the market, without a review of the products impact, hindering the public from understanding and being educated about the risks these products pose.<sup>45</sup> The presiding judge opined that irrespective of the Agency's awareness of the public health dangers e-cigarette devices present, this delay in product review requirement provided "manufacturers responsible for the public harm a holiday from meeting the obligations of the law."<sup>46</sup> He asserted that the guidance defeated the purpose of the Tobacco Control Act, exacerbating the situation by allowing manufacturers to "continue to advertise and sell products that are addictive and that target a youth market ... at a time when minors' use of tobacco

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<sup>41</sup> 21 U.S.C. § 387j(a)(2).

<sup>42</sup> Tara Lin Couch & Mark J. Vaders, *FDA Holds Public Meeting on PMTAs for Deemed Products Meeting Summary*, FOOD AND DRUG LAW INST., <https://www.fdpi.org/2019/11/fda-holds-public-meeting-on-pmtas-for-deemed-products-meeting-summary/>.

<sup>43</sup> *FDA's Comprehensive Plan for Tobacco and Nicotine Regulation*, F.D.A. (July 31, 2019), <https://www.fda.gov/tobacco-products/ctp-newsroom/fdas-comprehensive-plan-tobacco-and-nicotine-regulation>.

<sup>44</sup> *Am. Acad. of Pediatrics, et al. v. Food and Drug Admin., et al.*, 379 F.SUPP.3D 461, 493 (D. Md. 2019).

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

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

products like e-cigarettes is at an epidemic level and rising.”<sup>47</sup> The FDA was found to have acted illegally and the application submission deadline was moved to May 2020.<sup>48</sup> Despite this judgment, the deadline was pushed back 120 days in light of obstacles the COVID-19 pandemic posed to September 2020.<sup>49</sup>

### C. Increased Minimum Legal Age

In late 2019, legislation entitled Tobacco 21 was enacted, which raised the federal minimum age of legal access for the sale of tobacco products, including electronic nicotine delivery systems, from eighteen to twenty-one years.<sup>50</sup> Although the federal legal age was increased, Tobacco 21 does not preempt states and municipalities from passing and enforcing their own age restriction.<sup>51</sup>

States and municipalities age restrictions regarding the sale of tobacco products is governed by the Synar Amendment.<sup>52</sup> The Synar Amendment, enacted in 1992, was developed to "decrease youth access to tobacco" in light of evidence "about the health problems related to tobacco use by youth . . . [and] the ease with which youth could purchase tobacco products.”<sup>53</sup>

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<sup>47</sup> *Id.* at 492.

<sup>48</sup> *Id.* at 498.

<sup>49</sup> See generally Stephen M. Hahn, *Coronavirus (COVID-19) Update: Court Grants FDA’s Request for Extension of Premarket Review Submission Deadline for Certain Tobacco Products Because of Impacts from COVID-19*, F.D.A. (Apr. 23, 2020), <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-court-grants-fdas-request-extension-premarket-review-submission-deadline>.

<sup>50</sup> *Tobacco 21*; F.D.A. (Sept. 1, 2021), <https://www.fda.gov/tobacco-products/retail-sales-tobacco-products/tobacco-21>; *About the Synar Amendment and Program*, SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION (S.A.M.H.S.A.), <https://www.samhsa.gov/synar/about-synar> (last updated Apr. 14, 2022) (this legislation is an amendment to the Synar Amendment, see *infra*).

<sup>51</sup> See *Federal Tobacco 21: The Law of Land*, PREVENTING TOBACCO ADDICTION FOUND., <https://tobacco21.org/federal-tobacco-21-faq/> (“states are not required to pass their own laws to update their tobacco sales age to 21” under the Synar Amendment.).

<sup>52</sup> *About the Synar Amendment and Program*, *supra* note 50.

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

States are only required to enact laws that prohibit the sale of tobacco products to minors, specifically individuals under the age of eighteen.<sup>54</sup> The Substance Abuse and Mental Health Services Administration, which oversees the implementation of the Synar Amendment,<sup>55</sup> administers a “Substance Abuse Prevention and Treatment Block Grant” (“SABG”) program which provides funding to states.<sup>56</sup> Following the passage of Tobacco 21, as a condition of receiving the SABG, states must enact and enforce the new federal minimum age.<sup>57</sup> Additionally, states also must conduct random inspections to ensure compliance with minimum age requirements and report those findings to the federal government as a condition for receiving the grant.<sup>58</sup> Today, forty states have approved legislation that restricts individuals younger than twenty-one from being able to purchase a tobacco product.<sup>59</sup>

Meanwhile, the FDA began to conduct Undercover Buy Inspections under which a minor, working in conjunction with an designated FDA inspector, attempts to purchase a regulated tobacco product from “traditional ‘brick and mortar’ retail stores . . . as well as online retailers and manufacturers” to determine whether retailers have placed adequate safeguards to prevent the sale of items to adolescents.<sup>60</sup> The result of that effort is translated to the FDA, which then performs a review to determine whether a violation of Tobacco 21 has occurred.<sup>61</sup> Whether

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<sup>54</sup> See *Synar Program*, S.A.M.H.S.A., <https://www.samhsa.gov/synar> (last updated Apr. 4, 2022).

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

<sup>56</sup> *Substance Abuse and Mental Health Block Grants*, S.A.M.H.S.A. (April 12, 2022), <https://www.samhsa.gov/grants/block-grants> (last updated Apr. 12, 2022).

<sup>57</sup> 42 U.S.C. § 300x-26(a)(2); see *Revision to Guidance*, S.A.M.H.S.A. (June 12, 2020), <https://www.samhsa.gov/sites/default/files/synar-guidance-tobacco-21.pdf>.

<sup>58</sup> *Id.* at § 300x-26(a)(1).

<sup>59</sup> Pub. Health Law Ctr. at Mitchell Hamline Sch. of Law, *Youth Access to E-Cigarettes*, (Dec. 15, 2021), <https://www.publichealthlawcenter.org/sites/default/files/inline-files/States-with-Laws-Restricting-ECig-Youth-Access-Dec15-2021.pdf>.

