

# PATERNALISM AND THE MORAL JUSTIFICATIONS FOR THE E-CIGARETTE FLAVOR BAN

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## INTRODUCTION

By 2013, it appeared that the United States tobacco industry had finally slowed down.<sup>1</sup> Decades of tightening regulations, education programs, and mass media campaigns had slowly chipped away at the centuries-old pastime—smoking was no longer popular. As public health advocates celebrated the fiftieth anniversary of the U.S. Surgeon General’s 1964 Report on Tobacco and Health,<sup>2</sup> it appeared that cigarette use might fizzle out for good.<sup>3</sup> However, those celebrations were premature. A new, flameless sensation was already spreading like wildfire: the e-cigarette.

Ubiquitous today, e-cigarettes are the most popular form of electronic nicotine delivery systems.<sup>4</sup> Rather than igniting tobacco and producing smoke, e-cigarettes heat e-liquids into an aerosol or vapor that users inhale—a process often referred to as “vaping.”<sup>5</sup> These e-liquids typically contain nicotine. Though nicotine-free liquids are also available, they are less popular.<sup>6</sup>

The e-cigarette boom did not happen overnight. At first, e-cigarettes were dismissed as a mere fad.<sup>7</sup> E-cigarettes lacked many of the elements that made their conventional, combustible counterparts popular.<sup>8</sup> Even after reaching a new milestone when Oxford made the verb “vape”—“to inhale vapor through the mouth from a . . . device (such as an electronic

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<sup>1</sup> Eric A. Feldman, *Layers of the Law: The Case of E-Cigarettes*, 10 FIU L. REV. 111, 111–12 (2014); Samantha J. Gagliardo, Note, *No “E”-asy Way Out: Why the FDA Should Not Regulate E-Cigarettes Under the Current TCA Framework, Even With New Deeming Regulations*, 79 U. PITT. L. REV. 127, 128 (2017).

<sup>2</sup> See U.S. DEP’T OF HEALTH, EDUC., AND WELFARE, PUBLIC HEALTH SERVICE PUB. NO. 1103, SMOKING AND HEALTH: REPORT OF THE ADVISORY COMMITTEE TO THE SURGEON GENERAL OF THE PUBLIC HEALTH SERVICE (1964).

<sup>3</sup> Feldman, *supra* note 1, at 111–12.

<sup>4</sup> Electronic nicotine delivery systems are classified by their appearance, usually shaped to look like conventional tobacco products such as “cigarettes, cigars, cigarillos, pipes, or hookahs,” though they often also resemble everyday items such as pens and USB sticks. WORLD HEALTH ORGANIZATION [WHO], *Report on Electronic Nicotine Delivery Systems*, at 2 (July 21, 2014), <http://apps.who.int/gb/ctc/PDF/cop6/FTC COP6 10-en.pdf?ua=1>. See Wendy E. Parmet, *Paternalism, Self-Governance, and Public Health: The Case of E-Cigarettes*, 70 U. MIAMI L. REV. 879, 881, 924–25 (2016).

<sup>5</sup> *About Electronic Cigarettes (E-Cigarettes)*, CTRS. FOR DISEASE CONTROL, [https://www.cdc.gov/tobacco/basic\\_information/e-cigarettes/about-e-cigarettes.html](https://www.cdc.gov/tobacco/basic_information/e-cigarettes/about-e-cigarettes.html) (last updated Sept. 9, 2020).

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

<sup>7</sup> See Feldman, *supra* note 1, at 111; Gagliardo, *supra* note 1, at 128.

<sup>8</sup> Feldman, *supra* note 1, at 111 (noting that e-cigarettes appeared to lack many of the appeals of conventional cigarettes, such as “the ritual of lighting up, the smell of smoke, and the aesthetic of a smoke-filled room, but had the drawback of containing addictive quantities of nicotine”).

cigarette)”—the 2014 word of the year,<sup>9</sup> adults and teenagers alike continued to look upon the small but rapidly growing e-cigarette community with disdain and skepticism.<sup>10</sup> In just a few short years, however, the market for e-cigarettes exploded, reaching over forty million users globally in 2018 with no signs of slowing down.<sup>11</sup>

There were multiple reasons for the unexpected<sup>12</sup> success of e-cigarettes. Like conventional cigarettes, e-cigarettes typically contain nicotine,<sup>13</sup> which can have a variety of positive—and negative—effects.<sup>14</sup> However, since e-cigarette usage does not involve smoke inhalation, it presents a safer method of nicotine consumption than do conventional cigarettes.<sup>15</sup> Further, the lack of smoke makes e-cigarettes more concealable and less detectable.<sup>16</sup> This, coupled with the product’s recent lack of regulation,<sup>17</sup> makes e-cigarettes easier to obtain and use discreetly. Finally, and perhaps most controversially, e-liquids can be produced in a variety of flavors, which are incredibly popular among teens.<sup>18</sup>

These reasons, among many others, contributed to the current massive e-cigarette boom, but concerns have been mounting. A survey conducted in 2018 showed that roughly 20 percent of high school students had used e-cigarettes in the past thirty days.<sup>19</sup> Reports showed that e-cigarette aerosol

<sup>9</sup> Katy Steinmetz, *Oxford’s 2014 Word of the Year is Vape*, TIME (Nov. 17, 2014), <http://time.com/3590093/oxfords-2014-word-of-the-year-is-vape/>; *Vape*, MERRIAM-WEBSTER, <https://www.merriam-webster.com/dictionary/vape> (last visited Dec. 17, 2019).

<sup>10</sup> See Jodi Parker, *Alright, We Get It, You Vape*, L.A. TIMES HIGH SCHOOL INSIDER (Feb. 29, 2016), <https://highschool.latimes.com/corona-del-mar-high-school/alright-we-get-it-you-vape/>; Jené Gutierrez, *I Went to a Vape Conference to Mock It—Then the Vapers Changed My Mind*, DAILY DOT (Sept. 30, 2015), <https://www.dailydot.com/unclick/actually-vaping-is-cool/>.

<sup>11</sup> Lora Jones, *Vaping: How Popular Are E-Cigarettes?*, BBC NEWS (Sept. 15, 2019), <https://www.bbc.com/news/business-44295336>.

<sup>12</sup> Though, probably not unexpected by e-cigarette companies like Juul and its parent company, Pax Labs, which have seen tremendous growth since they first launched in 2017 and 2007 respectively. See, e.g., Jordan Crook, *Confirmed: Pax Labs Raises \$420 Million at a Valuation of \$1.7 Billion*, TECHCRUNCH (Apr. 22, 2019), <https://techcrunch.com/2019/04/22/yep-you-read-that-right-420-million/>.

<sup>13</sup> *About Electronic Cigarettes (E-Cigarettes)*, *supra* note 5.

<sup>14</sup> Nicotine is a stimulant that, when used in moderation, can have positive psychological effects. See Kate Kelland, *Is Nicotine All Bad?*, SCI. AM. (May 19, 2015), <https://www.scientificamerican.com/article/is-nicotine-all-bad/>. However, when used in excess, nicotine has severe harmful effects on both the nervous system and cardiovascular system. See *id.*

<sup>15</sup> *Quick Facts on the Risks of E-Cigarettes for Kids, Teens, and Young Adults*, CTRS. FOR DISEASE CONTROL, [https://www.cdc.gov/tobacco/basic\\_information/e-cigarettes/Quick-Facts-on-the-Risks-of-E-cigarettes-for-Kids-Teens-and-Young-Adults.html](https://www.cdc.gov/tobacco/basic_information/e-cigarettes/Quick-Facts-on-the-Risks-of-E-cigarettes-for-Kids-Teens-and-Young-Adults.html) (last updated Mar. 11, 2019) (noting that e-cigarettes are safer than conventional cigarettes, “[b]ut burned cigarettes are very dangerous, killing half of all people who smoke long-term.”).

<sup>16</sup> See Angus Chen, *Teenagers Embrace Juul, Saying It’s Discreet Enough to Vape in Class*, NPR (Dec. 4, 2017), <https://www.npr.org/sections/health-shots/2017/12/04/568273801/teenagers-embrace-juul-saying-its-discreet-enough-to-vape-in-class>; Associated Press, *Teens Have Figured Out How to be Sneaky While Vaping in School*, N.Y. POST (Apr. 29, 2018), <https://nypost.com/2018/04/29/teens-have-figured-out-how-to-be-sneaky-while-vaping-in-school/>.

<sup>17</sup> See U.S. DEP’T OF HEALTH & HUM. SERVS., *E-CIGARETTE USE AMONG YOUTH AND YOUNG ADULTS: A REPORT OF THE SURGEON GENERAL* 5, 7 (2016), [https://e-cigarettes.surgeongeneral.gov/documents/2016\\_sgr\\_full\\_report\\_non-508.pdf](https://e-cigarettes.surgeongeneral.gov/documents/2016_sgr_full_report_non-508.pdf) (recommending that all levels of government take action to prevent youth access to e-cigarettes).

<sup>18</sup> Angelica LaVito, *Juul Halting Sales of Most Flavors ‘Does Not Stop’ Trump Administration’s E-Cigarette Plans*, *Azar Says*, CNBC (Oct. 24, 2019), <https://www.cnbc.com/2019/10/24/juul-halting-sales-of-sweet-flavors-does-not-stop-trump-plans-hhs-secretary.html> (Describing how Juul, the most popular e-cigarette brand, previously sold a variety of flavors such as fruit, crème, mango, and cucumber. Following an announcement by the Trump administration of a flavor ban, the company preemptively discontinued sales of most of its flavors).

<sup>19</sup> *2018 NYTS Data: A Startling Rise in Youth E-Cigarette Use*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/tobacco-products/youth-and-tobacco/2018-nyts-data-startling-rise-youth-e-cigarette-use> (last updated May 4, 2020).

was not as harmless as previously thought.<sup>20</sup> Then, in August of 2019, the public's fears were confirmed with the first death related to e-cigarette use.<sup>21</sup> Negative news on e-cigarettes accelerated. Reports published on February 18, 2020 indicated over 2,800 cases of e-cigarette-associated lung illnesses in the United States with over sixty deaths.<sup>22</sup>

Against this backdrop, the debate over e-cigarettes has reached a boiling point. E-cigarette proponents arguing for lax regulations had often claimed that e-cigarettes were safe, or at least safer than conventional cigarettes, and that e-cigarettes would be a powerful tool to help adults quit smoking.<sup>23</sup> But with these claims cast into doubt, the Trump administration took action. In a surprising move, after giving mixed signals in its approach to e-cigarettes for months,<sup>24</sup> the administration responded to the perceived health crisis by both raising the minimum age of purchase for all tobacco products<sup>25</sup> and banning the manufacture and sale of virtually all flavored e-cigarettes<sup>26</sup> in what could be the first of many new, targeted regulations.

