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# FDA REGULATION OF ELECTRONIC NICOTINE DELIVERY SYSTEMS AND THE “DEEMING” RULE: WHAT’S LEFT FOR STATES?

WILLIAM TILBURG, KATHLEEN HOKE, & MELLISSA SAGER

*Beginning August 8, 2016, electronic nicotine delivery systems (“ENDS”), commonly referred to as electronic cigarettes or e-cigarettes, are subject to the authority of the U.S. Food and Drug Administration (“FDA”) and regulated as tobacco products under federal law. Laws prohibiting sales to minors, requiring ID checks, restricting vending machine purchases, and mandating health warning labels that currently apply to cigarettes, smokeless tobacco, and other “conventional tobacco products” will extend to ENDS. The new regulations do not have preemptive effect, meaning state and local governments retain authority to enact additional restrictions on the distribution, sale, and use of ENDS. At the same time, the European Union has embraced ENDS as a safer alternative to smoking conventional tobacco products, with laws reflecting that policy position.*

*The new regulations provoke the question of whether these devices, which aerosolize a liquid nicotine solution that is inhaled in a manner similar to conventional smoking, should be subject to the same restrictions as conventional tobacco products? ENDS aerosol contains toxicants, including known human carcinogens, but at significantly lower levels than found in conventional tobacco products. And, while the long term health effects associated with ENDS are unknown, they are almost certainly less harmful than conventional tobacco products. Experimental and observational studies also suggest ENDS may be effective smoking cessation tools. On the other hand, ENDS use among high school students increased tenfold from 2011 to 2015 (4.5% to 44.9%) and a growing body of evidence indicates youth ENDS users are significantly more likely to initiate use of conventional tobacco products.*

*In light of rising youth use, uncertainty surrounding the long term health effects, and potential for helping adult smokers quit, how should state and local governments regulate these devices? This article will summarize the new federal regulations governing ENDS, review scientific studies on the health effects and potential cessation benefits associated with ENDS, and discuss policy options to reduce youth access and use that do not*

*prevent or unduly burden adult smokers from using ENDS to quit smoking.*

## I. INTRODUCTION

Smoking has been the leading cause of preventable death in the United States for many decades.<sup>1</sup> This list of diseases and other negative health consequences caused by smoking is extensive; exposure to secondhand smoke creates similar health outcomes.<sup>2</sup> As a result, medical and public health professionals are naturally concerned about the marketing of any product that emulates smoking yet are eager to offer smokers truly effective tools for cessation.<sup>3</sup> This is why the electronic cigarette creates a conundrum for those working to reduce smoking and improve public health. Is this new product as bad as its namesake? Or is it a safe, viable method to achieve cessation?

As researchers embarked on the time-consuming and expensive process of determining the health effects and cessation potential of electronic cigarettes—now better terms electronic nicotine delivery systems or ENDS—the product exploded in the marketplace. No longer a quirky, expensive mystery device sold at mall kiosks, ENDS are becoming ubiquitous, available in cheap disposable versions and elaborate, pricey, reusable devices with high-tech options. The liquid nicotine market has likewise developed rapidly to offer consumers virtually any flavor imaginable and a variety of nicotine levels.<sup>4</sup> Specialty vape shops now pepper communities. ENDS are advertised in the same media venues as cigarettes—magazines and point-of-sale—and where cigarette promotion is forbidden—television and radio. Celebrities have touted the benefits of ENDS on network television and been seen using the product at major entertainment events.<sup>5</sup> ENDS are used indoors in places where smoking has long been

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1. OFFICE OF THE SURGEON GEN'L, U.S. DEPT OF HEALTH AND HUMAN SERV., THE HEALTH CONSEQUENCES OF SMOKING –50 YEARS OF PROGRESS, A REPORT OF THE SURGEON GENERAL, EXECUTIVE SUMMARY at iii (2014) (*hereinafter* “Surgeon General’s Report”), available at <http://www.surgeongeneral.gov/library/reports/50-years-of-progress/exec-summary.pdf>.

2. *See id.* (explaining that active smoking is causally associated with numerous cancer related illnesses and other illnesses, and secondhand smoking is causally associated with increased risk of stroke).

3. *See* Carrie Arnold, *Vaping and Health: What Do We Know about E-Cigarettes?*, 122 ENVTL. HEALTH PERSPECTIVES A244, A245–46 (2014), (reporting that, while health professionals believe e-cigarettes are not harmless, e-cigarettes may be a preferred alternative to smoking).

4. Joseph G. Allen et al., *Flavoring Chemicals in E-Cigarettes: Diacetyl, 2,3-Pentanedione, and Acetoin in a Sample of 51 Products, Including Fruit-, Candy-, and Cocktail-Flavored E-Cigarettes*, ENVTL. HEALTH PERSPECTIVES, at 3 (Dec. 8, 2015), <http://ehp.niehs.nih.gov/wp-content/uploads/advpub/2015/12/ehp.1510185.acco.pdf> (finding that over 7000 flavors of e-cigarettes are currently marketed); *see* Caroline Chen et al., *E-Cigarette Design Preference and Smoking Cessation: A U.S. Population Study*, AM. J. PREVENTATIVE MED. 356, 360 (2016) (explaining that users can choose higher strengths of nicotine and many different e-liquid flavors).

5. *See also* Brittny Stephens, *6 Times Leonardo DiCaprio Has Hit the Vape During a Big Event*, POPSUGAR (Feb. 12, 2016), <http://www.popsugar.com/celebrity/Leonardo-DiCaprio-Smoking-Vaping-Events-40023817#photo-40023817> (describing the overwhelming social media response to an award-

prohibited. Vaping consumers ardently supports ENDS, both as cessation devices and as a product offering the same enjoyment as cigarettes with much reduced risk or negative health outcomes. Within this frenzy, research moves forward as best possible.

Little is known about the long-term health effects and public health impact of ENDS. Preliminary research raises concerns, particularly to a public health community still waging a decades-long battle against the original cigarette. Policymakers and public health officials are stymied, having to take action and engage in public education with a modest amount of research. Caution has prevailed to some extent at the federal level; the FDA promulgated a regulation deeming ENDS tobacco products subject to the Family Smoking Prevention and Tobacco Control Act (“Tobacco Control Act”) and the agency’s regulatory power.<sup>6</sup> Effective August 8, 2016, the FDA regulations impose requirements and restrictions on ENDS, some relatively minor and others far more significant.<sup>7</sup> The impact of the regulation cannot yet be measured and we fully anticipate that FDA will issue additional provisions and guidance related to ENDS. Researchers will have to wait to determine the full impact of the federal regulation of ENDS. In the meantime, federal law gives wide room for state and local jurisdictions to do more.

Section II of this paper provides a brief history into ENDS. In Section III, we set out information about the marketing history, including data on sales, and in Section IV we explore the demographics of ENDS users. Section V discusses the available research, summarizing what is known and noting the need for additional research to support policymakers and public health professionals, Section VI includes the history of federal regulation of tobacco, which leads into Section VII, which explains the new FDA regulation of ENDS via the so-called deeming rule. Finally, Section VIII suggests policy options for state and local governments interested in expanding upon the regulatory scheme established by FDA.

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winning actor openly using a vape pen during a televised award show, among others); *Cf.* John Tozzi, *Celebrities Pitching E-Cigarettes Make a Nightmare for Public Health Officials*, BLOOMBERG BUS.WK. (June 30, 2014, 4:34 PM), <https://www.bloomberg.com/news/articles/2014-06-30/celebrities-pitching-e-cigarettes-make-a-nightmare-for-public-health-officials> (describing that through use of celebrities in marketing, e-cigarette brands are eroding the stigma of smoking that had been established in part by advertising bans); *see, e.g.*, CANADAVAPES, *Katherine Heigl & David Letterman Vape Electronic Cigarettes*, YOUTUBE (Sept. 29, 2010), <https://www.youtube.com/watch?v=ysGyflwwr1s> (presenting a clip from a network television show where two celebrities discuss e-cigarettes as a tool to quit smoking);

6. 21 C.F.R. §§ 1100, 1140, 1143 (2016).

7. *See* 21 C.F.R. § 1100, 1140, 1143 (2016) (stating that the rule extends the FDA’s authority to all statutorily defined “tobacco products,” prohibits the sale of such products to minors, and requires warning labels on the covered products).

## II. HISTORY OF THE DEVICES

Defining and describing an electronic nicotine delivery system (ENDS) is not an easy task as the product category has changed significantly over time and continues to be diverse and anything but static in design and features.<sup>8</sup> The changing nature of the product is exacerbated by users modifying the product in various ways; there are videos available on the Internet that offer advice on how to modify an ENDS for a more potent or pleasant user experience.<sup>9</sup> Similarly, the marketing of ENDS, such as where they are sold, how much they cost and how they are advertised, has been dynamic over the decade or so since the product has been on the market in the U.S.<sup>10</sup> We use the term ENDS in this piece to capture the array of products that allow a user to inhale aerosolized liquid, typically containing nicotine, through an electronic device but researchers, manufacturers and consumers use a variety of terms to refer to ENDS. A brief history of ENDS in the U.S. helps to define the landscape on which regulation of the product will proceed.

The first version—or generation—was the closed-system electronic cigarette, often referred to as the cig-alike.<sup>11</sup> Although far less popular now than later versions, cig-alike ENDS remain on the market today.<sup>12</sup> These first-generation devices are cylinder-shaped like cigarettes<sup>13</sup> and are about the same size, just slightly longer and larger in diameter.<sup>14</sup> The cig-alike body can be

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8. See generally *U.S. E-Cigarette Regulation: A 50 State Review*, PUB. HEALTH L. CTR. (2016), available at <http://www.publichealthlawcenter.org/sites/default/files/E-Cigarette-Legal-Landscape-50-State-Review-November-2016.pdf> (showing the various attempts of state legislatures to define and regulate e-cigarettes); see also *History of Electronic Cigarettes*, QUITDAY, <https://quitday.org/electronic-cigarettes/history-of-electronic-cigarettes/> (last visited Nov. 3, 2016) (discussing the rapid development of features and technologies following a surge in popularity of e-cigarettes).

9. See also Caleb Kekahbah, *E-Cig simplified.com – E-Cigarette Cartridge Modification*, YOUTUBE (Oct. 13, 2010), [https://www.youtube.com/watch?v=6\\_3Gbkz4150](https://www.youtube.com/watch?v=6_3Gbkz4150) (demonstrating homemade methods of modifying e-cigarettes). See MASHABLE, *How to Hack Your Own E-Cigarettes*, YOUTUBE (Jan. 24, 2014), <https://www.youtube.com/watch?v=rmxwnuTRMiw> (describing various methods of e-cigarette modification). [https://www.youtube.com/watch?v=6\\_3Gbkz4150](https://www.youtube.com/watch?v=6_3Gbkz4150) (demonstrating homemade methods of modifying e-cigarettes).