<sup>60</sup> *CTP Compliance & Enforcement*. F.D.A. (Dec. 1, 2021), <https://www.fda.gov/tobacco-products/compliance-enforcement-training/ctp-compliance-enforcement>.

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

or not a violation occurred, those results are posted on a designated website.<sup>62</sup> However, if the Agency determines that a violation was committed, a notice of compliance check inspection will be sent within a week to the retailer informing them a potential violation may have occurred.<sup>63</sup> A first time offender will be issued a warning letter,<sup>64</sup> while for a repeat violator, consequences can include a warning letter, civil money penalty, or no-tobacco sale order.<sup>65</sup>

#### **D. Flavor Ban**

In 2020, the sale of e-liquid cartridges in all flavors except methanol and tobacco was banned, unless the product had been authorized to be marketed following a PMTA approval by the FDA.<sup>66</sup> The prohibition was enacted with the goal of making e-cigarettes less appealing to adolescents, decreasing the rate of use among this demographic. The Agency denied applications for approximately fifty-five flavored ENDS products, finding that the applications “lacked sufficient evidence that [the products] have a benefit to adult smokers sufficient to overcome the public health threat posed by the well-documented, alarming levels of youth use of such products.”<sup>67</sup> However, because the FDA only had jurisdiction to regulate tobacco plant-based nicotine, the prohibition did not cover every device.<sup>68</sup> Therefore, the ban was confined to

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

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

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

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

<sup>66</sup> *FDA Finalizes Enforcement Policy on Unauthorized Flavored Cartridge-Based E-cigarettes that Appeal to Children, Including Fruit and Mint*, F.D.A. (Jan 2, 2020), <https://www.fda.gov/news-events/press-announcements/fda-finalizes-enforcement-policy-unauthorized-flavored-cartridge-based-e-cigarettes-appeal-children>.

<sup>67</sup> *FDA Denies Marketing Applications for About 55,000 Flavored E-Cigarette Products for Failing to Provide Evidence They Appropriately Protect Public Health*, F.D.A. (Aug. 26, 2021), <https://www.fda.gov/news-events/press-announcements/fda-denies-marketing-applications-about-55000-flavored-e-cigarette-products-failing-provide-evidence>.

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

cartridges or pre-filled pod devices, such as the ones manufactured by the once leading e-cigarette brand Juul.<sup>69</sup>

While the ban effectively decreased the number of adolescent users of devices such as Juuls, youth have turned to non-refillable or disposable devices.<sup>70</sup> These devices do not fall under the FDA's proscription since they contain synthetic nicotine created in labs.<sup>71</sup> Companies that were denied authorization to market their products modified their formulas by replacing tobacco plant-based nicotine with synthetic nicotine, effectively evading the FDA's oversight.<sup>72</sup> The Centers for Disease Control and Prevention released sales data demonstrating that since the enforcement of the flavor ban, "sales of disposable fruit- and candy-flavored devices have grown by 290 percent, to 6.46 million devices a month by November 2021[,]" while sales of tobacco-derived nicotine devices have "nearly vanished."<sup>73</sup>

In March of 2022, in an effort to close this gap, the FDA's existing authority to regulate tobacco-derived nicotine in ENDS devices was expanded to encompass nicotine synthesized in

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<sup>69</sup> *E-cigarettes: Facts, Stats and Regulations*, TRUTH INITIATIVE (June 15, 2021), <https://truthinitiative.org/research-resources/emerging-tobacco-products/e-cigarettes-facts-stats-and-regulations>.

<sup>70</sup> Sheila Kaplan, *Teens Find a Big Loophole in the New Flavored Vaping Ban*, N.Y. TIMES (Oct. 12, 2021), <https://www.nytimes.com/2020/01/31/health/vaping-flavors-disposable.html>.

<sup>71</sup> Michael Nedelman, *Spending Bill Aims to Close the Vaping Loophole*, CNN (Mar. 9, 2022, 11:26 AM), <https://www.cnn.com/2022/03/09/health/vaping-loophole-synthetic-nicotine-omnibus-bill/index.html>; see Nathaniel Wiexel, *Congress on Verge of Closing Vaping Loophole*, THE HILL (Mar. 9, 2022, 2:01 PM), <https://thehill.com/policy/healthcare/597542-congress-on-verge-of-closing-vaping-loophole/>.

<sup>72</sup> Jamie Ducharme, *The Vaping Industry as We Know It May Soon Disappear*, THE TIME (Sept. 3, 2021, 9:50 AM), <https://time.com/6094858/fda-e-cigarette-decision/> ("Vapor Salon, one of the brands turned down by the FDA . . . plan[ned] to start using synthetic nicotine . . . to avoid agency regulation."); see also Laurie McGinley, *Congress Moves to Give FDA New Powers Over Synthetic Nicotine Products Including a Youth Favorite – Puff Bar E-Cigarettes*, WASH. POST (Mar. 8, 2022, 6:54 PM) (companies such as Puff Bar returned to the market with devices containing tobacco-free nicotine following disapproval).

<sup>73</sup> Christina Jewett, *The Loophole That's Fueling a Return to Teenage Vaping*, N.Y. TIMES (Mar. 8, 2022), <https://www.nytimes.com/2022/03/08/health/vaping-fda-nicotine.html>.

laboratories.<sup>74</sup> The definition of “tobacco product”<sup>75</sup> was amended to include “nicotine from any source.”<sup>76</sup> The law went into effect on April 14, 2022 and requires manufacturers of synthetic nicotine products to submit a PMTA to the FDA by May 14, 2022 to remain on the market.<sup>77</sup> Absent FDA authorization by July 13, 2022, all synthetic nicotine products must be withdrawn from the market.<sup>78</sup> Further, manufacturers of tobacco-derived nicotine that were initially denied or refused authorization following the 2020 flavor ban, and diverted the source of the nicotine in their products to evade the FDA oversight, will be denied the opportunity to submit an application for approval and be banned on April 13, 2022.<sup>79</sup>

### **E. Recent ENDS Market Authorizations**

Tobacco manufacturers seeking to receive market authorization for their ENDS must submit a PMTA to the FDA.<sup>80</sup> Applicants must provide information regarding the device’s contents and effects,<sup>81</sup> and make a sufficient showing that the product is appropriate for the protection of the public health (“APPH”) before the device can be legally marketed.<sup>82</sup> In deciding whether to grant authorization, the FDA will weigh the “risks and benefits to the population as a whole . . . and [take] into account the increased or decreased likelihood that

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<sup>74</sup> Azim Chowdhury, Neelam Gill, & Josephine Hsa, *FDA Receives Authorization to Regulate Synthetic Nicotine*, NAT’L LAW REV (Mar. 16, 2022), <https://www.natlawreview.com/article/fda-receives-authorization-to-regulate-synthetic-nicotine>.