This Note addresses the extent to which e-cigarettes may be federally regulated in accordance with principles of autonomy and individual liberty by examining the recent e-cigarette flavor ban according to three moral justifications for public health laws. Part I of this Note discusses the background of e-cigarette regulation, the expansion of the Food and Drug Administration's (FDA) authority to regulate traditional tobacco products and e-cigarettes, the amended age requirement, and the new flavor ban. Part II introduces the justifications that public health laws fall under and argues that the most restrictive justification—hard paternalism—may be applied only under limited circumstances absent clear popular support. Finally, Part III explores how the flavor ban fits within this moral framework and ultimately concludes that the ban falls under the most restrictive hard-paternalist category, and, passed without a popular mandate, improperly infringes on individual rights.

## I. THE DELAYED RESPONSE TO E-CIGARETTES

Although a Beijing pharmacist invented e-cigarettes in 2003 to create a safer alternative to smoking, they were not marketed in the United States

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<sup>20</sup> *Quick Facts on the Risks of E-Cigarettes for Kids, Teens, and Young Adults*, *supra* note 15 (noting that e-cigarette aerosol exposes users and bystanders to many harmful substances).

<sup>21</sup> Betsy McKay & Talal Ansari, *Illinois Death Could be First Linked to Vaping*, WALL ST. J. (Aug. 23, 2019), <https://www.wsj.com/articles/illinois-death-could-be-first-linked-to-vaping-11566585891>.

<sup>22</sup> *Outbreak of Lung Injury Associated with the Use of E-Cigarette, or Vaping, Products*, CTRES. FOR DISEASE CONTROL, [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) (last updated Feb. 25, 2020).

<sup>23</sup> *See, e.g.*, Rich Lowry, *The Ridiculous Campaign Against Vaping*, POLITICO: OPINION (Sept. 18, 2019), <https://www.politico.com/magazine/story/2019/09/18/rich-lowry-vaping-campaign-228143>; Liam Sigaud & Steve Pociask, *A Vaping Ban Will Send Smokers Back to the Pack*, WALL ST. J.: OPINION (Sept. 12, 2019), <https://www.wsj.com/articles/a-vaping-ban-will-send-smokers-back-to-the-pack-11568325386>.

<sup>24</sup> *See infra* notes 89–96 and accompanying text.

<sup>25</sup> Marty Johnson, *FDA Officially Raises Tobacco Buying Age to 21*, HILL (Dec. 27, 2019), <https://thehill.com/policy/healthcare/476035-fda-officially-raises-tobacco-buying-age-to-21>.

<sup>26</sup> Ken Alltucker, *FDA Bans Mint- and Fruit-Flavored Vaping Products but Exempts Menthol and Tobacco*, USA TODAY (Jan. 2, 2020), <https://www.usatoday.com/story/news/health/2020/01/02/vaping-ban-fda-strikes-mint-and-fruit-flavored-products/2796299001/>.

until 2007.<sup>27</sup> Almost immediately after the e-cigarette's American debut, health authorities took notice of the new product. In 2008, the World Health Organization issued a report criticizing a variety of purported health and therapeutic claims asserted in e-cigarette marketing and product labeling.<sup>28</sup> A year later, the FDA reported that many nicotine-free cartridges were falsely labeled<sup>29</sup> and expressed concerns that flavored e-cigarettes were targeted at teens.<sup>30</sup> Despite these early concerns, both state and federal governments hesitated to regulate the new product. In 2009, the very same year as the FDA's initial report, Congress granted the FDA regulatory authority over "tobacco products" but declined to specifically include e-cigarettes in that category.<sup>31</sup> Despite the ability to classify and regulate e-cigarettes as a tobacco product, the FDA chose to wait several years before intervening in e-cigarettes. Even then, its final intervention was limited.<sup>32</sup>

#### A. THE FDA'S LATE ENTRANCE INTO TOBACCO

To understand why the FDA's response to e-cigarettes was rather limited until recently, it is important to note the regulatory history of tobacco and how the FDA's jurisdiction has expanded to cover e-cigarettes today.

For most of its history, the FDA made no attempt to regulate tobacco.<sup>33</sup> Until 1964, the tobacco industry went largely unregulated.<sup>34</sup> Smoking was deeply ingrained in American culture since its founding, and decades of aggressive advertising campaigns convinced many Americans that smoking was actually healthy for them.<sup>35</sup> Only with the publication of the Surgeon General's 1964 Report on Tobacco and Health did the federal government finally challenge this long-standing and pervasive industry, debunking these false, purported health benefits and linking tobacco to its many now well-known health risks, such as lung cancer and heart disease.<sup>36</sup>

<sup>27</sup> Sandee LaMotte, *E-Cigarettes: Where Do We Stand?*, CNN (Oct. 2, 2018), <https://www.cnn.com/2015/12/31/health/where-we-stand-now-e-cigarettes/>.

<sup>28</sup> E-cigarettes were originally marketed as "nicotine replacement therapy" devices like nicotine gum, lozenges, and patches, which are designed to help smokers break their tobacco addictions. *Marketers of Electronic Cigarettes Should Halt Unproved Therapy Claims*, WORLD HEALTH ORG. (Sept. 19, 2008), <https://www.who.int/mediacentre/news/releases/2008/pr34/en/>.

<sup>29</sup> The original report is no longer available on the FDA's website, but archived versions are available at B.J. Westenberger, *Evaluation of E-Cigarettes*, U.S. FOOD & DRUG ADMIN. (May 4, 2009), <https://web.archive.org/web/20170120080536/http://www.fda.gov/downloads/Drugs/ScienceResearch/ucm173250.pdf>.

<sup>30</sup> The original report is no longer available on the FDA's website, but archived versions are available at *FDA and Public Health Experts Warn About Electronic Cigarettes*, U.S. FOOD & DRUG ADMIN. (July 22, 2009), <https://web.archive.org/web/20090724133750/https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm173222.htm>.

<sup>31</sup> Congress gave the FDA regulatory authority over cigarettes, cigars, roll-your-own tobacco, and more, as well as other products that may be classified as "tobacco products." The Family Smoking Prevention and Tobacco Control Act of 2009, 21 U.S.C. § 387 (2019).

<sup>32</sup> See *infra* Section I.B.

<sup>33</sup> Though the FDA was first established in 1938 by the Food, Drug, and Cosmetic Act of 1938, it would not attempt to regulate tobacco until 1996. See *infra* notes 40–42 and accompanying text.

<sup>34</sup> Jonathan H. Adler, *Regulatory Obstacles to Harm Reduction: The Case of Smoking*, 11 NYU J.L. & LIBERTY 712, 715 (2017); see Bruce Yandle et al., *Bootleggers, Baptists & Televangelists: Regulating Tobacco by Litigation*, 2008 U. ILL. L. REV. 1225, 1248–50 (2008).

<sup>35</sup> Though unthinkable today, from the 1920s to the 1950s magazine ads for cigarettes included not just dubious physician endorsements, but featured pro-athletes, politicians, cartoon characters, children, and even Santa Claus. Stuart Elliot, *When Doctors, and Even Santa, Endorsed Tobacco*, N.Y. TIMES (Oct. 6, 2008), <https://www.nytimes.com/2008/10/07/business/media/07adco.html>.

<sup>36</sup> See *History of the Surgeon General's Reports on Smoking and Health*, CTRS. FOR DISEASE CONTROL, [https://www.cdc.gov/tobacco/data\\_statistics/sgr/history/index.htm](https://www.cdc.gov/tobacco/data_statistics/sgr/history/index.htm) (last updated Nov. 15,

While this landmark report was the first step in the federal government's campaign to phase out smoking, the government was otherwise still slow to act. Occasionally, administrative agencies and state governments would impose new labeling standards and advertisement restrictions only to be overridden or preempted by Congress.<sup>37</sup> The most meaningful nationwide regulation arose in 1998 from the Master Settlement Agreement (MSA) reached by numerous state Attorneys General and the five then-largest cigarette manufacturers.<sup>38</sup> The MSA forced cigarette companies to pay the participating states billions in settlements annually and refrain from various marketing efforts.<sup>39</sup>

The FDA originally was not granted explicit authority over tobacco products. However, because the Food, Drug, and Cosmetic Act of 1938 (FDCA)<sup>40</sup> authorized the FDA to regulate food, drugs, and cosmetics, the FDA could classify nicotine as a drug in 1996 in an effort to regulate tobacco.<sup>41</sup> This allowed the FDA to classify cigarettes and other tobacco products as drug delivery devices, further allowing the FDA to promulgate new regulations with the aims of addressing tobacco's health risks and limiting youth access.<sup>42</sup>

The tobacco industry responded by challenging the FDA's authority. In 2000, in *FDA v. Brown & Williamson*, the Supreme Court sided with the tobacco industry, finding that "Congress clearly precluded the FDA from asserting jurisdiction to regulate tobacco products."<sup>43</sup> The Court reasoned that Congress's tobacco-specific legislation passed after the FDCA demonstrated that Congress did not intend to delegate jurisdiction to the FDA.<sup>44</sup> Further, the Court noted that the FDCA instructed the FDA to remove any product if the FDA "determines that there cannot otherwise be reasonable assurance of its safety and effectiveness."<sup>45</sup> Accordingly, if the FDCA had given the FDA authority to regulate tobacco, the Court reasoned, the FDCA would require the outright ban of tobacco, which Congress could not have intended.<sup>46</sup> Thus, the FDA was forced to withdraw its regulations.

Finally, nine years later, Congress responded by passing The Family Smoking Prevention and Tobacco Control Act of 2009 (TCA).<sup>47</sup> The TCA granted the FDA regulatory authority over the manufacture, packaging, and

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2019) (discussing the impact and legacy of the Surgeon General's report on the still-ongoing antismoking campaign).

<sup>37</sup> Adler, *supra* note 34, at 715–16.