10. See Arnold, *supra* note 3, at A246–47 (discussing market changes including the shift in sales from a largely online market to more “brick-and-mortar stores”).

11. See Lynne Dawkins, *Cigalike vs. Refillable E-Cigarettes: Don’t Stub Out the Cigalikes Just Yet...*, SAVEE-CIGS.COM (Aug. 10, 2014), <https://saveecigs.wordpress.com/2014/08/10/cigalike-vs-refillable-e-cigarettes-dont-stub-out-the-cigalikes-just-yet/> (discussing the difference between a non-refillable, closed system e-cigarette and later refillable types of e-cigarettes).

12. See Tripp Mickle, *E-Cigarette Sales Rapidly Lose Steam*, WALL ST. J. (Nov. 17, 2015), <http://www.wsj.com/articles/e-cig-sales-rapidly-lose-steam-1447798921> (citing a “slowdown”, a 21% drop in sales, of cig-alike models of e-cigarettes).

13. See Volt – *Pro Starter Kit*, SMOKELESSIMAGE, Image 4, <http://smokelessimage.com/starter-kits/voltpro.html> (last visited Feb. 3, 2017); see also Dawkins, *supra* note 11.

14. See Konstantinos Farsalinos et al., *Nicotine Absorption from Electronic Cigarette Use: Comparison Between First and New-Generation Devices*, 4 SCI. REP. 1, 1 (2014) (explaining that these small devices are similar to regular tobacco cigarettes); Jessica M. Yingst et al., *Factors Associated with Electronic Cigarette Users’ Device Preferences and Transition From First Generation to Advanced*

constructed of metal or heavy plastic.<sup>15</sup> Coloration varies from those designed to look like a cigarette with a brown “filter” at one end and a longer section of white making up the shaft to those with an all-black design.<sup>16</sup> Although the cig-alike does not actually burn, most of the products have a lighted end that glows as the user draws on the cig-alike.<sup>17</sup> The coloration of the lighted end also varies, with some cig-alikes having a red/orange light, some a grey color and one popular product with a blue light.<sup>18</sup> The first-generation electronic cigarette is comprised of three parts: an enclosed battery, a reservoir for liquid, and a heating element.<sup>19</sup> The heating element uses power from the battery to change the liquid into an aerosol, often referred to as vapor.<sup>20</sup> The liquid reservoir in a cig-alike is a prefilled cartridge.<sup>21</sup> Some cartridges are inaccessible to the user, making the device disposable as the device has no purpose once the enclosed liquid is depleted through use.<sup>22</sup> The batteries in these cig-alikes are not rechargeable. The design of other cig-alikes differs in that the cartridge can be removed and replaced with another closed cartridge; these cig-alikes have a rechargeable battery, typically using a USB port for charging.<sup>23</sup> The voltage in the non-rechargeable or the rechargeable battery in a cig-alike is fixed, not subject to consumer alteration.<sup>24</sup> For non-disposable cig-alikes, the replacement cartridges

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*Generation Devices*, 17 NICOTINE & TOBACCO RES. 1242, 1243 (2015) (noting that the devices shaped like a cigarette are also classified as “cigalikes”).

15. Konstantinos Farsalinos et al., *Are Metals Emitted from Electronic Cigarettes a Reason for Health Concern? A Risk-Assessment Analysis of Currently Available Literature*, 12 INT’L. J. ENVTL. RES. & PUB. HEALTH 5215, 5216 (2015).

16. Rachel Grana et al., *Background Paper on E-Cigarettes*, WHO TOBACCO CONTROL PAPERS 1, 13–14 (2013), <http://escholarship.org/uc/item/13p2b72n>.

17. Hayden McRobbie, *Electronic Cigarettes*, NCSCT (2014), at 4, [http://www.ncsct.co.uk/usr/pub/e-cigarette\\_briefing.pdf](http://www.ncsct.co.uk/usr/pub/e-cigarette_briefing.pdf).

18. *What Is a Cigalike?*, VAPERANKS, <http://vaperanks.com/what-is-a-cigalike/> (last visited Feb. 20, 2017) (explaining that some cigalikes have LED tips that light up red because are designed to look like real tobacco cigarettes); Lindsay Fox, *Njoy Electronic Cigarette Review*, ECIGARETTE REVIEWED (Apr. 8, 2016), <http://ecigaretterevuewed.com/njoy-electronic-cigarette-review> (reviewing an electronic cigarette that has a grey plastic tip with an LED that lights up white as the user inhales); *How Blu Disposables Work*, BLU, <https://www.blu.com/en/US/explore/about-blu-products/disposable-e-cigarettes.html> (last visited Feb. 20, 2017) (explaining that when the user inhales, the blue LED tip with light up).

19. McRobbie, *supra* note 17.

20. Tianrong Cheng, *Chemical evaluation of Electronic Cigarettes*, 23 TOBACCO CONTROL ii11, ii11 (2014).

21. Chen et al., *supra* note 4, at 356.

22. *Id.*

23. *See id.* at 360 (explaining that closed system cig-alikes can be reloaded with cartridges filled by the manufacturers); *see also 4 Ways You Can Keep Your E-Cigarette Battery Charged and Working For You*, EVERSMOKE ELECTRONIC CIGARETTES, <http://www.learn.eversmoke.com/keep-your-e-cig-battery-charged.html> (last visited Feb. 20, 2017) (explaining that batteries do not last indefinitely, and can typically be plugged into a laptop or other device with a USB port).

24. *E-Cigarette Use Among Youth Adults: A Report of the Surgeon General*, U.S. DEP’T OF HEALTH & HUM. SERV. 151 (2016), available at [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); *see also* R.J. Reynolds Vapor Company, *VUSE: Digital vapor cigarettes, Frequently Asked Product Related Questions*, VUSE,

are not designed to be filled by the consumer; rather, they are supposed to be discarded and replaced with a new, pre-filled cartridge.<sup>25</sup> For this reason, cig-alikes, whether disposable or reusable, are referred to as closed-system ENDS.<sup>26</sup> Of course, some clever consumers found that they could save money by refilling the cartridges from vials of e-liquid.<sup>27</sup> This is an adulteration of the first-generation ENDS that foreshadowed the future generations.

Later generations of ENDS developed rapidly, with product changes reflecting increases in technology and enhanced flexibility for consumers to exercise more control over the device. Although the diversity in products makes it difficult to define any one product variety, there are common characteristics of the more modern ENDS devices.<sup>28</sup> In contrast to cig-alikes, most of the later generation ENDS products are open systems, meaning the product has a refillable reservoir or tank into which e-liquid is poured.<sup>29</sup> Open-system ENDS entered the market as e-pens and similar products.<sup>30</sup> This iteration of the ENDS does not look quite like a cigarette; rather, the product may look like a large pen or even a lipstick case.<sup>31</sup> These are generally cylindrical and modest in size.<sup>32</sup> Often these are worn on lanyard around the user's neck.<sup>33</sup> As with any consumer good, however, consumer demand and technology advances changed this product line quickly.<sup>34</sup> The more modern open-system ENDS boast a much larger e-liquid tank than early models; this is a factor of convenience as the

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<https://www.vusevapor.com/FooterLinks/ProductFAQs> (last visited Feb. 20, 2017) (“VUSE intentionally does not offer refillable replacement Cartridges to help ensure that our products cannot be modified and in turn, offer only a superior vaping experience.... The Lithium Polymer battery is housed inside the VUSE PowerUnit and is not accessible.”).

25. *Id.*

26. Chen et al., *supra* note 4, at 356.

27. *smokevapure, How To Fill An E-Cigarette Cartridge With E-Liquid*, YOUTUBE (Sept. 28, 2010), <https://www.youtube.com/watch?v=cr4yPtYvzO0>.

28. See Conference of the Parties to the WHO Framework Convention on Tobacco Control, *Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems (ENDS/ENNDS)*, ¶ 3, FCTC/COP/7/11 (Aug. 2016) (“All ENDS/ENNDS heat a solution (e-liquid) to create an aerosol which frequently contains flavourants, usually dissolved into Propylene Glycol or/and Glycerin.”).

29. See Nancy Kaufman & Margaret Mahoney, *E-Cigarettes: Policy Options and Legal Issues Amidst Uncertainty*, 43 J. L. MED. & ETHICS (SPEC. SUPP. TO VOL. 43.1) 23, 23 (2015).

30. See *id.* (noting that open-system ENDS rapidly entered the market in various designs including e-pens, vape pens, and other customizable devices).

31. See *Regulating Electronic Cigarettes and Similar Devices*, TOBACCO CONTROL LEGAL CONSORTIUM 1, 2 (2014) (describing modern ENDS which come in a “variety of shapes mimicking common household products, such as flash drives, pens, and lipstick.”); see also Grana et al., *supra* note 16, at 14, fig.2. (depicting an example of a pen-style ENDS).

32. See *Regulating Electronic Cigarettes and Similar Devices*, *supra* note 31 (stating that pen-style ENDS are shaped like cigarettes but slightly larger).

33. See Matt Richtel, *Where Vapor Comes Sweeping Down the Plain: E-Cigarettes Take Hold in Oklahoma*, N.Y. TIMES (Apr. 26, 2014), [https://www.nytimes.com/2014/04/27/business/e-cigarettes-take-hold-in-oklahoma.html?\\_r=0](https://www.nytimes.com/2014/04/27/business/e-cigarettes-take-hold-in-oklahoma.html?_r=0) (describing an e-cigarette user who wears his e-cigarette on a lanyard around his neck).

34. See Grana et al., *supra* note 16, at 12 (“Product engineering has been evolving since the first e-cigarettes were documented as arriving on the global market in 2007.”).

consumer is not required to refill the tank as frequently as with the first open-system models or as often as the cartridges would be replaced in a rechargeable cig-alike.<sup>35</sup> Many of these modern models allow the consumer to adjust the voltage of the heating element, either through changing the battery or making an adjustment on the device itself.<sup>36</sup> These are often referred to as variable voltage devices; the voltage delivered ranges from 3.0V to 7.0V.<sup>37</sup> Adjustments to the voltage impact the heating temperature which in turn impacts the quality and quantity of aerosol inhaled by the consumer and may impact the actual nicotine delivery.<sup>38</sup> High-tech versions of this line of ENDS could have pumps connected to micromechanical systems, allowing consumers more control over delivery of the aerosol.<sup>39</sup> Advanced ENDS may also contain “programmable logic units, integrated circuits, and other electronic components that are used to display average use cycle and safety warnings.”<sup>40</sup> These available variations result in more than 466 brands of ENDS on the market as of 2014.<sup>41</sup> Although technological advances coupled with anticipated product regulation may ultimately result in consistency, testing of existing ENDS products reveals that “[q]uality of product functioning and performance is highly variable and inconsistent.”<sup>42</sup>

Changes and diversity in the ENDS product lines are likewise mirrored in the e-liquid market. Initially, with closed systems, e-liquid was available in the sealed cartridges and in a few flavors.<sup>43</sup> As the open system product lines

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35. See *id.* at 13, 14 fig.2 (showing Figure 2 to illustrate a large, tank-style ENDS after noting that larger tank systems “hold several ml of e-liquid” requiring fewer refills).