<sup>75</sup> 21 U.S.C. § 321(rr) (“any product made or derived from tobacco that is intended for human consumption.”).

<sup>76</sup> Consolidated Appropriations Act, 2022. H.R. 2471, 117th Cong. § 111(a)(1) (2022) (enacted).

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

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

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

<sup>80</sup> See Azim Chowdhury & Neelam Gill, *Will FDA Extend Its Proposed Ban on Menthol Cigarettes and Characterizing Flavors in Cigars to Flavored ENDS Products?* FOOD AND DRUG LAW INST. (2021) <https://www.fdpi.org/2021/08/will-fda-extend-its-proposed-ban-on-menthol-cigarettes-and-characterizing-flavors-in-cigars-to-flavored-ends-products/>.

<sup>81</sup> see 21 C.F.R. § 1114.7(b)(1) (2021) (sets forth content that must be provided in the application and the format in which it must be submitted).

<sup>82</sup> 21 U.S.C. § 387j(c)(2).

existing users of tobacco products will stop using such products and . . . that those who do not use tobacco products will start using such products.”<sup>83</sup> Applicants seeking approval of flavored ENDS carry a higher burden of establishing a net benefit to the public health than an applicant seeking approval of a tobacco-flavored ENDS since evidence demonstrates that use of flavored ENDS is more common amongst youth.<sup>84</sup>

The FDA has granted marketing authorization to three companies for their vaping devices and accompanying tobacco-flavored e-liquid pods.<sup>85</sup> On October 12, 2021, the first approval was made to R.J. Reynolds Vapor Company’ for its Vuse Solo product.<sup>86</sup> Then in March and April of 2022, Logic Technology Development LLC and NJOY LLC received authorization, respectively.<sup>87</sup> The FDA found that each PMTA presented evidence that the overall harmful and potentially harmful constituent levels that can be found within the aerosol from those devices are lower than within the smoke produced from combustible cigarettes.<sup>88</sup> Among other considerations, the Agency also found that there are adequate procedures in place to ensure that the devices and e-liquids are created consistently.<sup>89</sup> While the Agency acknowledges the risks ENDS pose to youth and the number of youth who use some of the aforementioned approved

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<sup>83</sup> *Id.* at § 387j(c)(4); *see* Megan Schroeder, *supra* note 5 (“FDA weighs the potential negative public health impacts (e.g., harm from initiation and use among nonusers, particularly youth) against the potential positive public health impacts (e.g., benefit from adult users of more harmful tobacco products completely switching).”).

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

<sup>85</sup> *Premarket Tobacco Product Marketing Granted Orders*, F.D.A. (Apr. 26, 2022), <https://www.fda.gov/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-granted-orders>.

<sup>86</sup> *FDA Permits Marketing of E-Cigarette Products, Marking First Authorization of Its Kind by the Agency*. F.D.A. (Oct. 12, 2021), <https://www.fda.gov/news-events/press-announcements/fda-permits-marketing-e-cigarette-products-marking-first-authorization-its-kind-agency>.

<sup>87</sup> *Premarket Tobacco Product Marketing Granted Orders*, *supra* note 85.

<sup>88</sup> Megan Schroeder *supra* note 5; *see supra* note 85; *see also* *Technical Project Lead (TPL) Review of PMTAs: PM0000613.PD1 - PM0000615.PD1 and PM0000622.PD1*, F.D.A. (Oct. 12, 2021), <https://www.fda.gov/media/157959/download>.

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

products,<sup>90</sup> the decision relied on evidence suggesting that tobacco-flavored e-liquid pods, such as the ones granted permission, have a low youth appeal.<sup>91</sup> Additionally, the FDA found that the potential benefit to adult smokers would outweigh the risk to youth, provided that the applicant follows the imposed “marketing restrictions and postmarket requirements” to reduce youth exposure to ENDS marketing and mitigate the risk of initiation and use of such products by the youth.<sup>92</sup>

### **III. Adverse Effects of ENDS on Youth**

Although industry leaders in the ENDS market want us believe that their products are a safer alternative to traditional combustible smoking, such products are extremely injurious to the health of adolescents who are in the critical years of their development<sup>93</sup> and who comprise a staggering number of users. Despite the fact that e-cigarettes do not contain the toxins inherent in traditional cigarettes, they nevertheless deliver exceptionally high nicotine levels, containing the equivalent nicotine to a pack of cigarettes.<sup>94</sup> While further research on the health effects of e-cigarette content is underway, the findings to date are chilling.

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<sup>90</sup> *Id.* (national study conducted in 2021 found that ten percent of high school students regularly use Vuse).

<sup>91</sup> *Id.*; Cf. NIGEL GRAY & JACK HENNINGFIELD, TOBACCO: SCIENCE, POLICY AND PUBLIC HEALTH 70 (Peter Boyle et al. eds., Aug. 19, 2010) (“I believe that for the typical smoker nicotine satisfaction is the dominant desire, as opposed to flavor and other satisfactions.”); *see also* H.H.S *supra* note 26 (“companies also intended flavored smokeless tobacco products to facilitate “graduation” to unflavored products that more easily deliver more nicotine to the user.”).

<sup>92</sup> *Technical Project Lead (TPL) Review of PMTAs: PM0000613.PD1 - PM0000615.PD1 and PM0000622.PD1*, F.D.A. (Oct. 12, 2021), <https://www.fda.gov/media/157959/download>.

<sup>93</sup> *See Adult Smoking Cessation – The Use of E-Cigarettes*, C.D.C. (Jan 23, 2020), [https://www.cdc.gov/tobacco/data\\_statistics/sgr/2020-smoking-cessation/fact-sheets/adult-smoking-cessation-e-cigarettes-use/index.html](https://www.cdc.gov/tobacco/data_statistics/sgr/2020-smoking-cessation/fact-sheets/adult-smoking-cessation-e-cigarettes-use/index.html) (brain development continues until approximately twenty-five years of age).