<sup>38</sup> *Id.* at 716.

<sup>39</sup> *Id.* But see Yandle, *supra* note 34, at 1270–77 for a discussion of how the MSA failed to deliver on some of its promises.

<sup>40</sup> Food, Drug, and Cosmetic Act of 1938, 21 U.S.C. § 301 (2019).

<sup>41</sup> Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. 44396, 44418 (Aug. 28, 1996)

<sup>42</sup> Adler, *supra* note 34, at 716–17; Kevin Kanavy, Note, *How States and Localities Are in a Better Position Than the FDA to Address Youth Use of E-Cigarettes*, 31 LOY. CONSUMER L. REV. 606, 609 (2019).

<sup>43</sup> *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 126 (2000).

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

<sup>45</sup> *Id.* at 134 (quoting 21 U.S.C. § 360j(e)).

<sup>46</sup> *Id.* at 134–37 (citing *United States v. Rutherford*, 442 U.S. 544, 556 (1979)).

<sup>47</sup> 21 U.S.C.A. §§ 387–387u (West 2020).

advertising of cigarettes, cigars, and other specified tobacco products. It also set the minimum age to purchase such products at eighteen years nationally.<sup>48</sup>

#### B. E-CIGARETTES AND THE “DEEMING RULE”

The TCA was not limited to only the tobacco products listed in the initial statute. The statute further defined a “tobacco product” as “any product made or derived from tobacco that is intended for human consumption.”<sup>49</sup> This provision allows the FDA to deem products not listed in the TCA to be subject to its regulations if the products meet that definition. Despite this provision, the FDA did not deem e-cigarettes to be tobacco products until May 2016 in what is known as the “Deeming Rule.”<sup>50</sup>

Initially, the FDA was concerned that consumers could be deceived or misled into thinking that e-cigarettes had medical or therapeutic benefits.<sup>51</sup> Shortly before the passage of the TCA, the FDA began detaining shipments of e-cigarettes that it believed were being marketed as medical devices subject to the FDCA.<sup>52</sup> The FDA argued that although it lacked authority over conventional cigarettes under *Brown & Williamson*, it could still have authority over e-cigarettes because the Supreme Court found that Congress intended to exclude only *existing* tobacco products from the FDA’s regulatory authority.<sup>53</sup> Alternatively, the FDA argued that e-cigarette manufacturers had made unapproved therapeutic claims, which rendered their products subject to regulation as drugs regardless of whether they were truly medical devices within the scope of the FDCA.<sup>54</sup> On appeal in *Sottera, Inc. v. FDA*, the D.C. Circuit rejected both arguments. First, the court found that tobacco products could be regulated under the FDCA only if the manufacturers made therapeutic or medical claims—whether the product existed before the FDCA was passed was irrelevant. Second, the court found that the manufacturers in question had not made any such claims.<sup>55</sup> However, the D.C. Circuit did not completely foreclose the FDA’s regulation of e-cigarettes, observing that even though e-cigarettes fell outside the scope of the FDCA, they most likely came within the definition of “tobacco product” under the then newly-enacted TCA.<sup>56</sup>

Despite the door the D.C. Circuit had opened, the FDA chose to back off from attempting to regulate the e-cigarettes. At that time, the health impact of e-cigarettes remained unclear. The FDA was reluctant to interfere with the developing industry when the agency was uncertain whether intervention would do more harm than good. The FDA was well-aware that e-cigarettes

<sup>48</sup> 21 U.S.C.A. § 387f (d)(3)(A)(ii).

<sup>49</sup> 21 U.S.C.A. § 321(rr).

<sup>50</sup> 21 C.F.R. §§ 1100, 1140, 1143 (2016).

<sup>51</sup> For a brief time, e-cigarettes were marketed as therapeutic devices, but many manufacturers later abandoned those claims. See *Marketers of Electronic Cigarettes Should Halt Unproved Therapy Claims*, *supra* note 28. During the early 1900s, conventional cigarettes were also marketed as therapeutic devices, complete with physicians’ endorsements. Becky Little, *When Cigarette Companies Used Doctors to Push Smoking*, HISTORY (Sept. 11, 2019), <https://www.history.com/news/cigarette-ads-doctors-smoking-endorsement>.

<sup>52</sup> *Sottera, Inc. v. FDA*, 627 F.3d 891, 893 (D.C. Cir. 2010).

<sup>53</sup> *Id.* at 897.

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

<sup>55</sup> *Id.* at 895–98.

<sup>56</sup> *Id.* at 898 (“As we have already noted, the FDA has authority to regulate customarily marketed tobacco products—including e-cigarettes—under the Tobacco [Control] Act.”).

posed a variety of health risks.<sup>57</sup> But since e-cigarettes were likely safer than conventional cigarettes, the agency was cautiously optimistic that they might be useful tools to help curb smoking addictions. However, the FDA expressed concerns that in the wrong hands, e-cigarettes could just as easily become a gateway to smoking.<sup>58</sup>

Over time, the FDA's concerns were vindicated after new studies showed that not only were e-cigarettes growing in popularity among teens, but that teens were also more likely to begin smoking as a result.<sup>59</sup> Further, other studies questioned whether e-cigarettes were effective in helping adults quit smoking.<sup>60</sup> After years of similar studies, the FDA was given the support necessary to intervene. In 2016, they announced the Deeming Rule, through which the FDA finally declared that e-cigarettes could be regulated subject to the TCA as "tobacco products."<sup>61</sup>

Under the Deeming Rule, e-cigarettes are subject to the same regulatory standards as are conventional cigarettes and other specified tobacco products. The most important restrictions that the Deeming Rule applies to e-cigarettes are stricter labeling standards and a federal minimum age-of-purchase requirement.<sup>62</sup> To ensure proper labeling, the FDA requires e-cigarette manufacturers to submit premarket tobacco product applications for existing and newly-developed products, through which the FDA may grant or deny the product's sale on the market.<sup>63</sup> Existing products that were on the market as of August 8, 2016, the effective date of the Deeming Rule, were given a grace period under which manufacturers have until August 8, 2022 to submit product applications.<sup>64</sup> Accordingly, the labeling standards have not yet gone into full effect.

The age requirement was put into effect ninety days after the effective date of the Deeming Rule, or on November 6, 2016.<sup>65</sup> Subject to the TCA, e-cigarettes, like other tobacco products, could only be sold to customers ages

<sup>57</sup> The original report is no longer available on the FDA's website, but archived versions are available at *Electronic Cigarettes (e-Cigarettes)*, U.S. FOOD & DRUG ADMIN., <https://web.archive.org/web/20141216021527/https://www.fda.gov/NewsEvents/PublicHealthFocus/ucm172906.htm> (last updated Aug. 11, 2014) (noting that the agency regularly receives voluntary reports of illnesses and hospitalization associated with e-cigarette use).

<sup>58</sup> *Id.* (expressing concern that "e-cigarettes may lead young people to try other tobacco products, including conventional cigarettes, which are known to cause disease and lead to premature death."). But see Arman Azad, *E-Cigarettes Aren't a 'Gateway' to Teen Smoking, Study Says*, CNN (Nov. 4, 2019), <https://www.cnn.com/2019/11/04/health/vaping-smoking-gateway-study/index.html>.

<sup>59</sup> See, e.g., Jessica L. Barrington-Trimis et al., *E-Cigarettes, Cigarettes, and the Prevalence of Adolescent Tobacco Use*, 138 PEDIATRICS 2 (2016); Jonathan H. Mermin & Stephanie Zaza, *2015 Youth Risk Behavior Survey (YRBS) Results Released*, CTRS. FOR DISEASE CONTROL (June 9, 2016), [https://www.cdc.gov/nchhstp/dear\\_colleague/2016/dcl-060916-2015-youth-risk-behavior-survey-results-released.html](https://www.cdc.gov/nchhstp/dear_colleague/2016/dcl-060916-2015-youth-risk-behavior-survey-results-released.html).

<sup>60</sup> See, e.g., Girija Syamlal, et al., *Electronic Cigarette Use Among Working Adults – United States, 2014*, CTRS. FOR DISEASE CONTROL (June 10, 2016), <https://www.cdc.gov/mmwr/volumes/65/wr/mm6522a1.html>.

<sup>61</sup> 21 C.F.R. §§ 1100, 1140, 1143 (2016).

<sup>62</sup> See 21 C.F.R. § 1140.1 (2019).

<sup>63</sup> See FOOD & DRUG ADMIN., EFFECTIVE AND COMPLIANCE DATES APPLICABLE TO RETAILERS, MANUFACTURERS, IMPORTERS, AND DISTRIBUTORS OF NEWLY DEEMED TOBACCO PRODUCTS 4 <https://www.fda.gov/media/97951/download> [<https://web.archive.org/web/20201125054524/https://www.fda.gov/media/97951/download>] (last updated Nov. 2017).

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

<sup>65</sup> 21 C.F.R. § 1143.13 (2019).

eighteen or older,<sup>66</sup> with the onus on retailers to ensure compliance by requiring photo ID verification for all purchasers ages twenty-six and younger.<sup>67</sup> E-cigarettes are also prohibited from being sold in self-service vending machines unless the retailer ensures that individuals under eighteen cannot access the premises.<sup>68</sup> Additionally, e-cigarettes may not be given away as free samples.<sup>69</sup>

### C. TOBACCO 21

Though the labeling and product approval requirement has yet to go into full effect, the age restrictions have been in effect since 2016. However, the FDA's initial intervention had little impact. Even with nationwide restrictions in place, e-cigarette use among teens continued to grow, nearly doubling from 2017 to 2018.<sup>70</sup> To make matters worse, an increasing number of e-cigarette users, including teens, have sought hospital treatment for a variety of respiratory issues, with many dying.<sup>71</sup> By late 2019, it was clearer than ever that further measures were necessary to protect teens from continued e-cigarette use.

On December 19, 2019, Congress made its move. It amended the FDCA by raising the federal minimum age-of-purchase for tobacco products from eighteen to twenty-one.<sup>72</sup> This legislation, often referred to as "Tobacco 21," was approved by President Donald Trump on December 20, 2019 and took effect immediately.<sup>73</sup> Following the Deeming Rule, since e-cigarettes were classified as tobacco products, Tobacco 21 accordingly raised the minimum age for e-cigarette purchases nationwide.