36. See McRobbie, *supra* note 17, at 6 (explaining that users can adjust the voltage of the device by changing the settings directly on the device or replacing the coils and wicks in the device); see also Aaron Bonner, *Head in the Clouds: Vaping Culture Continues in Tuscaloosa*, THE CRIMSON WHITE (Sept. 8, 2016, 7:46 AM), <http://www.cw.ua.edu/article/2016/09/tuscaloosa-vape-culture> (“Those interested in modifying their kit can upgrade coils and batteries to increase voltage and intake...”).

37. Brown & Cheng, *Electronic Cigarettes: Product Characterisation and Design Considerations*, 23 TOBACCO CONTROL (SUPPLEMENTAL ISSUE 2), at ii7 (May 2014) (giving an example of a variable voltage range of “3-6 V in 0.1 V increments[.]”).

38. See Grana et al., *supra* note 16, at 12 (“Battery voltage differences and unit circuitry can result in great variability in the products’ ability to heat and convert the nicotine solution to an aerosol and, consequently, may affect actual nicotine delivery and other chemicals delivered to users and emitted in the exhaled aerosol.”).

39. See Brown & Cheng, *supra* note 37, at ii6 (describing that micromechanical systems (MEMS) that employ tiny pumps to deliver “specifically programmed quantities and combinations of e-liquids” the user can control).

40. *Id.*

41. See Shu-Hong Zhu et al., *Four Hundred and Sixty Brands of E-Cigarettes and Counting: Implications for Product Regulation*, 23 TOBACCO CONTROL (SUPP. ISSUE 3) iii3, iii4-5 (July 2014), [http://tobaccocontrol.bmj.com/content/tobaccocontrol/23/suppl\\_3/iii3.full.pdf](http://tobaccocontrol.bmj.com/content/tobaccocontrol/23/suppl_3/iii3.full.pdf) (following two comprehensive internet searches researchers identified 466 unique e-cigarette brands as of January 2014).

42. Grana et al., *supra* note 16 at 13.

43. See Chen et al., *supra* note 4, at 356.



developed, the e-liquid market expanded to meet—and increase—demand.<sup>44</sup> As of 2014, e-liquid was available in more than 7,700 flavors.<sup>45</sup> In fact, with the rise of vape shops—specialty stores that sell ENDS products and e-liquid—there is an unlimited number of flavors as “mixologists” can create blends or unique flavors upon request and consumers can mix their own at home.<sup>46</sup> Beyond flavor, the e-liquid market is also diverse with respect to nicotine content, with some e-liquid marketed as nicotine-free and others listing nicotine concentration, ranging from 0 to 36 mg/mL.<sup>47</sup> The accuracy of the nicotine level listed for e-liquid is in serious doubt, at least in the pre-FDA regulation era.<sup>48</sup> Research shows great variation in nicotine content, with some nicotine-free products testing as containing some amounts of nicotine and with a large %age of products with nicotine levels higher or lower than the listed amount.<sup>49</sup> And little is known about the chemical content of e-liquid, there being no ingredient disclosure requirements.<sup>50</sup> E-liquid is available in vials, bottles and “even the barrel.”<sup>51</sup>

The changes in ENDS and e-liquid result in—and perhaps from—changes in the marketing of the products. The early first generation of closed system ENDS were generally quite expensive and available only in mall kiosks and online.<sup>52</sup> A rechargeable, closed-system Smoking Everywhere product purchased by the Legal Resource Center in the mid-2000s cost \$175 and was purchased at a suburban mall kiosk in Maryland. Quickly, however, cheaper versions of the product were produced and marketed alongside cigarettes and other tobacco products at convenience stores, gas stations, pharmacies, and more.

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44. See Shu-Hong Zhu, *supra* note 41, at iii5 (2014) (noting that 242 new flavors were added per month during the study).

45. See *id.* at iii5 .

46. See Jean-François Etter, *Levels of Saliva Cotinine in Electronic Cigarette Users*, 109 ADDICTION 825, 828 (2014) (stating that some users mixed their own ‘home-made’ e-liquid with ingredients purchased online); see Christian McPhate, *Dark Clouds on E-Cigs’ Horizon Have Arrived*, DALLAS OBSERVER (Oct. 31, 2016), <http://www.dallasobserver.com/news/dark-clouds-on-e-cigs-horizon-have-arrived-8853795> (explaining that many vape shops have mixed e-liquids in their backrooms using food additives and nicotine).

47. See McRobbie, *supra* note 17, at 8.

48. See Maciej L. Goniewicz et al., *Nicotine Levels in Electronic Cigarette Refill Solutions: A Comparative Analysis of Products From the US, Korea, and Poland*, 26 INT’L J. DRUG POL’Y 583, 585 (2015) (describing a study that found that US e-liquid products showed significant differences between the labelled and detected nicotine).

49. See *id.* at 585.

50. See *id.* at 584 (explaining that currently the FDA has no authority to require ENDS manufacturers to disclose product ingredients, but predicting that the FDA will deem ENDS as tobacco products and bringing them within the scope of FDA regulation).

51. Nathan K. Cobb et al., *Novel Nicotine Delivery Systems and Public Health: The Rise of the “E-Cigarette”*, 100 AM. J. PUB. HEALTH 2340, 2340 (2010) (explaining that some e-liquid is sold in bottles); Matt Richtel, *Selling a Poison by the Barrel: Liquid Nicotine for E-Cigarettes*, N.Y. TIMES (Mar. 23, 2014), [https://www.nytimes.com/2014/03/24/business/selling-a-poison-by-the-barrel-liquid-nicotine-for-e-cigarettes.html?\\_r=1](https://www.nytimes.com/2014/03/24/business/selling-a-poison-by-the-barrel-liquid-nicotine-for-e-cigarettes.html?_r=1) (noting that e-liquid is sold in various amounts, from vials to barrels).

52. 2016 SURGEON GENERAL’S REPORT: E-CIGARETTE USE AMONG YOUTH AND YOUNG ADULTS, CDC (2016), at 14, 155, [https://www.cdc.gov/tobacco/data\\_statistics/sgr/e-cigarettes/index.html](https://www.cdc.gov/tobacco/data_statistics/sgr/e-cigarettes/index.html).

This took the product from the unique, high-cost category into the more affordable, easily-accessible category. By contrast, a disposable cherry e-hookah purchased by the Legal Resource Center in the early 2010s was approximately \$5 and available in a convenience store where cigarettes and other tobacco products were sold. And ultimately, changes in the product sparked the emergence of the vape shop where consumers can buy different reusable, open-system ENDS devices and try innumerable flavors, including special mixes blended in the vape shop.<sup>53</sup> As with many consumer products, ENDS are often purchased online.<sup>54</sup>

The diverse ENDS market is somewhat bifurcated now. Closed system ENDS often available in convenience stores tend to be marketed by cigarette manufacturers.<sup>55</sup> For example, Blu, a very popular rechargeable closed-system cig-alike was first produced by Lorillard Tobacco Company and is now produced by Imperial Tobacco.<sup>56</sup> Open-system ENDS devices and e-liquid, on the other hand, are made and distributed by any number of companies, many by small entrepreneurs.<sup>57</sup> These vendors are organized by a trade association, the Smoke-Free Alternatives Trade Association, or SFATA, which estimates that there are 22 manufacturers of hardware, 13 assemblers of devices, more than 1200 manufacturers and perhaps 15,000 vape shops across the country.<sup>58</sup> SFATA believes that small and mid-sized business dominate the ENDS market, pushing back against the belief that “Big Tobacco” is leading the charge in support of ENDS.<sup>59</sup>

The dynamic evolution of ENDS makes one thing clear—there is no “typical” ENDS product. Given the nascent nature of the product line, the increasing use of ENDS and the high-tech nature of the more modern devices, it

53. See *What Is A Vapeshop*, BILLOWBY, <https://billowby.com/blogs/learn/what-is-a-vapeshop> (last visited Feb. 20, 2017) (reporting that at first vape shops started as an outgrowth of traditional tobacconists, but popularity increased to allow for expanded product lines, and vape shops appeared with different mixes of flavors).

54. See Yadira Galindo, *Online E-cigarette Vendors Engage Customers Using Popular Internet Tools*, UC SAN DIEGO NEWS CTR. (Oct. 2, 2015), [http://ucsdnews.ucsd.edu/pressrelease/online\\_e\\_cigarette\\_vendors\\_engage\\_customers\\_using\\_popular\\_in\\_ternet\\_tools](http://ucsdnews.ucsd.edu/pressrelease/online_e_cigarette_vendors_engage_customers_using_popular_in_ternet_tools) (reporting that online sales comprise 25-30% of the \$2 billion annual e-cigarette market).

55. Mike Esterl, *Big Tobacco's E-Cig Push gets a Reality Check*, MARKETWATCH (Aug. 26, 2014, 3:59 PM), <http://www.marketwatch.com/story/big-tobaccos-e-cig-push-gets-a-reality-check-2014-08-26-154855951> (reporting that Altria group Inc. and Reynolds American Inc. quickly captured convenience store sales of closed-system “cigalikes”).

56. See Brian Solomon, *Reynolds, Lorillard Dump Blu E-cigarettes In \$27 Billion Merger*, FORBES (Jul. 15, 2014, 2:53 PM), <http://www.forbes.com/sites/briansolomon/2014/07/15/reynolds-lorillard-dump-blu-e-cigarettes-in-27-billion-merger/#733d9b0bd1c6> (explaining the Lorillard sold Blu to Imperial in 2014, after it merged with Reynolds).

57. See *About SFATA*, SMOKE-FREE ALTERNATIVES TRADE ASS'N, <http://sfata.org/about-sfata/> (last visited Feb. 20, 2017) (stating that the ENDS industry has provided over 70,000 jobs because of the recent increase in ENDS companies).

58. *Id.*

59. *Id.*

is impossible to surmise the future of ENDS. This, of course, frustrates researchers who need time to study the impact of the product while the ticking of time means the studied product has become altered or obsolete before the study's conclusion.