<sup>94</sup> Kristin Jones & Gary A. Salzman, *supra* note 9.

The nicotine that is dispensed from e-cigarettes is highly addictive and poses alarming health hazards to the brain development of adolescents.<sup>95</sup> It produces a euphoric sensation in the brain, a head rush, comparable to that of a high, that lures the user back for another pull.<sup>96</sup> It is the “amount and speed of nicotine delivery . . . [that] plays a critical role in the potential for abuse of tobacco products.”<sup>97</sup> Nicotine addiction has been likened to being as hard to quit as cocaine or heroin.<sup>98</sup> Additionally, nicotine can affect the brain development, specifically the brain cell activity, of adolescents.<sup>99</sup> This can lead to “disturbances in working memory and attention.”<sup>100</sup>

Usage of e-cigarettes has been linked to an increased risk of lung injuries, with higher odds of developing asthma and chronic obstructive pulmonary disease (“COPD”).<sup>101</sup> Most profound is the rise in cases of vaping use-associated lung injury (“EVALI”) that occurred in

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<sup>95</sup> *Supra* note 14.

<sup>96</sup> *Tobacco, Nicotine, and E-Cigarettes Research Report: Is Nicotine Addictive?* NAT’L INST. ON DRUG ABUSE (Jan. 2020), <http://www.drugabuse.gov/publications/research-reports/tobacco/nicotine-addictive> (“Addiction is characterized by compulsive drug-seeking and use, even in the face of negative health consequences.”).

<sup>97</sup> HOW TOBACCO SMOKE CAUSES DISEASE: THE BIOLOGY AND BEHAVIORAL BASIS FOR SMOKING-ATTRIBUTABLE DISEASE: A REPORT OF THE SURGEON GENERAL 181 (H.H.S. et al. eds., 2010).

<sup>98</sup> *Why it's so Hard to Quit Smoking*, Am. Heart Ass’n. (Oct. 17, 2018), <https://www.heart.org/en/news/2018/10/17/why-its-so-hard-to-quit-smoking>; see Sandra Blakeslee, *Nicotine: Harder to Kick . . . Than Heroin*, N.Y. TIMES (Mar. 29, 1987), <https://www.nytimes.com/1987/03/29/magazine/nicotine-harder-to-kickthan-heroin.html>.

<sup>99</sup> *The Effects of Nicotine on The Adolescent Brain*, UNDO (Feb 23, 2022), <https://tobaccofreeca.com/e-cigarettes/the-effects-of-nicotine-on-the-adolescent-brain/>.

<sup>100</sup> Natalia A. Goriounova & Huibert D. Mansvelder, *Short- and Long-Term Consequences of Nicotine Exposure during Adolescence for Prefrontal Cortex Neuronal Network Function*, COLD SPRING HARB PERSPECT MED. (Dec. 2, 2012), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3543069/>.

<sup>101</sup> Ermine Bircan et al., *Electronic Cigarette Use and its Association with Asthma, Chronic Obstructive Pulmonary Disease (COPD) and Asthma-COPD Overlap Syndrome Among Never Cigarette Smokers*, TOBACCO INDUCED DISEASES (Apr. 7, 2021), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8025916/>.

2019<sup>102</sup> and the continued risk the disease poses. EVALI is an inflammatory response that can present as pneumonia or damage to the air sacs within the lungs.<sup>103</sup> As of February 2018, there was a reported number of 2,807 hospitalizations related to EVALI cases and sixty-eight reported deaths from this condition.<sup>104</sup> Further, the chemical diacetyl, an ingredient found in e-cigarette devices, can cause popcorn lung which scars the air sacs in the lung and presents similarly to COPD: shortness of breath, wheezing, and coughing.<sup>105</sup> Meanwhile, the metal components of e-cigarette devices can also lead to serious lung damage, cancer, and many other adverse health manifestations.<sup>106</sup> The risks posed by inhalation of metals and gasses emitted from the atomizer in these devices increase as the liquid within the cartridge dissipates.<sup>107</sup>

#### **IV. Vaping Rates Decreased During the COVID-19 Pandemic**

The use of e-cigarettes amongst adolescents remarkably decreased during the onset of the coronavirus pandemic. The restrictions established at the start of the pandemic, such as sheltering-in-place orders and the shift to remote learning,<sup>108</sup> may have presented significant

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<sup>102</sup> *Outbreak of Lung Injury Associated with E-Cigarette Use, or Vaping*, C.D.C. (Feb. 25, 2020), [https://www.cdc.gov/tobacco/basic\\_information/e-cigarettes/severe-lung-disease.html](https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html); see generally Matt Richtel, et al., *Cases of Vaping-Related Lung Illness Surge, Health Officials Say*, N.Y. Times (Oct. 8, 2019), <https://www.nytimes.com/2019/08/14/health/vaping-marijuana-e-cigarettes.html>.

<sup>103</sup> Molly Wolf & Laura K. Rock, *EVALI: New Information on Vaping-Induced Lung Injury*, HARV. HEALTH PUB. (Apr. 4, 2020), <https://www.health.harvard.edu/blog/evali-new-information-on-vaping-induced-lung-injury-2020040319359>.

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

<sup>105</sup> Editorial Staff, *Popcorn Lung: A Dangerous Risk of Flavored E-Cigarettes*, AM. LUNG ASS'N. (July 6, 2016), <https://www.lung.org/blog/popcorn-lung-risk-ecigs>.

<sup>106</sup> See *Vaping May Increase Your Risk of Cancer*, UNDO (Oct. 13, 2021), <https://tobaccofreeca.com/e-cigarettes/vaping-may-increase-your-risk-of-cancer/>.

<sup>107</sup> See *What Do We Know About E-Cigarettes?* AM. CANCER SOC'Y (Apr. 11, 2022), <https://www.cancer.org/healthy/stay-away-from-tobacco/e-cigarettes-vaping/what-do-we-know-about-e-cigarettes.html> (Formaldehyde is released, which is a gas that can be found in many household products).