While the updated age requirement received bipartisan support and was likewise celebrated by both sides of the aisle,<sup>74</sup> many commentators questioned its effectiveness.<sup>75</sup> While a federal age limit seems like the most obvious and direct way to address teen tobacco use, Congress was raising an already existing age limit. In the few years that e-cigarettes were subjected

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<sup>66</sup> Until December 2019, the minimum age of purchase for all tobacco products was eighteen. Following a recent spending package, the age was pushed to twenty-one. *See infra* Section I.C.

<sup>67</sup> 21 C.F.R. §§ 1140.14(a)(1)–(2) (2019).

<sup>68</sup> *Id.* § 1140.14(b)(3).

<sup>69</sup> *Id.* § 1140.16(d).

<sup>70</sup> *See 2018 NYTS Data: A Startling Rise in Youth E-Cigarette Use*, *supra* note 19.

<sup>71</sup> *See Outbreak of Lung Injury Associated with the Use of E-Cigarette, or Vaping, Products*, *supra* note 22.

<sup>72</sup> H.R. Con. Res. 1865, 116th Cong. (2019) (enacted); Sheila Kaplan, *Congress Approves Raising Age to 21 for E-Cigarette and Tobacco Sales*, N.Y. TIMES (Dec. 19, 2019), <https://www.nytimes.com/2019/12/19/health/cigarette-sales-age-21.html/>.

<sup>73</sup> *Tobacco 21*, U.S. FOOD & DRUG ADMIN. (Feb. 12, 2020), <https://www.fda.gov/tobacco-products/retail-sales-tobacco-products/tobacco-21>.

<sup>74</sup> Despite the past several years being characterized by increasingly polarized politics, Senators Mitch McConnell (R-KY) and Tim Kaine (D-VA) worked closely together to change the age requirement. Ella Nilsen, *The FDA Has Officially Raised the Age to Buy Tobacco Products to 21*, VOX (Dec. 27, 2019), <https://www.vox.com/2019/12/27/21039149/fda-officially-raised-age-to-buy-tobacco-from-18-to-21>.

<sup>75</sup> As various states have debated and even implemented their own twenty-one-year age requirements over the past decade, many critics have pointed out that most smokers begin smoking before age eighteen; raising the requirement further would make no difference. *See, e.g.*, Eric Levenson, *Raising the Smoking Age to 21 Is Pointless*, ATLANTIC (Nov. 25, 2013), <https://www.theatlantic.com/national/archive/2013/11/raising-smoking-age-21-pointless/355497/>. Various commentators have argued that the new requirement will likewise be ineffective. *See, e.g.*, Kennedy Polcyn, *Raising the Smoking Age is Ineffective*, LOY. PHX: OPINION (Jan. 14, 2020), <http://loyolaphoenix.com/2020/01/raising-the-smoking-age-is-ineffective/>.



to the eighteen-year age requirement, teen e-cigarette use continued to grow.<sup>76</sup> Some states and localities had even passed their own twenty-one-year age requirements.<sup>77</sup> However, the requirements' effectiveness at reducing e-cigarette use is unclear.<sup>78</sup>

#### D. A FLAVOR BAN TO CURE THE "TEEN EPIDEMIC"

If age restrictions were unsuccessful, then perhaps a different approach was necessary: a flavor ban. For years, the variety of flavors has been widely cited as one of the main reasons for the popularity of e-cigarettes, particularly among teens. Numerous studies show that the majority of teen "vapers"<sup>79</sup> use flavored e-liquids, whereas only a minority of adults use flavors.<sup>80</sup>

Shortly after news broke of the first death related to e-cigarette use, a handful of states attempted to push their own emergency bans in an effort to temporarily halt the sale of flavored products; however, few were able to move forward.<sup>81</sup> The first of these occurred in New York when its governor announced a ban on September 17, 2019, with the ban originally set to take effect on October 4, 2019.<sup>82</sup> Shortly before it could take effect, a state appellate court blocked the ban.<sup>83</sup> The court ultimately held that industry regulations were issues for the state's legislature rather than its executive.<sup>84</sup> New York was not the only state to face legal challenges. The governor of Michigan likewise attempted to issue an emergency ban on flavored e-cigarettes, but a Michigan Court of Claims judge ordered a six-month injunction after retailers argued that the governor's order improperly bypassed the state legislature.<sup>85</sup> Indeed, both Montana's and Oregon's bans were also blocked after retailers and manufacturers asserted that the bans

<sup>76</sup> See 2018 NYTS Data: *A Startling Rise in Youth E-Cigarette Use*, *supra* note 19.

<sup>77</sup> Prior to the new federal minimum, over twenty states enforced a higher minimum age for purchasing e-cigarettes, with many set at twenty-one years old. *Youth Access to E-Cigarettes: States with Laws Restricting Youth Access to E-Cigarettes*, PUB. HEALTH L. CTR. (Sept. 15, 2019), <https://www.publichealthlawcenter.org/sites/default/files/States-with-Laws-Restricting-Youth-Access-to-ECigarettes-September152019.pdf>. Various localities have also enacted their own age restrictions. *Raising the Tobacco Age to 21*, CAMPAIGN FOR TOBACCO-FREE KIDS, <https://www.tobaccofreekids.org/what-we-do/us/sale-age-21> (last updated Jan. 9, 2020).

<sup>78</sup> While some studies have shown that state and local age restrictions may be effective at reducing cigarette use, see INST. OF MED., PUBLIC HEALTH IMPLICATIONS OF RAISING THE MINIMUM AGE OF LEGAL ACCESS TO TOBACCO PRODUCTS 206 (Richard J. Bonnie et al. eds., 2015) (estimating that a twenty-one-year requirement would reduce smoking initiation among fifteen to seventeen-year-olds by 25%), the broader trend of increasing teen use of e-cigarettes has continued steadily, see 2018 NYTS Data: *A Startling Rise in Youth E-Cigarette Use*, *supra* note 19.

<sup>79</sup> A term used to describe someone that "vapes" or uses e-cigarettes. See *Vape*, *supra* note 9.

<sup>80</sup> M.B. Harrell et al., *Flavored E-Cigarette Use: Characterizing Youth, Young Adult, and Adult Users*, PREVENTATIVE MED. REP. 33, 34 (2016) (finding that between 63.3% and 85.3% of e-cigarette users under the age of eighteen use flavored e-cigarettes, whereas only 17% of users ages eighteen to thirty-four use them).

<sup>81</sup> Jamie Ducharme, *As the Number of Vaping-Related Deaths Climbs, These States Have Implemented E-Cigarette Bans*, TIME (Sept. 25, 2019), <https://time.com/5685936/state-vaping-bans/>.

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

<sup>83</sup> *Id.*; Kanishka Singh, *New York Court Blocks State Ban on Flavored E-Cigarettes*, REUTERS (Oct. 3, 2019), <https://www.reuters.com/article/us-health-vaping-new-york/new-york-court-blocks-state-ban-on-flavored-e-cigarettes-idUSKBN1WJ0IK>.

<sup>84</sup> *Judge Blocks NY Ban on Flavored Vaping Products*, NBC N.Y. (Jan. 12, 2020), <https://www.nbcnewyork.com/news/local/judge-blocks-ny-ban-on-flavored-vaping-products/2258607/>.

<sup>85</sup> David Eggert, *Judge Blocks Michigan's Ban on Flavored E-Cigarettes*, ABC NEWS (Oct. 15, 2019), <https://abcnews.go.com/Health/wireStory/judge-blocks-michigans-ban-flavored-cigarettes-66293648>.

were procedurally improper.<sup>86</sup> Only three states were able to enforce flavor bans: Massachusetts, Rhode Island, and Washington.<sup>87</sup> Even then, those states' bans were continually criticized as unnecessarily paternalistic.<sup>88</sup>

The idea of a federal flavor ban had also been discussed but initially appeared unlikely. Shortly after the first reports of various e-cigarette-related illnesses, the Trump administration first proposed banning all flavored e-cigarettes.<sup>89</sup> But as many critics pointed out, since menthol-flavored cigarettes are still available,<sup>90</sup> a complete flavor ban could drive e-cigarette users to use their more harmful counterparts.<sup>91</sup> After modifying the proposal to restrict all flavors except menthol,<sup>92</sup> however, the administration received backlash from both sides of the e-cigarette debate. Proponents of a full ban argued that exempting menthol would undermine the aim of the ban because many teens prefer menthol and would therefore continue to seek out and use e-cigarettes.<sup>93</sup> Opponents argued that the ban would unfairly rob adults of their ability to use the flavors they like.<sup>94</sup> By early December 2019, after some commentators warned that the flavor ban may cost the administration votes going into 2020,<sup>95</sup> it appeared that the president had retreated from the issue.<sup>96</sup>

The passage and subsequent signing of Tobacco 21 on December 20, 2019 signaled a renewed interest in the flavor ban. On January 2, 2020, just a few weeks after President Trump approved the new measure, the FDA announced its final decision to confront e-cigarettes head-on with the

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<sup>86</sup> Ducharme, *supra* note 81.

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

<sup>88</sup> See Ryan Blethen, *Temporary Washington State Ban on Flavored Vape Products Begins; Health Board's Vote Prompted Chants of 'Shame'*, SEATTLE TIMES (Oct. 10, 2019, 11:45 AM), <https://www.seattletimes.com/seattle-news/health/flavored-vape-products-temporarily-banned-by-state-board-of-health-to-chants-of-shame/>; *Dozens Protest Flavored Tobacco Ban, Vaping Tax*, CBS BOSTON (Nov. 19, 2019, 5:17 PM), <https://boston.cbslocal.com/2019/11/19/dozens-protest-flavored-menthol-tobacco-ban-vaping-tax-massachusetts/>; *Rhode Island is Latest State to Ban Flavored Vaping Products*, CBS BOSTON (Sept. 25, 2019), <https://boston.cbslocal.com/2019/11/19/dozens-protest-flavored-menthol-tobacco-ban-vaping-tax-massachusetts/>.

<sup>89</sup> Jennifer Maloney & Alex Leary, *Trump Plans to Ban Most Vaping Flavors*, WALL ST. J. (Sept. 11, 2019, 6:58 PM), <https://www.wsj.com/articles/trump-administration-considering-ban-on-nontobacco-flavored-vaping-products-11568220504>.