### III. MARKET HISTORY AND SALES

ENDS sales have increased sharply since their introduction to the U.S. market in 2007.<sup>60</sup> From 2009 to 2014 annual sales increased from \$39 million to nearly \$2 billion, with average sales more than doubling each year.<sup>61</sup> The growth rate slowed significantly in 2015, but sales still surpassed \$3 billion.<sup>62</sup> Preliminary estimates for 2016 exceed \$4 billion and industry projections indicate continued growth through at least 2023, when annual sales could surpass \$20 billion.<sup>63</sup> The 2014-2015 market slowdown was accompanied by a dramatic shift in the retail location and categories of products sold.<sup>64</sup> Previously, disposable “cig-alikes” purchased in convenience stores and other mass retail establishments dominated the category.<sup>65</sup> Beginning in 2014, however, open-system personal vaporizers became the most widely purchased ENDS product.<sup>66</sup> These refillable devices accounted for nearly two-thirds of all ENDS sales this year.<sup>67</sup> At the same time vape shops and online retailers continue to increase their market share at the expense of convenience stores and other mass retail

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60. See Kathleen Burke, *The Government Crackdown is Here: What the FDA Regulations Mean for E-cigarettes*, MARKETWATCH (Aug. 8, 2016, 10:21 AM), <http://www.marketwatch.com/story/the-government-crackdown-is-here-what-the-fda-regulations-mean-for-e-cigarettes-2016-05-05>.

61. See *E-Cigarette Use Among Youth Adults: A Report of the Surgeon General*, U.S. DEP'T OF HEALTH AND HUM. SERV. 152-153(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).

62. See Susan Adams, *Can E-Cigarettes Survive The War Against Vaping*, FORBES (May 5, 2016, 10:56 AM), <http://www.forbes.com/sites/susanadams/2016/05/05/can-e-cigarettes-survive-the-war-against-vaping/#39f7059269b2> (commenting that the size of the U.S. e-cigarette industry exceeded \$3 billion sales in 2015, but that sales in convenience stores and big retailers shrunk 6.2 %).

63. See Susan Adams, *E-Cigarette Manufacturers Say New Regulations Will Devastate the Industry*, FORBES (May 5, 2016, 3:01 PM), <http://www.forbes.com/sites/susanadams/2016/05/05/e-cigarette-manufacturers-say-new-regulations-will-devastate-the-industry/#3bdc27730bb> (estimating that the e-cigarette industry was worth just under \$4 billion dollars last year); BIS RESEARCH, *Global E-Cigarette & Vaporizer, Device and Aftermarket, Analysis and Forecast, 2016-2025*, RES. & MARKETS (Sept. 2016), <http://www.researchandmarkets.com/reports/3845485/global-e-cigarette-and-vaporizer-device-and> (predicting that the e-cigarette market will grow to \$47 billion by 2025).

64. See Mike Esterl, *Big Tobacco's E-Cig Push Gets a Reality Check*, MARKETWATCH (Aug. 26, 2014, 3:59 PM), <http://www.marketwatch.com/story/big-tobaccos-e-cig-push-gets-a-reality-check-2014-08-26-154855951> (documenting a shift in the e-cigarette market to “vape shops”).

65. See *id.* (connecting the decrease in e-cigarette convenience store sales to an increase in the vape shop market).

66. See *Open System Vaporizers Officially Overtake E-Cigs, Top \$1 Billion in Sales for the First-Time Ever*, MARKETWATCH (Sept. 25, 2014), <http://www.marketwatch.com/story/open-system-vaporizers-officially-overtake-e-cigs-top-1-billion-in-sales-for-the-first-time-ever-2014-09-25>.

67. See U.S. DEP'T OF HEALTH AND HUM. SERV., *supra* note 61, at 150.

channels.<sup>68</sup> Combined, these emerging retail channels account for 70 % of all ENDS sales.<sup>69</sup>

Total ENDS sales pale in comparison to the domestic cigarette market, which exceeds \$100 billion annually, but the ENDS market is growing at a faster rate.<sup>70</sup> In 2015, convenience store sales grew more than 7 % for ENDS versus 3 % for cigarettes, and convenience stores represent the smallest retail market for ENDS.<sup>71</sup> While cigarette sales still represent 32 % of all convenience store sales – the largest share of any product – sales have been declining for a quarter-century.<sup>72</sup> The 3 % growth last year was followed by 5 straight years of decline.<sup>73</sup> The timing of this growth raises the question of whether dual use of ENDS and cigarettes is contributing to the renewed cigarette sales growth.

#### IV. WHO IS USING ENDS?

##### A. Adult Use

As the retail sales data indicate, ENDS use is increasing rapidly.<sup>74</sup> The Centers for Disease Control and Prevention estimate that 1 in 8 adults age 18 years or older have ever used ENDS, a threefold increase over the past two years,

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68. See Esterl, *supra* note 64 (documenting the decrease in convenience store sales in comparison to vape shop and online sales).

69. See Martinne Geller, *Special Report: When it Comes to E-Cigs, Big Tobacco is Concerned for your Health*, REUTERS (Mar. 23, 2015, 1:52 PM), <http://www.reuters.com/article/us-ecigarettes-regulations-specialreport-idUSKBN0MJ0GN20150323>.

70. See Tripp Mickle, *E-Cigarette Sales Rapidly Lose Steam*, WALL ST. J. (Nov. 17, 2015, 7:15 PM), <http://www.wsj.com/articles/e-cig-sales-rapidly-lose-steam-1447798921> (explaining that, cigarette volumes are down 0.5% in 2015 while ENDS have grown 114% in the past five years).

71. See *Where The Gains Are*, CSP (Apr. 15, 2016), <http://www.cspdailynews.com/category-data/cmh/tobacco/tobacco-cigarettes-2016> (reporting the growth in unit sales for cigarettes and electronic smoking devices); see also *Study Shows Shopping Habits of E-Cig Users*, CONVENIENCE STORE DECISIONS (Aug. 9, 2016), <http://www.cstoredecisions.com/2016/08/09/study-shows-shopping-habits-e-cig-users/> (stating that only 8% of polled respondent bought ENDS products at a “convenience store”).

72. See Samantha Oller, *Preliminary Overview Data From NACS State Of The Industry Summit 2016*, CSP DAILY NEWS (May, 2016), <http://www.cspdailynews.com/print/csp-magazine/article/preliminary-overview-data-nacs-state-industry-summit-2016> (finding cigarettes accounted for \$50,367 of \$156,411 total in store sales, equaling roughly 32%); see also *Convenience Stores: Keep the Core; Appeal to More*, TIMES & TRENDS, <https://www.iriworldwide.com/iri/media/iri-clients/T.%20May%202013%20Convenience%20Stores%2006042013.pdf> (last visited Mar. 10, 2017) (noting that volume sales in convenience stores are down sharply and identifying as the primary factor that the smoking rate has declined 50% since 1965).

73. Salynn Boyles, *Convenience Store Cigarette Sales Grew in 2015*, MEDPAGE TODAY (Mar. 10, 2017), <https://www.medpagetoday.com/pulmonology/smoking/63753>.

74. King, Brian A. et al., *Trends In Awareness And Use Of Electronic Cigarettes Among US Adults, 2010–2013*, NICOTINE TOBACCO RES. 17.2 (2015): 220 (finding awareness and use of e-cigarettes through enhanced marketing is rapidly increasing).

and 1 in 20 use ENDS regularly.<sup>75</sup> Age and smoking status are the best predictors of ENDS use. Nearly 1 in 4 adults age 18-24 years have ever used ENDS, with use declining steadily as age increases.<sup>76</sup> Differences across age groups were even more defined when examining non-smoking ENDS users.<sup>77</sup> Nearly half of current cigarette smokers and more than half of former cigarette smokers have ever used ENDS.<sup>78</sup> Those cigarette smokers actively attempting to quit were also twice as likely as other smokers to have tried ENDS.<sup>79</sup> These data indicate older adults are using ENDS to quit smoking, while the majority of young adult (18-24) ENDS users are never-smokers.

### B. Youth Use

While cigarette smoking rates among high school youth have decreased significantly over the past quarter-century (28% in 1991 to 11% in 2015)<sup>80</sup>, an estimated 5.6 million Americans currently under the age of 18 are still projected to die prematurely from a smoking-related disease.<sup>81</sup> Moreover, the rate of decline has slowed in recent years, and one recent national survey showed a slight increase in cigarette smoking among high school youth between 2014 and 2015 (9.2% to 9.3%).<sup>82</sup> There is growing concern that the slowing decline in youth cigarette smoking rates is associated with the increased prevalence of ENDS use. Since 2011, youth ENDS use has skyrocketed, particularly among

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75. CHARLOTTE A. SCHOENBORN & RENEE M. GINDI, U.S. DEP'T OF HEALTH & HUMAN SERVICES, NCHS DATA BRIEF NO. 217, ELECTRONIC CIGARETTE USE AMONG ADULTS: UNITED STATES, 2014 (2015), <https://www.cdc.gov/nchs/data/databriefs/db217.pdf> (finding that 12.6% of adults had tried an e-cigarette and 3.7% use them everyday); *see also id.* at 223 (reporting that 3.3% adults had ever used ENDS in 2010).

76. *See* Schoenborn & Gindi, *supra* note 75 (finding 21.6% of those aged 18-24 have used an ENDS product with use declining steadily as age increases).

77. *See id.* at 5 (reporting that 9.7% of adults aged 18-24 had tried an electronic cigarette despite having never tried a traditional cigarette compared to 4.9% of all adults over the age of 24).

78. *Id.*

79. *See id.* (finding 20.3% of those adults who had attempted to quit in the past year had tried an electronic cigarette compared to 11.8% of cigarette smokers who had not tried to quit).

80. *Current Cigarette Smoking Among U.S. High School Students Lowest in 24 years*, NAT'L YOUTH RISK BEHAV. SURVEYS, 1991–2015, [http://www.cdc.gov/media/dpk/healthy-living/youth-risk-behavior-survey/images/yrbs\\_release\\_graphics\\_smoking\\_2016.pdf](http://www.cdc.gov/media/dpk/healthy-living/youth-risk-behavior-survey/images/yrbs_release_graphics_smoking_2016.pdf) (last visited Feb. 20, 2017).

81. *Youth and Tobacco Use*, CDC, [http://www.cdc.gov/tobacco/data\\_statistics/fact\\_sheets/youth\\_data/tobacco\\_use/index.htm](http://www.cdc.gov/tobacco/data_statistics/fact_sheets/youth_data/tobacco_use/index.htm) (last updated Apr. 14, 2016).