<sup>108</sup> See Maggie Fox, *More Than 2 million US Teens Use E-Cigarettes, a Quarter of Them Daily, CDC and FDA Find*, CNN (Sept. 30, 2021) <https://www.cnn.com/2021/09/30/health/youth-tobacco-survey-vaping/index.html> (survey found “higher rates of e-cigarette use among high

barriers to accessing such devices within the targeted age group. One study comparing current e-cigarette use during pre-COVID-19 and after stay-at-home directives were issued found higher odds of curtailed use amongst participants aged fifteen to twenty.<sup>109</sup> Participants between the ages of fifteen to seventeen and eighteen to twenty showed to have thirty-five percent and twenty-eight percent lower odds of continuous use, respectively.<sup>110</sup> Notably, reduced access to retail environments was reported as the reason for approximately fifty-eight percent of the sample, with approximately thirty-nine percent of the subset noting a change in store hours and about forty-one percent noting “difficulty finding consumer goods in stores.”<sup>111</sup> Another study found that of the sample that showed a reduced usage, approximately twenty percent noted an inability to get e-cigarettes, twenty-five percent indicated a fear of experiencing adverse health effects such as weakened lungs, fifteen percent contributed the decrease to being at home and potentially getting caught by their parents, and thirty-two percent reported a combination of the factors.<sup>112</sup>

During the pandemic, there was also evidence of increased online purchasing of e-cigarettes. Participants reported that the ease in which they were able to purchase e-cigarettes depended on “what kind of retailer they attempted to purchase from ([e.g.], local, independently

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school[ers] . . . who took the survey in school compared to those participating [elsewhere,] . . . raising concern that rates would be much higher if the survey had been conducted entirely in schools as in previous years.”)

<sup>109</sup> Jennifer M. Kreslake et al., *E-Cigarette Use Among Youths and Young Adults During the COVID-19 Pandemic: United States, 2020*, AM. J. OF PUB. HEALTH ASS’N. (May 5, 2021), <https://ajph.aphapublications.org/doi/10.2105/AJPH.2021.306210>.

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

<sup>111</sup> *Youth Vaping Declines During Pandemic as Adolescents Report Less Retail and Social Access to Products*, TRUTH INITIATIVE (Apr. 15, 2021), <https://truthinitiative.org/research-resources/emerging-tobacco-products/youth-vaping-declines-during-pandemic-young-people>.

<sup>112</sup> Shivani Mathur Gaiha, Lauren Kass Lempert, & Bonnie Halpern-Felsher, *Underage Youth and Young Adult E-Cigarette Use and Access Before and During the Coronavirus Disease 2019 Pandemic*, [J]AMA NETWORK OPEN (Dec. 3, 2020), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7716191/>.

owned vs. large commercial retailer)” and indicated that “specific stores were known for not checking IDs or being unable to recognize fake IDs.”<sup>113</sup> Additionally, approximately fifty-five percent of youth that reported having easier access to e-cigarettes during COVID-19 attributed it to receiving deliveries from vape shops or friends who were able to purchase products in bulk and then resell them.<sup>114</sup>

## **V. Imposing Stricter Regulations**

Despite the federal government's and the Agency's efforts to curb adolescent use of ENDS products through regulations and oversight, youth continue to discover ways to obtain these items.<sup>115</sup> In fact, there remains several reports of adolescents still being able to purchase these products in person<sup>116</sup> and online. It is vital that strong action is taken to effectively decrease the number of adolescent e-cigarette users now that the FDA has jurisdiction over ENDS products containing nicotine derived from tobacco leaf and nicotine synthesized in laboratories.

### **A. Point-of-Sale Transactions**

#### **1. In-Person Sales**

The current practices utilized by store retailers to verify a patron's age are inadequate. Under federal law, in-person transactions demand that store clerks verify the patron's age with a

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<sup>113</sup> Sara J. Schiff et al., *Assessing Vaping Products When Underage: A Qualitative Study of Young Adults in Southern California*, NICOTINE TOBACCO RESEARCH (May 2021), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8628866/>.

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

<sup>115</sup> F.D.A, ENFORCEMENT PRIORITIES FOR ELECTRONIC NICOTINE DELIVERY SYSTEMS (ENDS) AND OTHER DEEMED PRODUCTS ON THE MARKET WITHOUT PREMARKET AUTHORIZATION (REVISED): GUIDANCE FOR INDUSTRY 44 (Apr. 2020) (“The reality is that youth have continued access to ENDS products in the face of legal prohibitions and even after voluntary actions by some manufacturers.”).

<sup>116</sup> *See Tobacco Compliance Check Retailer Violation Report*, ANNE ARUNDEL CNTY. DEP'T OF HEALTH (May 3, 2022), <https://www.aahealth.org/tobacco-retailer-violation/> (recent data from recent underage tobacco sales compliance checks showing that underage shoppers are still able to purchase products due to the clerk not asking for identification).

government-issued photographic identification document.<sup>117</sup> Meanwhile, the FDA has not set forth specific guidelines for store owners to adopt to ensure compliance with the law other than creating free resources for store clerks to use in calculating the customer's age, such as the digital age verification calendar and the FDA Age Calculator.<sup>118</sup> However, these tools function solely as a calculator and do not take into account the use of fake identification cards. Despite these efforts, some retailers do not check identification cards, are unable to discern fake identification cards, and even when asking for qualifying documents, do not thoroughly examine them to ensure the patron is of legal age.<sup>119</sup>

The FDA must promulgate regulations requiring e-cigarette manufacturers to add a barcode on items being transported to conventional brick and mortar stores that will lock the product and prevent it from being sold until a valid photographic identification document, that includes a date of birth, is produced and scanned. The addition of a barcode to an e-cigarette product will increase the enforcement of age-verifying document checks, as products cannot be sold without providing such qualifying information. Today, all fifty states produce driver licenses that display a 2D Barcode on either side of the card.<sup>120</sup> If the product does not become unlocked upon scanning of a 2D barcode, this will indicate that the patron is underage and/or that the card is invalid, either because it has expired or because it is a fake. Additionally, the FDA must direct these manufacturers not to sell their products to retailers who do not adopt this system, effectively increasing compliance with federal law.