<sup>90</sup> Though the TCA banned flavored conventional cigarettes, menthol was exempted from the ban because it helps "reduce the irritation and harshness of smoking." See *Menthol and Other Flavors in Tobacco Products*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/tobacco-products/products-ingredients-components/menthol-and-other-flavors-tobacco-products> (last updated Jan. 3, 2020). Many commentators have criticized this exemption as studies show that menthol cigarettes are more addicting and targeted at African American smokers. *Id.*

<sup>91</sup> Michael Siegel, *E-Cigarette Flavor Bans Will Drive More People Back to Smoking*, INSIDE SOURCES: OPINION (Feb. 19, 2019), <https://www.insidesources.com/e-cigarette-flavor-bans-will-drive-more-people-back-to-smoking/>.

<sup>92</sup> Jennifer Maloney & Alex Leary, *White House Expected to Ban Vape Flavors Except Tobacco and Menthol*, WALL ST. J. (Nov. 1, 2019), <https://www.wsj.com/articles/trump-administration-expected-to-ban-vape-flavors-except-tobacco-and-menthol-11572649682>.

<sup>93</sup> Robert Preidt, *1 in 4 High School Kids Vape, Mint Flavor Preferred*, WEBMD (Nov. 5, 2019), <https://www.webmd.com/mental-health/addiction/news/20191105/1-in-4-high-school-kids-vape-mint-flavor-preferred> (noting that mint's popularity among teens "calls into question whether regulations or sales suspensions of flavored e-cigarettes that exclude mint flavors would meaningfully reduce youth vaping").

<sup>94</sup> See Lowry, *supra* note 23.

<sup>95</sup> Yusra Murad, *As Trump Mulls Guidance on Vaping, Flavor Ban Could Cost Him 11% of His Voters*, MORNING CONSULT (Nov. 27, 2019), <https://morningconsult.com/2019/11/27/as-trump-mulls-guidance-vaping-flavor-ban-could-cost-him-tenth-of-his-voters/>.

<sup>96</sup> Annie Karni et al., *Trump Retreats from Flavor Ban for E-Cigarettes*, N.Y. TIMES (Nov. 17, 2019), <https://www.nytimes.com/2019/11/17/health/trump-vaping-ban.html>.

enactment of the flavor ban.<sup>97</sup> Under the new ban, companies were ordered to cease the manufacture, distribution, and sale of all flavored cartridge-based e-cigarettes (other than tobacco or menthol) within thirty days.<sup>98</sup>

Although both the amended age requirement and flavor ban were met with great fanfare and enacted almost immediately, the laws have gone largely unnoticed and ignored. Not long after the ban took effect, reports of the then-emerging coronavirus pandemic flooded news outlets, causing the e-cigarette debate to seemingly vanish from the public discourse overnight.<sup>99</sup> This lack of attention, coupled with the relative recency of the measures and lack of data from the few successful state bans, leaves little available data on their actual effect on youth access.<sup>100</sup> Without any clear evidence as to the ban's effectiveness, in the most generous light, the ban appears to put the rights of many individuals at stake for an uncertain public benefit. Given this uncertain benefit, a careful examination of the ban is necessary to assess whether such a trade-off may be adequately justified.

## II. JUSTIFICATIONS FOR PUBLIC HEALTH LAWS

Although it seems clear that teen access to e-cigarettes should be restricted, the government does not have complete authority to combat a public health threat—even one widely agreed to exist—when the threat involves an individual's voluntary self-harm rather than harm imposed by others.

At the root of this limitation on public health laws is fear of government overreach. Public health laws that seek to restrict the rights of the individual for the good of the individual are paternalistic and threaten individual liberty. These laws operate according to the assumption that “the state . . . can know the interests of individual citizens better than the citizens know them themselves,” and thus allow the state to restrict individuals from making choices that it deems detrimental to themselves.<sup>101</sup>

Accordingly, many have critiqued such laws as anti-individual and anti-liberty. Commentators like Peter Schwartz argue that by deeming individuals

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<sup>97</sup> *FDA Finalizes Enforcement Policy on Unauthorized Flavored Cartridge-Based E-Cigarettes that Appeal to Children, Including Fruit and Mint*, U.S. FOOD & DRUG ADMIN. (Jan. 2, 2020), <https://www.fda.gov/news-events/press-announcements/fda-finalizes-enforcement-policy-unauthorized-flavored-cartridge-based-e-cigarettes-appeal-children>.

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

<sup>99</sup> While China had already been grappling with the outbreak and spread of the coronavirus for several months, the virus did not truly catch Americans' attention until early February when reports of the quarantine aboard the Diamond Princess cruise ship broke. See Julia Thompson & Hannah Yasharoff, *Coronavirus Cases on Diamond Princess Soar Past 500, Site of Most Infections Outside China*, USA TODAY (Feb. 19, 2020, 8:14 AM), <https://www.usatoday.com/story/travel/cruises/2020/02/18/coronavirus-jose-andres-provides-meals-diamond-princess-passengers/4788804002/>. Shortly after, many news outlets stopped reporting updates on the e-cigarette health crisis. See *Vaping: Latest News & Updates*, WALL ST. J., <https://www.wsj.com/news/collection/vaping1007-c63cd58a> (last visited Aug. 20, 2020).

<sup>100</sup> See Erika Edwards, *Ban on Flavored E-Cigarettes Won't Help Youth Already Addicted, Experts Say*, NBC NEWS (Sept. 11, 2019, 3:36 PM), <https://www.nbcnews.com/health/vaping/ban-flavored-e-cigarettes-won-t-help-youth-already-addicted-n1052531>. But see Jen Christensen, *One Town's Flavor Ban Seemed to Work to Cut Youth Tobacco Use*, CNN (Oct. 24, 2019, 12:01 AM), <https://www.cnn.com/2019/10/24/health/flavor-ban-worked/index.html>.

<sup>101</sup> 3 JOEL FEINBERG, *THE MORAL LIMITS OF THE CRIMINAL LAW: HARM TO SELF* 23 (1989) [hereinafter *HARM TO SELF*].

incapable of making rational choices, the state adopts “the role of a paternalistic nanny, zealously protecting the citizen against his own actions.”<sup>102</sup> The New York Court of Appeals expressed similar concerns over an administrative ban on the sale of large sodas.<sup>103</sup> Though the court ultimately reversed the ban on the basis of regulatory overreach, noting the lack of legislative authorization, it emphasized that the reason legislative support is required for seemingly paternalistic laws is to prevent the state from overriding individual autonomy. Otherwise, unelected agencies could restrict individual rights without individual say.<sup>104</sup>

However, despite these critiques, paternalist health laws indeed exist on both the state and federal levels. Certain medications may only be obtained and used with a physician’s prescription, as ordinary consumers simply lack the requisite knowledge to make informed decisions about them. Drivers and passengers must wear seatbelts, as the cost to their freedom is negligible compared to the lives saved and injuries prevented. These examples are fairly uncontroversial. Yet, laws targeting the consumption of alcohol, fried food, and cigarettes are met with tremendous opposition. Where is the line drawn?

Ultimately, whether any such law may be accepted depends on the extent to which its impact on individual liberty can be justified. Where a law necessarily restricts individual liberty, the law is presumptively invalid unless it can be justified based on the law’s stated purpose and likely impact.<sup>105</sup> These justifications vary depending on context; for example, criminal laws typically have moral normative components absent from regulatory areas.<sup>106</sup> In the case of public health, laws are typically justified under either (1) the harm principle, (2) soft paternalism, or (3) an exception to the prohibition on hard paternalism.<sup>107</sup>

#### A. THE HARM PRINCIPLE: PREVENTING INDIVIDUALS FROM HARMING OTHERS

The harm principle “seeks to prevent individuals from causing harm to others.”<sup>108</sup> In its most straightforward and least controversial application,<sup>109</sup> the harm principle allows the state to restrict conduct that poses a risk of

<sup>102</sup> Peter Schwartz, *The Threat of the Paternalistic State*, CAPITALISM MAG. (Aug. 6, 2002), <https://www.capitalismmagazine.com/2002/08/the-threat-of-the-paternalistic-state/>.

<sup>103</sup> *In re* N.Y. Statewide Coal. of Hispanic Chambers of Commerce v. N.Y.C. Dept. of Health & Mental Hygiene, 16 N.E.3d 538 (N.Y. 2014).

<sup>104</sup> *Id.* at 547–48 (noting that “[a]n agency that adopts a regulation . . . that interferes with commonplace daily activities preferred by large numbers of people must necessarily wrestle with complex value judgments concerning personal autonomy and economics”).

<sup>105</sup> 1 JOEL FEINBERG, *THE MORAL LIMITS OF THE CRIMINAL LAW: HARM TO OTHERS* 7–10 (1987).

<sup>106</sup> As Feinberg notes, a feature of criminal laws largely absent from public health laws is a desire to enforce moral norms. *See id.* at 11–12. He describes one of the liberty-limiting principles in criminal law as “legal moralism,” according to which “it is reasonably necessary to prevent inherently immoral conduct whether or not such conduct is harmful or offensive to anyone.” *Id.* at 12.

<sup>107</sup> Some commentators use different names to refer to these categories, but generally these three justifications are the most often discussed when assessing public health laws. *See, e.g.*, HARM TO SELF, *supra* note 101, at 11; Parmet, *supra* note 4; Thaddeus Mason Pope, *Is Public Health Paternalism Really Never Justified? A Response to Joel Feinberg*, 30 OKLA. CITY U.L. REV. 121, 121 (2005).

<sup>108</sup> Thaddeus Mason Pope, *Balancing Public Health Against Individual Liberty: The Ethics of Smoking Regulations*, 61 U. PITT. L. REV. 419, 428 (2000).

<sup>109</sup> John Stuart Mill, whose views on individual liberty are often regarded as extreme and idealistic, recognized that restraints on the individual capacity to do harm to others are necessary for a cohesive society. JOHN STUART MILL, *ON LIBERTY* 178–79 (Project Gutenberg 2011) (1859), <https://www.gutenberg.org/files/34901/34901-h/34901-h.htm>.

bodily harm to others, such as assault, homicide, and drunk driving. Likewise, the harm principle may also prevent conduct that poses a risk of financial harm to others, such as fraud and theft.