82. *See* Tushar Singh et al., *Tobacco Use Among Middle and High School Students—United States, 2011–2014*, 64 MORBIDITY & MORTALITY WKLY. REP. 381, 385 (2015) (finding that 9.2% of high school students used cigarettes in 2014); *see also* Tushar Singh et al., *Tobacco Use Among Middle and High School Students—United States, 2011–2015*, 65 MORBIDITY & MORTALITY WKLY. REP. 361, 366 (2016) (finding that 9.3% of high school students used cigarettes in 2015).

high school students.<sup>83</sup> From 2011 to 2015 ENDS “ever-use” increased from less than 1 in 20 (4.5%) to nearly 1 in 2 (44.9%) among U.S. high school students, and “current-use” increased from 1 in 100 (1.5%) to 1 in 4 (24.1%).<sup>84</sup> ENDS are now the most commonly used tobacco product among high school students, at more than double the rate of cigarettes (24.1% to 10.8%).<sup>85</sup> Moreover, youth ENDS users are significantly more likely to transition to cigarette smoking than youth non-users.<sup>86</sup> Recent studies indicate that among “never-smokers,” youth ENDS users were 2 to 4 times more likely than non-users to (1) initiate cigarette smoking or (2) intend to smoke cigarettes in the future.<sup>87</sup>

In contrast to adults, most youth ENDS users have never smoked cigarettes. If kids are experimenting with ENDS and transitioning to cigarettes or other conventional tobacco products the adverse impact on population health could reverberate for decades. Therefore, when crafting ENDS regulations any potential benefits ENDS provide to adult users must be weighed against the

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83. *E-cigarette Use Triples Among Middle and High School Students in Just One Year*, CDC NEWSROOM, <http://www.cdc.gov/media/releases/2015/p0416-e-cigarette-use.html> (last visited Feb. 20, 2017).

84. *Notes from the Field: Electronic Cigarette Use Among Middle and High School Students – United States, 2011-2012*, 62 MORBIDITY & MORTALITY WKLY. REP. 729, 729 (2013) (finding that in 2011, 4.7% of high school students had ever used e-cigarettes and 1.5% currently used them); see also *Youth Risk Behavior Surveillance – United States, 2015*, 65 MORBIDITY & MORTALITY WKLY. REP. 1, 17 (2016) (finding that in 2015, 24.1% of high school students currently use electronic vapor products and 44.9% had ever used them).

85. *Youth Risk Behavior Surveillance – United States, 2015*, *supra* note 84, at 81, 91.

86. See Adam M. Leventhal et al., *Association of Electronic Cigarette Use With Initiation of Combustible Tobacco Product Smoking in Early Adolescence*, 314 JAMA 700, 707 (2015) (noting that high school students in Los Angeles who used e-cigarettes were more likely than those who never used e-cigarettes to report initiation of combustible tobacco use).

87. See, e.g., Rebecca Bunnell et al., *Intentions to Smoke Cigarettes Among Never-Smoking US Middle and High School Electronic Cigarette Users: National Youth Tobacco Survey, 2011-2013*, 17 NICOTINE TOBACCO RES. 228, 233 (2015) (reporting that youth who used electronic cigarettes were twice more likely to have intentions to smoke regular cigarettes than youth who never smoked electronic cigarettes); see also Victor M. Cardenas et al., *Use of Electronic Nicotine Delivery Systems and Recent Initiation of Smoking Among US Youth*, 61 INT’L J. PUB. HEALTH 237, 239 (2016) (finding that the use of electronic cigarettes was associated with recent initiation of cigarette smoking among youth); see also Leventhal et al., *supra* note 86, at 706 (noting that high school students in Los Angeles who used e-cigarettes were more likely than those who never used e-cigarettes to report initiation of combustible tobacco use); see also Ji-Yeun Park et al., *E-Cigarettes Use and Intention to Initiate or Quit Smoking Among US Youths*, 106 AM. J. PUB. HEALTH 672, 675 (2016) (finding that youth who used electronic cigarettes were more likely to have intention to smoke cigarettes than youth who had never used electronic cigarettes); see also Brian A. Primack et al., *Progression to Traditional Cigarette Smoking After Electronic Cigarette Use Among US Adolescents and Young Adults*, 169 JAMA PEDIATRICS 1018, 1022 (2015) (identifying an association between use of electronic cigarettes and progression to traditional cigarette smoking among youth); see also Jessica L. Barrington-Trimis et al., *E-Cigarettes and Future Cigarette Use*, 138 PEDIATRICS 1, 6 (2016) (reporting that youth that used electronic cigarettes were six times more likely of initiating cigarette than youth who never used electronic cigarettes); see also Thomas A. Wills et al., *Longitudinal Study of E-cigarette Use and Onset of Cigarette Smoking Among High School Students in Hawaii*, TOBACCO CONTROL 5 (Jan. 25, 2016), <http://tobaccocontrol.bmj.com/content/early/2016/01/05/tobaccocontrol-2015-052705.abstract> (concluding that youth who uses electronic cigarettes are more likely to start smoking cigarettes).

burdens of increased youth use.

## V. HEALTH EFFECTS

Since ENDS are relatively new to the market, the long-term health effects are still largely unknown.<sup>88</sup> The absence of federal regulation and the large variance in ingredients and toxicant concentrations across brands likewise makes the toxicity of these products difficult to quantify.<sup>89</sup> However, the limited clinical research conducted to this point indicates that ENDS contain carcinogens and toxic chemicals, albeit at lower levels than cigarettes. In 2009, FDA analyzed numerous ENDS products and found they contained carcinogens, including nitrosamines, and “toxic chemicals such as diethylene glycol, an ingredient used in anti-freeze.”<sup>90</sup> More recent clinical studies indicate dozens of e-liquid brands contain a litany of dangerous toxicants, including, “propylene glycol, glycerin, tobacco specific nitrosamines, tobacco alkaloids, carbonyls, ethylene glycol, diacetyl, and acetyl propionyl. . . heavy metals, and volatile organic compounds.”<sup>91</sup> While some studies have found lower toxicant levels in ENDS aerosol than combustible tobacco, the levels frequently exceeded existing federal occupational safety limits on exposure to these chemicals.<sup>92</sup> Moreover, nicotine, the key ingredient in most e-liquid, is highly addictive, has immediate biochemical effects on the brain and body and is toxic in high doses.<sup>93</sup>

In 2011, the National Institutes of Health (NIH) and FDA announced a joint study called the Population Assessment of Tobacco and Health study (PATH), which will analyze tobacco use behaviors, including ENDS use, among 46,000 Americans age 12 years and older.<sup>94</sup> In addition, NIH-FDA are jointly funding Tobacco Centers of Regulatory Science (TCORS) at fourteen academic research

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88. 42 C.F.R. §59.203 (2017).

89. See *E-cigarettes and Lung Health*, AM. LUNG ASSOC., <http://www.lung.org/stop-smoking/smoking-facts/e-cigarettes-and-lung-health.html> (last visited Feb. 20, 2017) (explaining that varying toxin levels in e-cigarette aerosols is one of the reasons the American Lung Association is calling for FDA oversight of e-cigarettes).

90. *FDA and Public Health Experts Warn About Electronic Cigarettes*, FDA (July 22, 2009), <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm173222.htm>.

91. 42 C.F.R. §59.203 (2017) (responding to rule comment on toxicity of e-cigarettes).

92. See *id.* at 29,032 (explaining that the FDA recognizes that aerosol exhaled by e-cigarette users may be less harmful than smoke from combustible tobacco); see also Konstantinos E. Farsalinos et al., *Evaluation of Electronic Cigarette Liquids and Aerosol for the Presence of Selected Inhalation Toxins*, 17 NICOTINE & TOBACCO RES. 168, 170–71 (2015) (reporting the presence of diacetyl and acetyl propionyl in levels higher than National Institute for Occupational Safety and Health safety limits).

93. U.S. DEP’T OF HEALTH AND HUMAN SERVICES, *THE HEALTH CONSEQUENCES OF SMOKING: NICOTINE ADDICTION: A REPORT OF THE SURGEON GENERAL 6–16* (Thomas E. Novotny & William R. Lynn eds., 1988), <https://profiles.nlm.nih.gov/ps/access/NNBBZD.pdf>.

94. *FAQs for Researchers*, POPULATION ASSESSMENT OF TOBACCO & HEALTH, <https://pathstudyinfo.nih.gov/UI/FAQsResMobile.aspx> (last visited Feb. 19, 2017).

centers to determine the toxicity and health effects associated with tobacco products, including ENDS.<sup>95</sup> These TCORS are expected to contribute substantially to the evidence-base FDA will use to inform its decision-making on ENDS regulation and ultimately reduce tobacco-related death and disease in the United States.<sup>96</sup>

### A. Dual Use

Regardless of age, concomitant ENDS and cigarette use, commonly referred to as “dual use,” presents a growing public health concern.<sup>97</sup> National surveys show that a significant number of adult and youth ENDS users are also using traditional cigarettes.<sup>98</sup> In fact, more than 3 in 4 current ENDS users, adult and youth, are also current cigarette smokers.<sup>99</sup> Many tobacco users believe that cutting down on cigarette smoking by adding another tobacco product, such as ENDS, reduces health risks.<sup>100</sup> However, dual use leads to increased exposure to toxicants, and may be associated with an increased risk of negative health outcomes, including: cardiovascular disease, pancreatic and esophageal cancers,

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95. See *Centers Research Portfolio*, NIH, <https://prevention.nih.gov/tobacco-regulatory-science-program/research-portfolio/centers> (last visited Feb. 19, 2017) (informing of the collaborative effort between the Tobacco Regulatory Science Program and the Food and Drug Administration Center for Tobacco Products to conduct research in order to assist with the development of regulations); see also *Notice of Intent to Publish a Funding Opportunity Announcement for Tobacco Centers of Regulatory Science for Research Relevant to the Family Smoking Prevention and Tobacco Control Act*, NIH, <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-151.html> (last visited Feb. 19, 2017) (explaining that the purpose of the program, in part, is to study the toxicity and health effects of tobacco products).

96. *Id.*

97. See *Dual Use of Tobacco Products*, CDC, <http://www.cdc.gov/tobacco/campaign/tips/diseases/dual-tobacco-use.html> (last visited Feb. 19, 2017) (explaining that dual use is not an effective way to safeguard health even when using less cigarettes yet adding other tobacco products).

98. See *Notes from the Field: Electronic Use Among Middle and High School Students – United States, 2011–2012*, 62 MORBIDITY & MORTALITY WKLY. REP. 729, 729 (2013) (reporting that among middle school and high school students current use of both e-cigarettes and conventional cigarettes increased); see also Schoenborn & Gindi, *supra* note 75, at 6 (stating that use of e-cigarettes was highest among current and former cigarette smokers).