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<sup>117</sup> See *supra* part II.B.

<sup>118</sup> *This is Our Watch*, F.D.A. (Jan. 3, 2020), <https://www.fda.gov/tobacco-products/retail-sales-tobacco-products/our-watch>.

<sup>119</sup> See *supra* part II.B.

<sup>120</sup> *ID Scanner Coverage Chart: Driver's License Machine Readable Technologies for U.S. Jurisdictions*, ID SCANNER (June 2019), <https://www.idscanner.com/knowledge-base/coverage-chart/>.

The proposed approach is one that has been adopted by Juul to counteract the backlash it has received as a result of its once-dominant position as the leading e-cigarette brand as well as the false advertising it made to adolescents.<sup>121</sup> To incentivize retailers into adopting these standards they set forth and to help to support the necessary modifications, such as investing in barcode readers and training staff on how to use the new system, Juul dedicated \$100 million.<sup>122</sup> As of the middle of 2019, fifty retail chains committed to signing onto the program, encompassing forty thousand locations.<sup>123</sup> Retailers that have not adopted Juul's program are prohibited from selling Juul products.<sup>124</sup> Because of the large number of retail stores that currently have installed this technology, have established set procedures for when Juul products are sold, and have trained their staff to be knowledgeable on that system, there will not be a harsh transition for store owners to implement the proposal. For retailers who do not already utilize a scanner, it is important that they and their staff are trained on how to use them. E-cigarette manufacturers may argue that the expense of incorporating this technology onto their products is too costly for small businesses. However, it is certainly a small cost to pay for the devastating number of youths using these products. A study focusing on the effectiveness of Juul's program by looking at age-verification compliance before and after the implementation of

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<sup>121</sup> See *infra* part V,B.

<sup>122</sup> *Juul Labs Continues to Build on National Program to Reduce Underage Use*, JUUL LABS, INC. (Aug. 29, 2019), <https://www.juullabs.com/youth-prevention/>.

<sup>123</sup> Chris Morris, *Juul Will Require Retailers to Scan IDs Before Sales*, Fortune (Aug. 29, 2019), <https://fortune.com/2019/08/29/juul-mandatory-id-check-retailers-underage/>.

<sup>124</sup> *Retailer Access Control Standards: Business & Technical Requirements*, JUUL LABS, INC, <https://www.juullabsretailer.com/wp-content/uploads/sites/11/2021/11/2021-RACS-Technical-Requirements.pdf> (Juul established the Retail Access Control Standards program which locks their product until valid identification is scanned).

the program revealed that the failure rate was reduced from 36.8 percent to 0.2 percent.<sup>125</sup> It can be said that the program has been successful in its objective.

To counteract any privacy concerns patrons may have in the scanning of their photographic identification cards, it is important that the capability of the scanners be limited to producing the same information that can be found on the front of the identification card and to verifying the authenticity of the document itself. Today, many large commercial retailers have used scanning systems in their day-to-day operations. Walgreens, for example, scans patrons' identification cards for the purchase of alcohol, and they are not alone. Scanning of such documents is not unheard of. As a matter of fact, some states, such as California, have issued laws permitting the scanning of a driver's license or identification card for purposes of verifying age or the authenticity of the document.<sup>126</sup> Further, the suggested capability is extremely less problematic than other scanning systems that are used for purposes of verifying age in relation to alcohol sales. PatronScan is a scanning technology, mostly used by nightclubs, that in addition to verifying the patron's age and authenticity of the identification card, allows business owners the option of reporting a patron's transgressions or banning a patron from the establishment, which is then made available to through the system to all other business owners upon scanning of that patron's identification card.<sup>127</sup>

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<sup>125</sup> Tengjiao Chen et al., *Improving Retailer Compliance for Tobacco Purchases: Pilot Study Findings*, AM. J. HEALTH BEHAV. (May 1, 2021), <https://www.ingentaconnect.com/contentone/png/ajhb/2021/00000045/00000003/art00011?crawler=true&mimetype=application/pdf>; see *Pilot Study of RACS Programs Shows Dramatic Improvement in Retailer Compliance*, JUUL LABS, INC. (Oct. 10, 2019), <https://www.juullabs.com/pilot-study-of-racs-program-shows-dramatic-improvement-in-retailer-compliance/>.

<sup>126</sup> See CAL. CIV. CODE § 1798.90.1(a)(1) (Deering 2019); see also 22 FLA. STAT. ANN. § 322.143 (2) (2014) (sets forth when a driver's license or government issued identification card may be scanned).

<sup>127</sup> @PatronScan, TWITTER (Nov. 12, 2019, 5:49 PM) <https://twitter.com/patronscan/status/1194386792801169408?ext>; see Susie Cagle, *This ID*

## 2. Online Sales

Following the restrictions put in place due to COVID-19, research has shown that adolescents have turned to online retailers to purchase their e-cigarette products.<sup>128</sup> ENDS are accessible to youth even when online retailers have age verification processes in place; they are “often easily circumvented.”<sup>129</sup> Despite regulations that have been enacted to prevent this very thing from occurring, enforcement has been inadequate. To combat online purchases of e-cigarettes among adolescents, enforcement efforts must be strengthened at both point-of-purchase and point-of-delivery.

In 2009, Prevent All Cigarette Trafficking (“PACT”) Act came into effect, applying stricter regulations to the sale of tobacco products online.<sup>130</sup> Namely, it required remote sellers to pay taxes on the delivery of tobacco products and to “check the age and ID of customers both at

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*Scanner Company is Collecting Sensitive Data on Millions of Bargoers*, MEDIUM (May 29, 2019), <https://onezero.medium.com/id-at-the-door-meet-the-security-company-building-an-international-database-of-banned-bar-patrons-7c6d4b236fc3>; see also Keristen Holmes, *What are Establishments Doing With Your ID Information Once it's Scanned?*, ABC 10 (Sept. 13, 2018, 9:18 AM), <https://www.abc10.com/article/news/local/sacramento/what-are-establishments-doing-with-your-id-information-once-its-scanned/103-593841443> (ordinance requiring clubs and bars in Sacramento to use the PatronScan ID System was passed).