### 1. The Indirect Harm Principle

The harm principle is typically used to justify restricting conduct that harms others directly, usually through contact or proximity<sup>110</sup> to one's body or property. However, some commentators argue that harm can extend beyond that, as some seemingly self-regarding conduct can cause indirect harm.

Underlying the indirect harm principle is the recognition that otherwise self-regarding conduct often has broader economic or societal repercussions that may indirectly impact others. While indirect harm has not been directly addressed by lawmakers or courts in the context of public health, indirect harm in the economic context was recognized and discussed at length by the Supreme Court in *Wickard v. Filburn* as a means of justifying some of President Franklin D. Roosevelt's New Deal economic regulations.<sup>111</sup> In *Wickard*, a farmer challenged the constitutionality of federal quotas that limited wheat production in an effort to raise its sale price. The Court ultimately ruled in favor of the government, finding that the quotas were a valid exercise of the Commerce Clause. The Court reasoned that if an individual grew excess wheat for home consumption, the individual would purchase less wheat from others, thereby reducing the demand for wheat and indirectly harming other farmers.<sup>112</sup> Thus, the government was justified in regulating an activity that was seemingly of "local character."<sup>113</sup>

Whether the same indirect effect analysis in the economic context applies to indirect harm within the public health sphere is debatable. Proponents of the indirect harm theory argue that as a general rule, individual decisions regarding health invariably affect others. For instance, the decision not to wear a seatbelt may physically harm only the actor. However, this decision would increase the severity of car accident injuries, forcing insurers to pay increased medical costs, which would in turn be passed along to other consumers.

An extreme example of a public health concern that could be regulated according to a broad interpretation of the indirect harm principle would be obesity. Lawrence O. Gostin argues:

Obesity primarily affects the individual, but it also has high socioeconomic costs. The aggregate consequences of individual choices are countless preventable disabilities and deaths, affecting families and the entire community. Obesity-attributable medical

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<sup>110</sup> For instance, in jurisdictions that recognize the tort of infliction of emotional distress, there is no requirement for direct physical contact, but instead the victim must be within the "zone of danger." See, e.g., *Dillon v. Legg*, 68 Cal. 2d 728 (1968).

<sup>111</sup> *Wickard v. Filburn*, 317 U.S. 111 (1942).

<sup>112</sup> *Id.* at 128 ("But if we assume that [the home-grown wheat] is never marketed, it supplies a need of the man who grew it which would otherwise be reflected by purchases in the open market.").

<sup>113</sup> See *id.* at 124–25 (noting that the notions of whether activity may be "of local character" is irrelevant to its analysis of Congress's reach with the Commerce Clause, as the true test is whether the activity creates a substantial economic effect).

expenditures reached \$75 billion in the United States in 2003, with substantial additional indirect costs in lost productivity . . . . The government arguably has a legitimate interest in controlling medical and social costs of individuals' unhealthy behaviors that are borne by society at large.<sup>114</sup>

Though Gostin's reasoning appears sound, many have criticized laws aimed at obesity, arguing that they impermissibly restrict individual autonomy.<sup>115</sup> Indeed, the relation between one's individual health and that of others appears quite tenuous. Absent a special interest in another's health and wellbeing,<sup>116</sup> an individual's health could only indirectly affect others by way of increased social healthcare costs.<sup>117</sup>

While increased social healthcare costs are just as real as those described in *Wickard*, collective costs alone cannot form a sufficient basis to invoke the indirect harm principle. Nearly any otherwise self-regarding action can impose broader social costs; unless the government should be permitted to dictate every individual action, a higher standard, be it a bright-line rule or metric for determining sufficiently costly forms of conduct, is necessary to protect individual liberty. For instance, unhealthy behavior leads to increased medical treatment. Conversely, healthy behavior leads to less medical treatment. Absent some sufficiently high and articulated standards, under the indirect harm principle, the government could not only justifiably restrict unhealthy behavior but also mandate healthy behavior. To that end, the government could dictate people's diets, exercise, consumer habits, dress, travel, and so forth, so long as it could demonstrate that these behaviors promote individual health. Justice Roberts warned against this exact form of government overreach in *NFIB v. Sebelius*.<sup>118</sup> In *Sebelius*, the government defended an individual mandate that required citizens to purchase health insurance. The government argued that the mandate was a valid exercise of its power under the Commerce Clause, as healthy individuals' failure to purchase insurance created higher costs for unhealthy individuals.<sup>119</sup> Writing for the Court, Roberts upheld the individual mandate but rejected the government's Commerce Clause argument, expressing concern that the government's justification of indirect harms "would bring countless decisions an individual could *potentially* make within the scope of federal regulation, and . . . empower Congress to make those decisions for him."<sup>120</sup>

#### B. SOFT PATERNALISM: PROTECTING INDIVIDUALS' AUTONOMY

Soft paternalism seeks to protect autonomy by preventing individuals from assuming risks without adequate information, decision-making

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<sup>114</sup> Lawrence O. Gostin, *Law as a Tool to Facilitate Healthier Lifestyles and Prevent Obesity*, 297 *JAMA* 87, 87 (2007).

<sup>115</sup> See, e.g., Richard A. Epstein, *What (Not) To Do About Obesity: A Moderate Aristotelian Answer*, 93 *GEO. L.J.* 1361 (2005).

<sup>116</sup> For instance, a dependent child would have an interest in their parents' continued health to provide for them, and a sports team would have a contractual interest in its star athlete's continued health.

<sup>117</sup> See Epstein, *supra* note 115, at 1369.

<sup>118</sup> *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 548 (2012).

<sup>119</sup> *Id.*

<sup>120</sup> *Id.* at 552 (Roberts, C.J., dictum).

capacity, or freedom from coercion. John Stuart Mill provided the example of preventing a traveler from unknowingly crossing a dilapidated bridge.<sup>121</sup> This principle is uncontroversial, as there is “[no] real infringement of his liberty[,] for liberty consists in doing what one desires, and he does not desire to fall into the river.”<sup>122</sup>

The most common examples of soft paternalist laws deal with proper labeling and informed consent. For instance, laws requiring food packaging labels to disclose common allergens, ingredients, and dietary information are soft paternalist in that they are designed to provide the consumer with adequate information about the product. Laws imposing age requirements for certain conduct, such as gambling or purchasing alcohol and tobacco, are designed to protect minors, as minors lack the capacity to consent. In both of these categories of soft-paternalist laws, state intervention is justified because it promotes autonomy by restricting involuntary conduct.

### C. HARD PATERNALISM: PREVENTING INDIVIDUALS FROM SELF-HARM

Hard paternalism is perhaps the most controversial justification despite numerous existing laws that use it as their sole justification.<sup>123</sup> The principle seeks to protect individuals from engaging in conduct that is likely to harm themselves. Unlike soft paternalism, which only prevents involuntary conduct, hard paternalism constrains individuals’ decisions even when they are informed and voluntary.

While the belief in individual autonomy, and by extension an increased scrutiny of hard paternalism, is deeply ingrained in American culture and society, many liberal<sup>124</sup> commentators tend not to simply scrutinize paternalism but outright reject it. In their view, individual autonomy is vital to a free society; thus, the state has no authority to rob its citizens of their autonomous decision-making, even if their decisions are objectively detrimental. Returning to Mill’s bridge analogy, according to the liberal view, the state may have a valid soft-paternalist justification for stopping a traveler to inform them that a bridge is dilapidated.<sup>125</sup> But should the traveler insist on crossing the bridge, the state may not stop them, as that would be an exercise of hard paternalism.<sup>126</sup>

Despite the general disdain for hard paternalism, many hard-paternalist laws exist and seem fairly reasonable. How can such laws be widely accepted despite the presumption against hard paternalism? This Note suggests that two exceptions, or “sub-justifications,” may be used to further justify otherwise unjustifiable hard-paternalist laws: the soft-paternalist strategy and the self-governance rationale.

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<sup>121</sup> MILL, *supra* note 109, at 182.

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

<sup>123</sup> For example, seatbelt laws, motorcycle helmet laws, tobacco taxes, and sugar taxes.

<sup>124</sup> Liberal in the classical sense that these commentators believe in idealized notions of individual liberty and autonomy, not to be confused with the more recent political label ascribed to progressive politics.

<sup>125</sup> MILL, *supra* note 109, at 182.

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

### 1. The Soft-Paternalist Strategy

The soft-paternalist strategy was proposed by legal scholar Joel Feinberg in an attempt to reconcile his rejection of hard paternalism with his admission that many hard-paternalist laws appear reasonable.<sup>127</sup> In essence, Feinberg argues that these well-accepted hard-paternalist laws are actually soft-paternalist. Rather than trying to prevent individual harm, the state intervenes “to establish whether [the harmful conduct] is voluntary or not.”<sup>128</sup> In cases where the harmful conduct is extreme, the state may safely presume that the individual is not acting voluntarily, and may accordingly stop that individual until and unless they sufficiently demonstrate voluntariness.<sup>129</sup> For example, in Mill’s bridge hypothetical,<sup>130</sup> after informing a traveler that the bridge is dilapidated, should the traveler insist upon crossing, the state may forcibly stop the traveler to ensure that their decision does not stem from “ignorance, coercion, derangement, drugs, or other voluntariness-vitiating factors.”<sup>131</sup> Therefore, what appears to be a state action restricting individual conduct may actually be justified under soft paternalism because the individual’s actions are “substantially nonvoluntary.”<sup>132</sup>

The issue with the soft-paternalist strategy is that hard-paternalist laws are not simple consent checks; the laws restrict conduct equally, regardless of whether it is voluntary.<sup>133</sup> Feinberg suggests that this is because hard-paternalist laws are aimed primarily at conduct with unusually high risks.<sup>134</sup> These high risks accordingly create a presumption of involuntariness, which requires a higher burden of proof by the individual to establish that their actions are truly voluntary.<sup>135</sup> Since it is incredibly rare for an individual to truly engage in such risky conduct voluntarily, and given the logistical difficulties of effectively parsing out the voluntary risk-takers from the involuntary, Feinberg concludes that hard-paternalist laws are accepted as the most practical solution to a subjective judgment problem.<sup>136</sup>

On its face, the soft-paternalist strategy makes sense. Intuitively, we want to be more certain that an individual is acting voluntarily if they want to go skydiving as opposed to eating a greasy double cheeseburger, though both clearly entail risks. It logically follows, then, that certain kinds of conduct are so inherently risky, dangerous, or ill-advised that it should be

<sup>127</sup> HARM TO SELF, *supra* note 101, at 24 (“If we reject hard paternalism entirely . . . we seem to fly in the face of both common sense and . . . long-established customs and laws.”).