99. See CDC, *supra* note 97 (reporting 76.3% youth that currently uses e-cigarettes also uses conventional cigarettes); see also Brian A. King et al., *Trends in Awareness and Use of Electronic Cigarettes Among US Adults, 2010–2013*, 17 NICOTINE & TOBACCO RES. 219, 224 (2015), available at <https://academic.oup.com/ntr/article/17/2/219/2858030/Trends-in-Awareness-and-Use-of-Electronic> (reporting 76.8% of adults that currently uses e-cigarettes also uses conventional cigarettes).

100. See Pratibha Nayak et al., *A Qualitative Study of Vape Shop Operators’ Perceptions of Risks and Benefits of E-Cigarette Use and Attitude Toward Their Potential Regulation by the US Food and Drug Administration, Florida, Georgia, South Carolina, or North Carolina, 2015*, 13 PREVENTING CHRONIC DISEASE 1, 3 (2016) (reporting on how sellers of ENDS products stated that customers used ENDS for “lifestyle factors, including health and disease conditions...”).



and inflammatory bowel disease.<sup>101</sup> Moreover, light smoking (1-4 cigarettes per day) and non-daily smoking are still associated with a significantly higher risk of cancer, COPD, and heart disease.<sup>102</sup> The only effective way to reduce the health risks associated with smoking is to quit.<sup>103</sup> Dual use commonly prevents, rather than assists, smokers from quitting, and as such presents an obstacle to reducing the health risks associated with cigarette smoking.<sup>104</sup> Future ENDS research must focus on whether the devices promote cessation or dual use, and policy initiatives should seek to prevent dual use.

### B. Cessation

Central to the debate surrounding ENDS is the potential for these devices to assist cigarette smokers to quit. As indicated by their increasing popularity among current and former smokers, a significant proportion of adult ENDS users report using the devices to attempt to quit.<sup>105</sup> In fact, less than 3 % of adult non-smokers age 25–64 years old have ever tried ENDS, compared to more than 50 % of current and former smokers.<sup>106</sup> It's clear that cigarette smokers more commonly use ENDS, and that they primarily use the devices in an attempt to quit smoking, but do ENDS actually assist with smoking cessation? We don't know.

What we do know is that ENDS are not approved smoking cessation devices. FDA has approved a variety of smoking cessation products, including prescription medications, skin patches, lozenges, and gum.<sup>107</sup> These approved products have been subject to rigorous pre-market review required in the

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101. Lucy Popova & Pamela Ling, *Alternative Tobacco Product Use and Smoking Cessation: A National Study*, 103 AM. J. PUB. HEALTH 923, 923 (2013).

102. Rebecca E. Schane et al., *Health Effects of Light and Intermittent Smoking*, 121 J. AM. HEART ASS'N 1518, 1519–20 (2010).

103. See *Quitting Smoking*, CDC, [http://www.cdc.gov/tobacco/data\\_statistics/fact\\_sheets/cessation/quitting/](http://www.cdc.gov/tobacco/data_statistics/fact_sheets/cessation/quitting/) (last updated Feb. 1, 2017) (“People who stop smoking greatly reduce their risk for disease and early death.”).

104. *Dual Use of Tobacco Products*, CDC, <http://www.cdc.gov/tobacco/campaign/tips/diseases/dual-tobacco-use.html> (last updated Jan. 23, 2017).

105. See Schoenborn & Gindi, *supra* note 75, at 3 (indicating that e-cigarettes are much more popular among current and recent former smokers than long-term former smokers and never smokers); see also Terry F. Pechacek et al., *The Potential That Electronic Nicotine Delivery Systems Can be a Disruptive Technology: Results From a National Survey*, 18 NICOTINE & TOBACCO RES. 1989, 1994 (2016) (reporting that “data suggest[s] that about 2.4 million former smokers perceived that the use of ENDS may have helped in quitting use of regular cigarettes.”).

106. Schoenborn & Gindi, *supra* note 75, at 3.

107. U.S. DEPT. OF HEALTH & HUMAN SERV., *INNOVATIVE PRODUCTS AND TREATMENTS TO ACHIEVE ABSTINENCE FROM TOBACCO USE, REDUCTIONS IN CONSUMPTION OF TOBACCO, AND REDUCTIONS IN THE HARM ASSOCIATED WITH CONTINUED TOBACCO USE* (2013), available at <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/UCM348930.pdf>.

FDCA.<sup>108</sup> ENDS are not among these approved products and no ENDS manufacturer has submitted their product to FDA for evaluation or approval.<sup>109</sup>

We also know that the clinical studies conducted to this point indicate that there is significant uncertainty about the efficacy of ENDS as cessation devices.<sup>110</sup> This uncertainty is largely the result of poor study methodology. Most existing studies are limited by a lack of randomized trials, small sample sizes, poor survey design, and/or variance in outcome measures.<sup>111</sup> Moreover, the rapid evolution of the devices and the lack of standardization in the devices and e-liquid make long-term study virtually impossible; as soon as one product is subject to significant study, it is essentially obsolete.<sup>112</sup> The majority of published, peer-reviewed studies, however, demonstrate a positive association between ENDS and smoking cessation.<sup>113</sup>

The potential for ENDS as smoking cessation devices cannot be easily brushed aside. An estimated 480,000 Americans die each year from cigarette smoking-related illness.<sup>114</sup> Any product that has the potential to reduce the number of cigarette smokers must be examined. ENDS cessation research is still in its early stages, and there is a need for more carefully designed and methodically sound studies to determine whether and how these devices may be helpful.

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108. *See id.* (explaining that FDA’s premarket approval process applies to products that aim to treat or cure tobacco dependence).

109. *Electronic Cigarettes*, BETOBACCOFREE.GOV, <http://betobaccofree.hhs.gov/about-tobacco/Electronic-Cigarettes> (last visited Feb. 19, 2017); *see also Medical Device Databases; Premarket Approval*, FDA, <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm> (last visited Feb. 19, 2017) (demonstrating how as of Feb. 8, 2017 no ENDS product appears to have been submitted to the FDA for approval for smoking cessation).

110. Muhannad Malas et al., *Electronic Cigarettes for Smoking Cessation: A Systematic Review*, 18 NICOTINE & TOBACCO RES. 1926, 1927 (2016).

111. *Id.* at 1927, 1931.

112. *See* Barbara Davis et al., *Nicotine Concentrations in Electronic Cigarette Refill and Do-It-Yourself Fluids*, 17 NICOTINE & TOBACCO RES. 134, 139–40 (2015) (discussing the variability of nicotine concentrations and colors in identical refill cartridges and calling for greater standardization in the manufacturing process); *see also* Farsalinos et al., *supra* note 14, at 6 (arguing that Electronic Cigarette “technology is progressing at a fast pace and research is sometimes unable to follow this progress and assess the efficacy of such devices promptly.”). (explaining that Electronic Cigarette “technology is progressing at a fast pace and research is sometimes unable to follow this progress and assess the efficacy of such devices promptly.”).

113. Malas et al., *supra* note 110, at 1931–32 (finding that limited evidence seems to indicate that e-cigarettes may be useful to help some smokers quit).

114. *Fast Facts*, CDC, [http://www.cdc.gov/tobacco/data\\_statistics/fact\\_sheets/fast\\_facts/](http://www.cdc.gov/tobacco/data_statistics/fact_sheets/fast_facts/) (last updated Dec. 20, 2016).

## VI. REGULATORY HISTORY

*A. Tobacco Regulation Prior to 1996*

Prior to 1996, a hodgepodge of federal, state and local laws governed the cultivation, manufacture, advertising and promotion, distribution, and sale of tobacco products. The issue of tobacco and health was directly regulated by Congress primarily through six federal statutes: the Federal Cigarette Labeling and Advertising Act (1965), the Public Health Cigarette Smoking Act of 1969, the Alcohol and Drug Abuse Amendments of 1983, the Comprehensive Smoking Education Act (1984), the Comprehensive Smokeless Tobacco Health Education Act (1986), and the Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act (1992).<sup>115</sup> These statutes established advertising and packaging health warnings, prohibited radio and television advertisements<sup>116</sup>, required the Secretary of Health and Human Services (HHS) to submit a triennial report on “the addictive property of tobacco<sup>117</sup>,” and made receipt of federal substance abuse block grant dollars contingent on states enacting and enforcing minimum purchase age restrictions.<sup>118</sup> Many state and local governments

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115. *See generally, e.g.*, Federal Cigarette Labeling and Advertising Act, Pub. L. No. 89–92, 79 Stat. 282 (1965) (codified at 15 U.S.C. §§ 1331–1340) (generally providing for national standards on cigarette packaging); *see also* Public Health Cigarette Smoking Act of 1969, Pub. L. No. 91–222, 84 Stat. 87 (1970) (requiring stronger warning language on cigarette packaging and banning cigarette advertising on television and radio); *see also* Alcohol and Drug Abuse Amendments of 1983, Pub. L. No. 98–24, 97 Stat. 175 (1983) (establishing a new title called the Administration and Coordination of the National Institute of Mental Health, the national institute on Alcohol Abuse and Alcoholism, and the National Institute on Drug Abuse); *see also* Comprehensive Smoking Education Act, Pub. L. No. 98–474, 98 Stat. 2200 (1984) (amending the Federal Cigarette Labeling and Advertising Act to create a rotational label warning system, requiring cigarette packages and advertisements to rotate through four different warnings every three months); *see also* Comprehensive Smokeless Tobacco Health Education Act of 1986, Pub. L. No. 99–252, 100 Stat. 30 (1986) (requiring health warnings on all packages and advertisements for smokeless tobacco); *see also* Alcohol, Drug, Abuse and Mental Health Administration Reorganization Act, Pub. L. No. 102–321 § 202, 106 Stat. 394 (1992) (substantially amending the Public Health Service Act to replace provisions relating to the Alcohol, Drug Abuse and Mental Health Administration, the National Institute on Alcohol Abuse and Alcoholism, the National Institute on Drug Abuse and the National Institute of Mental Health.).

116. 15 U.S.C. §§ 1331 (1994) (stating Congress’s policy to inform the public about any potentially negative health effects of smoking, using labeling and advertising regulations); 1333 (1994) (mandating that cigarette packages, cigarette advertisements, and outdoor billboards advertising cigarettes must have a Surgeon’s General Warning on them); 4402(a) (1994) (requiring that smokeless tobacco products carry a label warning of its potential health consequences). They also prohibit the advertisement of tobacco products through “any medium of electronic communication” subject to regulation by the Federal Communications Commission (FCC). 15 U.S.C. § 1335 (1994) (prohibiting advertisements of cigarettes or little cigars on electronic communications); 4402(d) (1994) (requiring manufacturers, packagers, or importers of smokeless tobacco products to submit a plan to the FTC specifying how they will comply with 4402(a)).

117. 42 U.S.C. § 290aa(b)(2) (1994) (requiring the Secretary of HHS to report every three years to Congress on certain research findings concerning “the addictive property of tobacco.”).