<sup>128</sup> See Shivani Mathur Gaiha, Lauren Kass Lempert, & Bonnie Halpern-Felsher, *Underage Youth and Young Adult E-Cigarette Use and Access Before and During the Coronavirus Disease 2019 Pandemic*, [J]AMA NETWORK OPEN (Dec. 3, 2020), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7716191/> (about twenty percent of youth noted it was easier to access e-cigarettes because of the switch to online purchasing).

<sup>129</sup> see Andrew C. Stokes, *Declines in Electronic Cigarette Use Among US Youth in the Era of COVID-19 – A Critical Opportunity to Stop Youth Vaping in Its Tracks*. [J]AMA NETWORK OPEN (Dec. 3, 2020), <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2773487>; see also Shivani Mathur Gaiha et al., *supra* note 124 (approximately twenty-eight percent of youth who purchased e-cigarettes online indicated that the website did not verify their age).

<sup>130</sup> See *Prevent All Cigarette Trafficking (PACT) Act Enhances the Requirements of the Federal Jenkins Act*, CA DEP'T OF TAX & FEE ADMIN., <https://www.cdtfa.ca.gov/taxes-and-fees/pact.htm> (last visited Mar. 5, 2022) (the PACT Act amends the Jenkins Act of 1949 which was created to frustrate illicit sale by requiring sellers shipping traditional cigarettes to buyers across state lines to report the sale to the buyer's state tobacco tax administrators).

purchase and at delivery.”<sup>131</sup> In 2020, Congress passed the Consolidated Appropriations Act of 2021, which amended the PACT Act such that the definition of cigarettes was expanded to ENDS products – all vaping products regardless of whether they contain nicotine.<sup>132</sup> Additionally, the United States Postal Service was prohibited from making direct-to-consumer deliveries for any of the qualifying cigarette products.<sup>133</sup> For sales that are made directly to consumers through other carriers and private delivery services, valid identification containing a birth date must be checked at the place of delivery to ensure that the customer is over the federal minimum age of 21 and that customer’s signature must be attained.<sup>134</sup> Furthermore, this legislation requires online sellers of cigarette products to verify the customer’s age, identity, and address at point of sale through a commercially available database that compares the purchases identifying information against a data source.<sup>135</sup> Online retailers who have failed to comply with the requirements of the PACT Act will be placed on a non-compliant list which is distributed to entities such as credit card companies and common carriers to ensure that their products cannot be purchased and shipped.<sup>136</sup>

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<sup>131</sup> Ann Boonn, *The PACT Act: Preventing Illegal Internet Sales of Cigarettes, Smokeless Tobacco & E-Cigarettes*, CAMPAIGN FOR TOBACCO-FREE KIDS (Mar. 2, 2021) <https://www.tobaccofreekids.org/assets/factsheets/0361.pdf>.

<sup>132</sup> Consolidated Appropriations Act, 2021, H.R. 133, 116th Cong. (2020) (enacted); *see* 15 U.S.C. §§ 375(2)(A), (7) (ENDS products include “an e-cigarette; . . . and any component, liquid, part, or accessory of a device described [above], without regard to whether the component, liquid, part, or accessory is sold separately from the device.”).

<sup>133</sup> *Id.*; *see* 18 U.S.C. § 1716E(1).

<sup>134</sup> 15 U.S.C. § 376a(b)(4).

<sup>135</sup> *Id.* at § 376a(b)(4)(iii).

<sup>136</sup> *See generally* Azim Chowdhury & Galen D. Rende, *Congress Amends the PACT Act to Apply to All Vaping Products, Placing Huge Burden on Small Manufacturers as Third-Party Common Carriers Refuse to Ship Products*, NAT’LLAW REV (Feb. 4, 2021), <https://www.natlawreview.com/article/congress-amends-pact-act-to-apply-to-all-vaping-products-placing-huge-burden-small>.

Retailers must exercise due diligence to meet the published legal requirement at point of purchase. Each site that sells an ENDS product must have a system that requires the purchaser to upload a valid government identification card. Those that rely on purchasers to confirm that they are of legal age to purchase an ENDS product by checking a box must immediately update their systems. Retailers with disclaimers of minimum age or requiring certifications or legal age are equally ineffective to meet the age verification requirements. Unfortunately, even those who use a third-party commercial database do not always curtail purchases of underage youth. This is because the law requires only that the purchaser provide a name, birthday, and place of residence, which is then to be compared in the database to ensure that individual lives at that place of residence.

Additionally, every delivery service must adopt a system that requires the purchasers' valid identification cards to be scanned at point of delivery to ensure that the person accepting the package matches the identity of the person who placed the order. Today, FedEx and the United Parcel Service have followed behind the United States Postal Service and approved of similar shipping restrictions prohibiting shipping direct-to-consumer but also to retailers.<sup>137</sup> Additionally, delivery apps DoorDash has also prohibited the delivery of any tobacco product.<sup>138</sup> However, local vape shops, private delivery services, and e-cigarette or vape online stores can freely establish their own delivery systems and there is no certain way of knowing whether delivery persons do check identification cards. Therefore, it is important that in addition to

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<sup>137</sup> See *Tobacco Shipping is Prohibited*, FEDEX, <https://www.fedex.com/en-us/shipping/guidelines-for-shipping-tobacco.html>; see also *Shipping Tobacco*, FedEx, <https://www.ups.com/us/en/support/shipping-support/shipping-special-care-regulated-items/prohibited-items/tobacco.page>.

<sup>138</sup> See *Can I add tobacco products to my DoorDash menu?* DOORDASH, [https://help.doordash.com/merchants/s/article/Can-I-add-tobacco-products-to-my-DoorDash-menu?language=en\\_US](https://help.doordash.com/merchants/s/article/Can-I-add-tobacco-products-to-my-DoorDash-menu?language=en_US).

establishing a new system of scanning cards, it is important that such distributors are required by the FDA to verify that they have and are enforcing that system.