<sup>128</sup> HARM TO SELF, *supra* note 101, at 12.

<sup>129</sup> HARM TO SELF, *supra* note 101, at 12.

<sup>130</sup> See MILL, *supra* note 109, at 182.

<sup>131</sup> HARM TO SELF, *supra* note 101, at 12.

<sup>132</sup> HARM TO SELF, *supra* note 101, at 12.

<sup>133</sup> For instance, drivers receive tickets for driving without seatbelts, regardless of whether they made an informed choice to forgo the safety precaution.

<sup>134</sup> See HARM TO SELF, *supra* note 101, at 174–86.

<sup>135</sup> HARM TO SELF, *supra* note 101, at 127 (“It is rare in the collective experience of the human race for people voluntarily to season their eggs with arsenic, or stroll across unsafe bridges, or swim in highly polluted waters. . . . Hence we are entitled to infer, in the absence of any other information, that a person intent on doing one of those things, is doing so by mistake.”).

<sup>136</sup> Feinberg suggests four ways that these kinds of risky conduct could be approached, ranging from the current practice of simply banning the behavior to establishing “tribunals to determine the voluntariness of specific agreements.” HARM TO SELF, *supra* note 101, at 174–75. He ultimately concludes that the alternatives to a simple ban are impractical, which is why bans are accepted despite the potential injustice they may cause. HARM TO SELF, *supra* note 101, at 174–75.



near-impossible to establish true consent.<sup>137</sup> And since true consent to extremely risky conduct is not only difficult to establish but also exceedingly rare, it makes sense as a matter of social policy to ban the conduct altogether, even at risk of unjustly restricting the rights of the rare consenting party.

This category of conduct that is deemed near-impossible to consent to presents a challenge of its own, however. Feinberg gives little guidance as to how conduct may be designated within this category. Though Feinberg suggests that the requisite voluntariness correlates with the risk and degree of harm, there is no objective formula available. Without a clear metric, if left solely to the state's discretion, the state could invoke the soft-paternalist strategy arbitrarily by deeming certain conduct unreasonably risky without regard for individual differences of opinion or priorities.<sup>138</sup>

This leaves one solution. Without any intrinsic metric by which conduct may be judged individually, conduct should be assessed against other kinds of conduct generally agreed to be unlikely to be undertaken voluntarily. Existing hard-paternalist laws should serve as a comparative framework by which all conduct should be assessed to determine whether the soft-paternalist strategy reasonably applies.

## 2. The Self-Governance Rationale

Alternatively, should the soft-paternalist strategy not apply, a hard-paternalist law may be justified according to the self-governance rationale.<sup>139</sup> Hard paternalism is generally rejected because it invites the state to restrict individual autonomy. These concerns can be placated, however, if individuals choose to voluntarily restrict their own conduct through democratic or legislative processes. Indeed, the self-governance rationale provides justification for otherwise hard-paternalist laws provided that they are the “manifestation of a population’s [positive] liberty to take collective action to protect its health via self-governance.”<sup>140</sup> In this manner, an otherwise hard-paternalist law may be justified without fear of overreach, as the restrictions upon individual autonomy would be self-imposed, rather than mandated by a potentially unaccountable government entity.

It is up for debate what would represent an ideal expression of self-governance. Of course, as with any issue involving individual or group rights, the traditional concerns of liberty and equality of process apply; a popular vote whereby a majority unilaterally imposes a law upon a minority could hardly be considered “self-governance.” That said, while there is disagreement over whether such self-governing, hard-paternalist laws should ideally be passed on a local, state, or federal level, for purposes of this Note, that determination is unnecessary. The most important aspect of the self-

<sup>137</sup> HARM TO SELF, *supra* note 101, at 175 (“Thus, even though in theory liberal principles establish a right to euthanasia or to assistance in suicide, if *C* should see *A* about to shoot *B*, he ought to be entitled forcibly to restrain him without personal liability unless or until it can be established that *B* has consented, and consented ‘voluntarily enough.’ Since death is irrevocable, of course, what is ‘voluntary enough’ must be determined by stringent standards, so that a mere reassuring word from the primary parties would not be enough to require *C* to withdraw.”).

<sup>138</sup> See Pope, *supra* note 107, at 164 (“Feinberg’s argument comes very close (perhaps too close) to judging the reasonableness of the conduct . . .”).

<sup>139</sup> Parmet, *supra* note 4, at 907–08, 953–54.

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

governance rationale is that it requires, at minimum, some form of the people's support, thereby preventing the least preferred form of regulation—purely administrative or executive orders—which may be passed without any such support.<sup>141</sup>

In this manner, hard-paternalist laws may still be justified; they simply must reflect the will of the people.

### III. JUSTIFYING THE FLAVOR BAN

Since many studies have confirmed that the use of flavors—such as mint, doughnut, mango, taffy, and more<sup>142</sup>—are largely responsible for e-cigarettes' popularity among teens,<sup>143</sup> banning flavors in e-cigarettes appears to be a sensible means of reducing their illicit use by underage individuals since other, more targeted age restrictions have thus far failed to prevent such use.

The question then is whether a ban on flavored e-cigarettes can be justified under the justifications discussed in Part II—the harm principle, soft paternalism, and hard paternalism—as an acceptable limitation on personal liberty. Though the flavor ban primarily affects teens (who are deemed incapable of consenting), it cannot be considered solely soft-paternalist because it also impacts adults that use flavored e-cigarettes. Viewed in the least favorable light, the ban may be classified as hard-paternalist and therefore subject to the highest scrutiny. Nonetheless, this Note concludes that it could have been justified with the help of the self-governance rationale. However, because the ban was passed as a unilateral administrative rule, the ban unjustifiably infringes upon individual rights.

#### A. HARM PRINCIPLE

Arguments for new laws restricting e-cigarettes that seek justification under the harm principle are frequent, but the particular restriction imposed by the flavor ban seems unlikely to succeed under this principle. While studies show that flavored e-cigarettes are more prevalent than unflavored e-cigarettes, there is no direct link between flavors and harm to others. This leaves only a tenuous argument that eliminating flavors may reduce the harm to others caused by e-cigarettes generally, and as discussed below, the flavor ban fails to get to the root of the problem.

Until recently, it was assumed that secondhand aerosol from e-cigarettes was largely harmless, which is why e-cigarettes escaped the many restrictions on smoking cigarettes that aimed to reduce the effects of secondhand smoke.<sup>144</sup> Recent studies have disproven this assumption,

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<sup>141</sup> *Id.* at 955.

<sup>142</sup> See Deborah Netburn, *The E-Cigarette Boom: Study Finds 466 Online Brands, 7,700 Flavors*, L.A. TIMES (June 17, 2020, 4:54 PM), <https://www.latimes.com/science/sciencenow/la-sci-sn-e-cigarette-7700-flavors-20140617-story.html>.

<sup>143</sup> See Harrell, *supra* note 80.

<sup>144</sup> See Karen Wilson, *Not Just "Harmless Water Vapor"*, AAP J. & PERIODICALS (Oct. 15, 2019), <https://www.aapublications.org/news/aapnewsmag/2019/10/15/not-just-harmless-water-vapor-hospital-pediatrics-10-15-19.full.pdf> (challenging the original marketing and long-popular misconception that e-cigarettes only produce "harmless water vapor").

however, showing that both firsthand and secondhand aerosol contained a variety of harmful chemicals and ultrafine particles.<sup>145</sup>

Given what is known about teenagers' preferences, eliminating most flavors could reduce the overall consumption of e-cigarettes. One consequence of this change in consumption would be that the exposure of non-users to secondhand aerosol in public places would be reduced as well.<sup>146</sup>

However, to the minimal extent that the flavor ban aims to address secondhand aerosol at all, the ban does so in a roundabout way. Aerosol is not confined to just flavored e-cigarettes; banning just flavors in an effort to reduce overall consumption is not only overly drastic and restrictive, but also unnecessary given that less-restrictive alternatives could be passed. For instance, federal laws aimed at reducing secondhand cigarette smoke could be updated to apply to e-cigarette aerosol, such as those banning use in federally regulated spaces like federal buildings, universities, and airplanes.<sup>147</sup>

Further, while targeting flavors could reduce secondhand aerosol by simply discouraging e-cigarette use outright, it is unlikely that users would actually be discouraged because of the ban's menthol flavor exemption. Studies have shown that menthol is one of the most popular flavors among teens.<sup>148</sup> Were the government truly interested in banning flavors as a proxy to limiting the overall consumption of e-cigarettes, and in turn, secondhand aerosol, it would not allow such a popular flavor to remain on the market. Not only is the ban poorly tailored to reducing secondhand aerosol—the only harm for which it may seek justification according to the harm principle—the menthol exemption further undercuts what little effect the flavor ban could have in reducing secondhand harm. Accordingly, the ban is not justified under the harm principle.

### 1. The Indirect Harm Principle

Arguments in favor of the flavor ban according to the indirect harm principle are plausible, but the ban likewise fails under this justification since

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<sup>145</sup> See Michael O. Schroeder, *Secondhand Vaping: What Risks Does Aerosol From E-Cigarettes Pose for Kids?*, U.S. NEWS (July 9, 2019), <https://health.usnews.com/conditions/articles/secondhand-vaping-risks-for-kids> (noting that secondhand aerosol from e-cigarettes contains ultrafine particles and substances that can be harmful); see also Jennifer E. Bayly et al., *Secondhand Exposure to Aerosols From Electronic Nicotine Delivery Systems and Asthma Exacerbations Among Youth With Asthma*, 155 CHEST 88 (2019) (reporting a higher incidence of asthma attacks among youth with asthma that were exposed to secondhand aerosol from e-cigarettes).

<sup>146</sup> Because e-cigarettes emit aerosol rather than smoke, they are less detectable and often used in public places, even in schools. See Gabriella Borter & Matthew Lavietes, *From Removing Doors to Checking Sleeves, U.S. Schools Seek to Snuff Out Vaping*, REUTERS (Sept. 11, 2019, 3:38 AM), <https://www.reuters.com/article/us-health-vaping/from-removing-doors-to-checking-sleeves-u-s-schools-look-to-snuff-out-vaping-idUSKCN1VW17G>.