118. 42 U.S.C. § 300x-26(a)(1) (1994) (making the States’ receipt of certain federal block grants contingent on their making it unlawful “for any manufacturer, retailer, or distributor of tobacco products to sell or distribute any such product to any individual under the age of 18.”).

supplemented federal laws by imposing tobacco excise taxes, establishing licensing and zoning restrictions on the manufacture and distribution of tobacco products, and limiting the use of lighted tobacco products on public transportation and in government buildings.<sup>119</sup> However, no federal agency was granted express regulatory authority over tobacco products and enforcement was divided among several agencies, including, the Alcohol and Tobacco Tax and Trade Bureau<sup>120</sup>; Bureau of Alcohol, Tobacco, Firearms, and Explosives<sup>121</sup>; Federal Communications Commission<sup>122</sup>; Federal Trade Commission<sup>123</sup>; and Substances Abuse and Mental Health Services Administration.<sup>124</sup>

Given its expansive drug authority, the U.S. Food and Drug Administration (FDA) was perhaps best-suited to comprehensively regulate tobacco, but for decades disavowed jurisdiction.<sup>125</sup> Under the Food, Drug, and Cosmetic Act (FDCA), FDA has authority to regulate the safety of food, drugs, and cosmetics.<sup>126</sup> While originally intended to reduce abuses in the food and cosmetics industries, the FDCA nonetheless contains powerful provisions regulating “drugs,” “devices,” and “combination products.”<sup>127</sup> These provisions

119. Julie A. Fishman et al., *State Laws on Tobacco Control—United States, 1998*, 48 MORBIDITY & MORTALITY WKLY. REP. 21 (1999), <http://www.cdc.gov/mmwr/preview/mmwrhtml/ss4803a2.htm>.

120. *TTB’s Mission – What We Do*, ALCOHOL AND TOBACCO TAX AND TRADE BUREAU, <https://www.ttb.gov/consumer/responsibilities.shtml> (last visited Feb. 22, 2017) (explaining that the agency enforces the laws regulating tobacco manufacturing and importing business and deals mainly with Federal excise taxes on tobacco products).

121. *Alcohol & Tobacco*, BUREAU OF ALCOHOL, TOBACCO, FIREARMS, & EXPLOSIVES, <https://www.atf.gov/alcohol-tobacco> (last visited Feb. 22, 2017) (explaining that the ATF enforces laws against contraband tobacco in interstate commerce).

122. *Program Content Regulations*, FED. COMM. COMM’N, <https://www.fcc.gov/media/program-content-regulations> (last visited Feb. 22, 2017) (“Advertisements for cigarettes, little cigars and smokeless tobacco are prohibited on any medium of electronic communication subject to the jurisdiction of the Federal Communications Commission.”).

123. *Federal Trade Commission Cigarette Report for 2013*, FTC (2016) <https://www.ftc.gov/system/files/documents/reports/federal-trade-commission-cigarette-report-2013/2013cigaretterpt.pdf> (enforcing advertising laws that govern tobacco products).

124. *About the Synar Amendment and Program*, SAMHSA, <https://www.samhsa.gov/synar/about> (last visited Feb. 22, 2017) (describing SAMHSA’s role in implementing the Synar amendment, a law that requires states to enact and enforce laws prohibiting the sale or distribution of tobacco products to minors).

125. *See, e.g.*, 1972 Hearings 239, 242 (statement of Comm’r Edwards) (“[R]egulation of cigarettes is to be the domain of Congress,” and “[a]ny such move by FDA would be inconsistent with the clear congressional intent”); *see also* 1983 House Hearings 74 (statement of Assistant Secretary Brandt) (explaining that FDA does not have the authority to regulate tobacco because it “is something that Congress has reserved to itself”); *see also* 1983 Senate Hearings 56 (statement of Assistant Secretary Brandt) (“Congress has assumed the responsibility of regulating the tobacco industry and regulating cigarettes”).

126. *See* Food, Drug, and Cosmetic Act, Pub. L. No. 717, 52 Stat. 675 (1938) (establishing the Food Drugs and Cosmetics act and granting authority to regulate food, drugs, devices, or cosmetics introduced into interstate commerce).

127. *See* Food, Drug, and Cosmetic Act section 301, 501–505 (1938) (prohibiting adulterated and misbranded drugs and devices and authorizing FDA to regulate them); *See* Safe Medical Devices Act of 1990 section 16 (amending the FDCA to authorize regulation of “products that constitute a combination of a drug, device, or biological product.”).

authorize FDA to regulate any non-food article (“drugs”) or instrument (“devices”), or combination of the two (“combination products”) “intended to affect the structure or any function of the body.”<sup>128</sup> Moreover, the FDCA requires warning labels and prohibits false and misleading therapeutic claims for all drugs, devices, and combination products.<sup>129</sup> The Act also requires premarket approval for each, meaning a manufacturer must demonstrate to the agency that the product is safe before it can be made commercially available.<sup>130</sup>

Tobacco leaves contain nicotine, a highly addictive alkaloid stimulant, and a drug.<sup>131</sup> Yet, from its inception in 1906 following passage of the Pure Food and Drugs Act to 1994, FDA never asserted authority to regulate tobacco products.<sup>132</sup> In fact, the agency repeatedly testified before Congress that cigarettes and other tobacco products were outside the scope of its statutory authority “absent health claims establishing a therapeutic intent on behalf of the manufacturer or vendor.”<sup>133</sup> The agency even went so far as to argue that if tobacco products were within its jurisdiction “they would have to be removed from the market because it would be impossible to prove they were safe for their intended use” as required by the FDCA.<sup>134</sup>

128. 21 USC § 321(g), (h) (defining “drug” as “articles (other than food) intended to affect the structure or any function of the body” and “device” as “an instrument, apparatus, implement, machine, contrivance... intended to affect the structure or any function of the body.”); 21 USC § 353(g)(1)(A) (describing combination products as “products that constitute a combination of a drug, device, or biological product.”).

129. 21 U.S.C. § 352(a), (f) (2012) (deeming drugs or devices misbranded if the label is false or misleading or if the label does not bear adequate warnings); 21 USC § 353(g)(1) (authorizing FDA to regulate combination products).

130. See 21 U.S.C. § 360e (2012).

131. *Nicotine Addiction and Your Health*, BETOBACCOFREE.GOV, <http://betobaccofree.hhs.gov/health-effects/nicotine-health/index.html> (last visited Feb. 22, 2017) (explaining that tobacco leaves contain nicotine, a highly addictive drug); see also *Nicotine (Code C691)*, NAT’L CANCER INST. (Jan. 30, 2016), [https://ncit.nci.nih.gov/ncitbrowser/ConceptReport.jsp?dictionary=NCI\\_Thesaurus&ns=NCI\\_Thesaurus&code=C691](https://ncit.nci.nih.gov/ncitbrowser/ConceptReport.jsp?dictionary=NCI_Thesaurus&ns=NCI_Thesaurus&code=C691) (defining nicotine as a plant alkaloid and addictive central nervous system stimulant).

132. *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 158 (2000) (describing how the FDA disavowed jurisdiction over tobacco products until 1994); *Significant Dates in U.S. Food and Drug Law History*, FDA <https://www.fda.gov/AboutFDA/WhatWeDo/History/Milestones/ucm128305.htm> (last updated Dec. 19, 2014) (explaining that FDA announced its decision to regulate nicotine in 1994 in response to a Citizen’s petition by the Coalition on Smoking OR Health).

133. *Brown & Williamson Tobacco Corp.*, 529 U.S. at 146 (citing Brief for Appellee (FDA) in Action on Smoking and Health v. Harris, 655 F.2d 236 (C.A.D.C.1980), in 9 Rec. in No. 97–1604 (CA4), Tab No. 4, pp. 14–15) (“In the 73 years since the enactment of the original Food and Drug Act, and in the 41 years since the promulgation of the modern Food, Drug, and Cosmetic Act, the FDA has repeatedly informed Congress that cigarettes are beyond the scope of the statute absent health claims establishing a therapeutic intent on behalf of the manufacturer or vendor”).

134. *Public Health Cigarette Amendments of 1971: Hearings before the Commerce Subcommittee on S. 1454*, 92d Cong., 2d Sess., 239 (1972) (statement of FDA Comm’r Charles Edwards); see also *Cigarette Labeling and Advertising: Hearings before the House Committee on Interstate and Foreign Commerce*, 88th Cong., 2d Sess., 18 (1964) (statement of Dept. of Health, Education, and Welfare (HEW) Secretary Anthony Celebrezze) (explaining that FDA jurisdiction over smoking products “might well completely outlaw at least cigarettes”).

*B.FDA’s About-Face on Tobacco Products*

In 1994, FDA announced it was considering regulating cigarettes and smokeless tobacco under its FDCA authority; marking a dramatic shift in agency policy after more than four decades of refusing to assert jurisdiction over tobacco products.<sup>135</sup> Earlier in the year, several health advocacy organizations submitted citizen petitions to FDA urging the agency to regulate cigarettes containing nicotine as drugs under the FDCA.<sup>136</sup> FDA Commissioner David Kessler responded by initiating an investigation to determine whether tobacco products containing nicotine were properly within the scope of the agency’s drug authority.<sup>137</sup>

The central question was whether nicotine meets the statutory definition of “drug” under the FDCA.<sup>138</sup> To satisfy the statutory definition, FDA had to determine whether: (1) nicotine “affects the structure or any function of the body” and (2) these effects were “intended” by the manufacturer.<sup>139</sup> Intent could be established by showing that a reasonable manufacturer would foresee the pharmacologic effects of the product, consumers would use it for the pharmacologic effects, or the manufacturer designs the products to be used for its pharmacologic effects.<sup>140</sup> Extensive scientific evidence conclusively demonstrated that nicotine affects the structure or function of the body, because it “causes and sustains addiction, and acts as a sedative, stimulant, and appetite suppressant.”<sup>141</sup> And, through its nearly 18-month investigation – led by then Associate Commissioner and current Director of the Center of Tobacco Products (CTP), Mitch Zeller – the agency also found that the pharmacological effects of nicotine were intended by tobacco manufacturers based on all three statutory criteria: (1) nicotine’s addictive properties were widely known; (2) nearly 90% of users were addicted to nicotine, and 50% of youth users smoked or used smokeless tobacco for the “buzz” or to lose weight; and (3) industry documents demonstrated that tobacco manufacturers were not only aware of nicotine’s effect on the body, but designed their products “to enhance those effects and uses.”<sup>142</sup>

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135. David A. Kessler et al., *The Food and Drug Administration’s Regulation of Tobacco Products*, 335 NEW ENG. J. MED. 988, 988 (1996).