### **3. Limits on Product Purchases**

Even with all of Congress's legislation, the FDA's regulations, and the above-mentioned proposed remedies, some young people will continue to have access to ENDS products and it is not a mystery as to where these youth get their product. Young people are getting their hands on e-cigarettes from individuals of legal age who are purchasing such products in large quantities and reselling them.<sup>139</sup> That is why it is important that the FDA mandates ENDS manufacturers, both online and in-person, to adopt measures that limit the number of devices and/or e-juice pods that may be purchased in a single transaction. To date, only one e-cigarette manufacturer has adopted this measure.<sup>140</sup> However, even that restriction does not appear to be sufficient. Customers should be restricted to purchasing only one disposable e-cigarette in a single transaction. Additionally, customers should only be able to purchase one device and one e-liquid pack when it comes to refillable products or pre-filled pods. Exceptions to this rule should only be made in the case where a device or e-liquid is plainly defective and the patron exchanges that defective product for a functioning replacement.

#### **B. Educational Resources**

Schools play a vital role in helping to reduce the number of adolescents who use e-cigarettes. The decreased use of e-cigarettes throughout the first half of COVID-19 demonstrates

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<sup>139</sup> See *supra* part II.B; See generally *Evidence-Based Resource Guide Series: Reducing Vaping Among Youth and Young Adults*, S.A.M.H.S.A., (June 1, 2020), [https://store.samhsa.gov/sites/default/files/SAMHSA\\_Digital\\_Download/PEP20-06-01-003\\_508.pdf](https://store.samhsa.gov/sites/default/files/SAMHSA_Digital_Download/PEP20-06-01-003_508.pdf).

<sup>140</sup> See Jennifer Malone *Juul Introduces Checkout System to Combat Underage Purchases*. WALL ST. J. (Aug. 28, 2019), <https://www.wsj.com/articles/juul-introduces-checkout-system-to-combat-underage-purchases-11567051140> (Juul “limits each purchase to a maximum of one vaporizer and four refill packs.”).

that these products are being used more often during or after school.<sup>141</sup> Additionally, many youth users have reported that they have tried their first e-cigarette in a school context and have purchased these products from peers to avoid age verifications.<sup>142</sup>

Education focused on discussing the danger e-cigarettes have on one's health can help to reduce the number of adolescents who use them.<sup>143</sup> Due to the early deceptive marketing initiatives by ENDS industry leaders, many young people remain unaware of the dangers e-cigarettes pose, or that these products even contain nicotine. For instance, one study found that sixty-three percent of Juul users between the years of fifteen and twenty-four were unaware that Juul products contained nicotine.<sup>144</sup> In fact, the FDA issued a warning letter to Juul Labs Inc., asserting that the company violated federal law by promoting its products as healthier, less hazardous alternatives to traditional cigarettes without first acquiring FDA clearance.<sup>145</sup> Juul representatives entered a high school and told a class of ninth-graders that their products were "totally safe."<sup>146</sup> There are several other accounts of Juul representatives directly relaying similar messages to adolescents in schools and youth camps,<sup>147</sup> describing e-cigarettes as being "safer

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<sup>141</sup> *See supra* part IV.

<sup>142</sup> Sara J. Schiff et al., *supra* note 113.

<sup>143</sup> *See supra* part IV.

<sup>144</sup> *Id.*

<sup>145</sup> *FDA warns JUUL Labs for Marketing Unauthorized Modified Risk Tobacco Products, Including in Outreach to Youth*, F.D.A. (Sep. 9, 2019), <https://www.fda.gov/news-events/press-announcements/fda-warns-juul-labs-marketing-unauthorized-modified-risk-tobacco-products-including-outreach-youth>.

<sup>146</sup> Arman Azad, *Juul Went into a Ninth-Grade Classroom and Called its Device "Totally Safe," Teens Testify*, CNN (July 25, 2019), <https://www.cnn.com/2019/07/25/health/juul-reps-in-classroom-teen-testimony/index.html>.

<sup>147</sup> *See generally* Sheila Kaplan, *Juul Targeted School and Youth Camps, House Panel on Vaping Claims*, N.Y. TIMES (July 25, 2019), <https://www.nytimes.com/2019/07/25/health/juul-teens-vaping.html>.

than cigarettes[,]”<sup>148</sup> “99% safer than cigarettes[,]”<sup>149</sup> and a “safer alternative.”<sup>150</sup> Over the years, the company has developed a reputation for deliberately targeting youth, and its practices reflect that. In fact, it was not until 2018 that Juul began to place warnings on its product that they contain nicotine.<sup>151</sup>

Schools all across the country must dedicate an entire conversation to this topic, due to its widespread use among adolescents, the harm such products pose to youth development, and the high risk of addiction. Early intervention can have a major impact on whether youth initiate e-cigarette use; thus, education on the effects of e-cigarettes must begin by ninth grade, if not earlier. One important study found that “waiting an additional year [to begin educating youth,] . . . from 16 to 17 years old represents a 10.1% increase in the risk of [this population] becoming susceptible to e-cigarette use.”<sup>152</sup> Lastly, schools must implement and enforce strategies to help combat the use of e-cigarettes in and around school property.

## **Conclusion**

Adolescents have borne the brunt of rise of e-cigarettes. History has shown us how dangerous tobacco products are and how difficult it is to tackle the issue. The effort to combat this epidemic must be ongoing and remain a prominent concern among our society. There is still

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<sup>148</sup> *Examining JUULs Role in the Youth Nicotine Epidemic: Part I*, YOUTUBE (July 24, 2019), <https://www.youtube.com/watch?v=m3iEMrAd83o>.

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

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

<sup>151</sup> *Washington AG Ferguson Files Lawsuit Against JUUL for Targeting Underage Consumers in its Advertising, Product Design*, WASH. OFF. OF THE ATT’Y GEN. (Sept. 2, 2020), <https://www.atg.wa.gov/news/news-releases/ag-ferguson-files-lawsuit-against-juul-targeting-underage-consumers-its>; *see supra* part IV.

<sup>152</sup> Adriana Perez, et al., *Prospectively Estimating the Age of Initiation of E-Cigarettes Among U.S. Youth: Findings from the Population Assessment of Tobacco and Health (PATH) Study: 2013-2017*, J. OF BIOMETRICS AND BIostatISTICS (May 19, 2020), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7861570/>.

must more work that needs to be done, but a good place to start is by imposing requirements on retailers and raising awareness on the health effects e-cigarettes pose.