<sup>147</sup> While the federal government is restricted to spaces within its jurisdiction, twenty-eight states and the District of Columbia have passed their own smoke-free air laws, prohibiting smoking in most public places and workplaces. *Smokefree Air Laws*, AM. LUNG ASS'N <https://www.lung.org/our-initiatives/tobacco/smokefree-environments/smokefree-air-laws.html> (last updated Mar. 10, 2019). Eleven of those states and the District of Columbia have added e-cigarettes to their smoke-free air laws. *Id.*

<sup>148</sup> Preidt, *supra* note 93.

e-cigarette use causes less indirect harm than other more harmful, yet generally accepted forms of conduct.

E-cigarette use clearly causes indirect harm by harming the individual. Thousands of e-cigarette users have been hospitalized for various respiratory illnesses.<sup>149</sup> This, in turn, has imposed and will continue to impose financial burdens on society by way of increased insurance and healthcare costs. However, the mere existence of indirect harm does not justify regulating otherwise self-harming conduct, as doing so would invite unchecked government regulation.

The best way to determine the applicability of the indirect harm principle would be to compare the law's approach to other forms of self-harming conduct. In this case, the most instructive test would be to compare the indirect harm caused by flavored e-cigarettes to the indirect harm caused by cigarettes. Since e-cigarettes are less dangerous and less widely used,<sup>150</sup> it can be safely assumed that e-cigarettes cost society less than cigarettes do. Given that cigarettes are not heavily regulated on the basis of their indirect harm, the flavor ban cannot be justified according to the indirect harm principle.

#### B. SOFT PATERNALISM

Intuitively, soft paternalism would appear to be the most applicable justification for the flavor ban. The main goal of the flavor ban is to prevent teens from using e-cigarettes,<sup>151</sup> and laws restricting certain conduct for minors fall within soft paternalism's protection of those that lack, or have impaired, agency. However, because the ban would affect more than just minors,<sup>152</sup> the scope of the ban would extend beyond the limits of soft paternalism.

The age restriction imposed by the Deeming Rule (and debatably<sup>153</sup> by Tobacco 21 as well) was justifiable under soft paternalism. The restriction only prohibited minors under eighteen from purchasing e-cigarettes and was thereby narrowly tailored to meet the justification for soft paternalism. The problem with the flavor ban is that it is not so narrowly tailored, as it makes no distinction between minors and law-abiding adults.

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<sup>149</sup> *Outbreak of Lung Injury Associated with the Use of E-Cigarette, or Vaping, Products*, *supra* note 22.

<sup>150</sup> There have been over sixty deaths attributed to e-cigarette use in the United States. *Id.* In contrast, about 480,000 deaths are caused by cigarette smoking annually. *Tobacco-Related Mortality*, CTRS. FOR DISEASE CONTROL, [https://www.cdc.gov/tobacco/data\\_statistics/fact\\_sheets/health\\_effects/tobacco\\_related\\_mortality/index.htm](https://www.cdc.gov/tobacco/data_statistics/fact_sheets/health_effects/tobacco_related_mortality/index.htm) (last updated Apr. 28, 2020).

<sup>151</sup> When announcing his intent to ban flavors, President Trump stated, "We have a problem in our country. It's a new problem. It's called vaping, especially vaping as it pertains to innocent children." Maloney & Leary, *supra* note 89.

<sup>152</sup> See Sigaud & Pociask, *supra* note 23.

<sup>153</sup> While Tobacco 21 has the same soft-paternalist rationale, as with any age requirement, it has been more controversial because whereas people generally agree that minors under the age of eighteen may be deemed too young to make certain decisions, many argue that after eighteen, they should be treated as adults. See, e.g., Debra Saunders, *Old Enough to Vote, Not Old Enough to Smoke*, REAL CLEAR POL. (Dec. 29, 2019), [https://www.realclearpolitics.com/articles/2019/12/29/old\\_enough\\_to\\_vote\\_not\\_old\\_enough\\_to\\_smoke\\_142043.html](https://www.realclearpolitics.com/articles/2019/12/29/old_enough_to_vote_not_old_enough_to_smoke_142043.html) (arguing that raising the age requirement for tobacco to twenty-one suggests that personal decisions require more wisdom and maturity, yet "voting is a no-brainer").

A case could be made that adults could be restricted on a soft-paternalistic basis because e-cigarettes' effects on health are still not completely understood.<sup>154</sup> Since the risk associated with e-cigarettes is unknown, one could argue that all users of e-cigarettes are not in a position to give informed consent; thus, the government is justified on soft-paternalistic grounds to ban or restrict access to them.

Although the full risks associated with e-cigarettes are unknown, e-cigarettes are less dangerous than conventional cigarettes,<sup>155</sup> yet people are free to consume conventional cigarettes. The extent of harm posed by conventional cigarettes is well-known, but if people can consent to use them, why should it matter that the risk associated with e-cigarettes is unknown, so long as they are less risky than conventional cigarettes? Further, as many critics have pointed out, the flavor ban could have the unintended effect of driving e-cigarette users to smoke conventional cigarettes instead.<sup>156</sup> The inability to give informed consent argument also fails to account for why flavors, rather than e-cigarettes in general, are targeted. No data currently suggests that flavored e-cigarettes are significantly more dangerous than their unflavored counterparts. While removing most flavors would create fewer options, consumers would be just as free to knowingly or unknowingly harm themselves by using unflavored or menthol-flavored e-cigarettes or worse, by switching to conventional cigarettes. To the extent that consumers may mistakenly believe e-cigarettes are safe, a flavor ban or ban on all e-cigarettes would be too extreme, as stricter labeling and advertising standards would be a much less invasive alternative.

Since the flavor ban makes no distinction between adults and minors—that is, between individuals capable of consenting and those not capable—the ban cannot be justified under soft paternalism.

### C. HARD PATERNALISM

Because the flavor ban restricts the conduct of all individuals regardless of their ability to consent, the ban must therefore be hard-paternalistic. Although hard paternalism is typically disallowed, the ban may still be justifiable under either the soft-paternalist strategy or the self-governance rationale.

#### 1. The Soft-Paternalist Strategy

In the absence of any objective metric for determining what level of harm renders certain conduct irrational and therefore impossible to consent to, the use of flavored e-cigarettes must be compared to other forms of harmful conduct. One must therefore determine whether flavored e-cigarettes fall closer to the unreasonable or reasonable ends of this continuum. Fortunately, conventional cigarettes offer an easy comparison

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<sup>154</sup> While there are now confirmed cases of respiratory illness likely caused by e-cigarette use, further investigation is necessary to determine which products and substances are responsible, as well as the long-term effects. *Outbreak of Lung Injury Associated with the Use of E-Cigarette, or Vaping, Products*, *supra* note 22.

<sup>155</sup> See sources cited *supra* note 150.

<sup>156</sup> Sigaud & Pociask, *supra* note 23.

once again. While cigarettes are much more dangerous than greasy double cheeseburgers,<sup>157</sup> the use of cigarettes is still generally accepted. Flavored e-cigarettes probably fall somewhere between cigarettes and double cheeseburgers; both are accepted, so the flavor ban cannot be justified according to the soft-paternalist strategy.

## 2. Self-Governance

Since the flavor ban is ultimately hard-paternalistic and the soft-paternalist strategy does not apply, it would appear that the ban impermissibly infringes upon individual rights. However, the ban does not seem wholly unreasonable. After all, the most obvious and direct soft-paternalist law, an age restriction, was passed in 2016 and has ultimately failed to curb youth access to e-cigarettes, and it seems unlikely that the recent amendment with Tobacco 21 will make it any more effective. While the flavor ban would also restrict adults, it is still designed to target minors. The federal government lacks any alternative measures that would target minors without affecting adults. In this manner, the flavor ban represents a compromise that seeks to protect minors while minimizing its impact on adults.

Thus, one question remains: is the trade-off worth it? Is the autonomy of some adults less valuable than the protection of a substantially greater number of minors? Ultimately, much like the threshold question in the soft-paternalist strategy, there is no clear dividing line or metric.<sup>158</sup> For that reason, we should not let an administrative agency make that judgment call. To be justified, the ban must comport with the self-governance rationale, that is, it must be backed by a manifestation of public opinion rather than by a unilateral administrative decision. The ban is a hot button issue for good reason.<sup>159</sup> It should at least represent the will of the people rather than be an administrative decision or otherwise enacted without the consent of those whose rights are at stake.

## CONCLUSION

Although the government typically has broad authority over matters of public health, laws regulating individual conduct require further moral justification to ensure that the government does not impermissibly restrict individual autonomy. At first glance, the recent e-cigarette flavor ban cannot be justified according to the primary justifications for public health laws, as although the ban is aimed at curbing youth access to e-cigarettes, it would have the unintended consequence of restricting many adults as well.

For that reason, the ban is a strictly hard-paternalist law that should be rejected for its restrictions upon individual autonomy. However, since the

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<sup>157</sup> See Madelyn Fernstrom, *Debunked: Cheeseburger as Bad as Smoking*, TODAY (Mar. 5, 2014, 4:17 PM), <https://www.today.com/health/debunked-cheeseburger-bad-smoking-2D79324674>.

<sup>158</sup> It is unclear how effective a flavor ban would be at deterring teens from using e-cigarettes. Though a handful of states enacted flavor bans before the FDA, several were blocked by state courts, and the others were in effect for only a few months before the federal flavor ban took effect. *See supra* notes 81–88 and accompanying text.

<sup>159</sup> *See, e.g.*, David Abrams & Matthew L. Myers, *Do E-Cigarettes Do More Good Than Harm?*, WALL ST. J. (Feb. 6, 2019, 10:00 PM), <https://www.wsj.com/articles/do-e-cigarettes-do-more-good-than-harm-11549508401>.

2020]

*Paternalism and the Moral Justifications*

241

government has a valid interest in protecting minors, and given the failure of age restrictions promulgated by the Deeming Rule and Tobacco 21, the flavor ban may be a necessary restriction. Because of the interests at stake and the current lack of data as to the effectiveness of a flavor ban, whether the ban should have been passed is a decision best left to the people, be it through legislative processes or otherwise, in order to protect individual autonomy in accordance with the self-governance rationale.