136. DAVID KESSLER, A QUESTION OF INTENT: A GREAT AMERICAN BATTLE WITH A DEADLY INDUSTRY 50–51, 87 (2001) (describing citizen petitions that demanded the FDA begin classifying low-tar cigarettes as a drug).

137. Kessler et al., *supra* note 135.

138. *Id.*

139. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321(g)(1)(C) (2012).

140. Kessler et al., *supra* note 135, at 991.

141. Brief for Petitioner, *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000) (No. 98-1152) (citing FDA Jurisdictional Determination 61 Fed Reg 44,630).

142. Mitch Zeller, *20 Years Later: Returning to FDA to Regulate Tobacco*, FDA (Dec. 11, 2013), <https://blogs.fda.gov/fdavoices/index.php/2013/12/20-years-later-returning-to-fda-to-regulate-tobacco/> (describing how Mitch Zeller investigated the tobacco industry from 1994-1996 and career at the Center

The agency's findings conclusively established that nicotine is a drug within FDA regulatory authority, but the question quickly became how to most appropriately utilize this authority.<sup>143</sup> At the time, 1 in 4 American adults were daily cigarette smokers, and millions more used smokeless tobacco.<sup>144</sup> Given the sheer size of the adult population regularly using tobacco products and addicted to nicotine, and that 80 % of daily smokers began smoking before the age of 18, FDA chose to focus on preventing youth from initiating tobacco use.<sup>145</sup>

On August 11, 1995, the proposed rule entitled "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco Products to Protect Children and Adolescents" was published in the Federal Register.<sup>146</sup> The proposed rule focused heavily on restricting youth access to cigarettes and smokeless tobacco, and limiting the advertising and marketing of these products to children.<sup>147</sup> The rule prohibited the sale of cigarettes and smokeless tobacco to individuals under the age of 18; required retailers to verify a purchaser's age by photographic identification; prohibited free product samples and vending machines, except in adult-only facilities; limited outdoor advertising, advertising in publications with significant youth readership, and advertising near schools and playgrounds; prohibited the sale or distribution of brand-identified promotional nontobacco items such as hats and tee shirts; and required manufacturers to provide intended use information on all cigarette and smokeless tobacco product labels and in cigarette advertising.<sup>148</sup>

### *C. Litigation Following FDCA "Drug" and "Device" Regulation*

The proposed rule generated the most responses in FDA history, with more than 700,000 submissions during the public comment period, representing the views of more than 1 million individuals and entities.<sup>149</sup> Major tobacco manufacturers were among the organizations that submitted detailed comments

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of Tobacco Products); Brief for Petitioner at 4–5, *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000) (No. 98-1152) (citing FDA Jurisdictional Determination 61 Fed Reg 44,635–36, 44,701, 44,849–50) (explaining the evidence that caused FDA to assert jurisdiction over tobacco).

143. Kessler et al., *supra* note 135, at 191.

144. *Cigarette Smoking Among Adults—United States, 1995*, 46 MORBIDITY & MORTALITY WKLY. REP. 1217 (1997), <http://www.cdc.gov/mmwr/preview/mmwrhtml/00050525.htm>; see also Elizabeth A. Mumford et al., *Smokeless tobacco use 1992–2002: trends and measurement in the Current Population Survey-Tobacco Use Supplements*, 15 TOBACCO CONTROL 166, 168 (2006).

145. Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco Products to Protect Children and Adolescents, 61 Fed. Reg. 44,396, 44,398 (Aug. 18, 1996) (to be codified at 21 C.F.R. 801).

146. Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco Products to Protect Children and Adolescents, 60 Fed. Reg. 41,314 (Aug. 11, 1995) (elucidating the proposed rule).

147. See *id.* at 41,314 (explaining the proposed rule's intent to restrict access to and advertising of cigarettes and smokeless tobacco products).

148. *Id.*

149. Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. 44,396, 44,418 (Aug. 28, 1996) (to be codified at 21 C.F.R. pt. 801).

to FDA.<sup>150</sup> They also filed a joint lawsuit against FDA to enjoin the agency from promulgating a final rule regulating cigarettes and smokeless tobacco products less than one month after the rule was announced.<sup>151</sup> Brown & Williamson, Lorillard, Phillip Morris, R.J. Reynolds, and others, argued (1) FDA lacks jurisdiction to regulate cigarettes and smokeless tobacco, and (2) the advertising and marketing restrictions included in the proposed rule violate their First Amendment rights.<sup>152</sup>

FDA succeeded, in part, in District Court, successfully arguing that the FDCA authorizes the agency to regulate tobacco products as “drugs” or “devices.”<sup>153</sup> The Court found this authority is limited, however, to regulating the sale and distribution of tobacco products, and does not include advertising and marketing restrictions.<sup>154</sup> In its decision, the District Court held that (1) Congress had not withheld jurisdiction to regulate tobacco products from FDA; (2) the agency may regulate tobacco products pursuant to its FDCA authority; (3) labeling restrictions and restrictions on youth access were authorized by the FDCA; and (4) restrictions on the advertisement and promotion of tobacco products were outside the scope of the FDCA.<sup>155</sup> The decision was immediately appealed to the U.S. Court of Appeals for the Fourth Circuit.<sup>156</sup>

In *Brown & Williamson Tobacco Corp. v. Food & Drug Administration*, the Court of Appeals rejected FDA’s assertion of jurisdiction over tobacco products as customarily marketed (e.g., absent medical or therapeutic claims).<sup>157</sup> The Court of Appeals reversed the District Court decision, finding that tobacco products were neither a “drug” nor “device” within the FDCA and that Congress did not intend to include customarily marketed tobacco products within FDA’s jurisdiction.<sup>158</sup> In support of its opinion, the Court cited FDA’s longstanding position that tobacco products were outside the scope of the FDCA, and that reading tobacco products into the statute “might well” lead to a ban.<sup>159</sup> The FDCA requires that new devices be proven safe or effective prior to distribution or sale in the United States, and if there is a reasonable likelihood a device may cause injury, illness, or death, FDA must issue an immediate cease-distribution

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150. *Id.*

151. Liza Goitein et al., *Developments in Policy: The FDA’s Tobacco Regulations*, 15 YALE L. & POL’Y REV. 399, 404 (1996).

152. *Id.* at 399.

153. *Coyne Beahm, Inc. v. U.S. Food & Drug Admin.*, 966 F. Supp. 1374, 1380 (M.D.N.C. 1997) (holding that cigarettes are classified as a “drug” or “device” and therefore available for regulation).

154. *Id.* at 1398–1400.

155. *Id.* at 1377, 1379, 1388, 1400.

156. *Brown & Williamson Tobacco Corp. v. FDA*, 153 F.3d 155, 160 (4th Cir. 1998) (reversing the district court and holding that FDA lacked proper jurisdiction to regulate tobacco products), *aff’d*, 529 U.S. 120, S. Ct. 1291 (U.S. 2000).

157. *Id.* at 161, 176.

158. *Id.* at 162.

159. *Id.* at 170, 172.



order.<sup>160</sup> Since FDA concluded tobacco products were “dangerous,” “unsafe,” and kill more than 400,000 American each year, the Court concluded that the FDCA would require the agency to ban tobacco products, contrary to Congressional intent.<sup>161</sup>

In assessing Congressional intent, the Court reviewed decades of proposed and enacted tobacco legislation.<sup>162</sup> The main conclusions were Congress (1) repeatedly decided against granting FDA authority over tobacco products, and (2) reserved for itself regulatory authority over tobacco products.<sup>163</sup> First, Congress considered more than a dozen bills between 1956 and 1989 that would have granted FDA authority over tobacco products.<sup>164</sup> Each bill failed, indicating that Congress was aware FDA lacked jurisdiction and did not want the agency regulating tobacco products. Second, Congress did enact several statutes directly regulating the advertising, marketing, packaging and sale of tobacco products. Passage of FCLAA, CSTHEA, and other legislation demonstrated clear intent not to delegate regulatory authority to FDA.<sup>165</sup> With this information the Court reversed the holding of the District Court and concluded that FDA lacked the authority to regulate tobacco products under the FDCA.<sup>166</sup> FDA sought certiorari in the Supreme Court.<sup>167</sup>

#### *D. FDA v. Brown & Williamson*

The Supreme Court granted certiorari and in a 5-4 split affirmed the Court of Appeals’ decision that FDA lacked jurisdiction to regulate tobacco products as customarily marketed under the FDCA.<sup>168</sup> Delivering the opinion for the Court, Justice O’Connor used much the same logic as the lower court: (1) tobacco products do not “fit” the FDCA because the statute requires FDA to ban dangerous drugs or devices, and (2) Congress did not delegate its authority to regulate tobacco products.<sup>169</sup>

The Court held that tobacco products did not “fit” the objective and scope

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160. 21 U.S.C. § 360e (2012) (requiring FDA to consider the safety and effectiveness of a device when considering it for premarket approval); 21 U.S.C. § 360h(e)(1)(A) (2012) (authorizing FDA to recall devices that would cause serious adverse health consequences or death when used as intended).

161. *Brown & Williamson Tobacco Corp.*, 153 F.3d at 163, 166, aff’d, *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000).

162. *Id.* at 171–75.

163. *Id.* at 175–76.

164. *Id.* at 175 & n.26.

165. *See id.* at 172–75 (explaining that Congress’s enactment of FCLAA, CSTHEA, and other legislation “cannot be harmonized with FDA’s assertion of jurisdiction over tobacco products”).

166. *Id.* at 176.

167. *See generally* Petition for a Writ of Certiorari, *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000) (No. 98-1152).

168. *See Brown & Williamson Tobacco Corp.*, 529 U.S. at 131, 161 (O’Connor, J. majority).

169. *See id.* at 143, 160–61.

of the FDCA, because the FDCA was enacted to ensure that all drugs and devices subject to its provisions are safe for their intended use.<sup>170</sup> This requires a balancing test where FDA determines whether the therapeutic benefits of a drug or device outweigh the potential health risks to the consumer.<sup>171</sup> According to the Court, conducting such an analysis with tobacco products would be impossible.<sup>172</sup> As FDA’s exhaustive investigation demonstrated, tobacco products are “unsafe, dangerous, and cause great pain and suffering from illness.”<sup>173</sup> Thus, designating tobacco products as “devices” under the FDCA would require the agency to ban their distribution and sale. Since Congress refused to ban tobacco products, instead choosing to regulate their advertising and promotion, agency regulation would “plainly contradict congressional intent,” and therefore fall outside the scope of the FDCA.<sup>174</sup>

Congress’ history of tobacco-specific legislation further demonstrated to the Court that FDA lacked jurisdiction to regulate tobacco products under the FDCA.<sup>175</sup> Between 1965 and 1992 Congress enacted six separate statutes regulating tobacco in the interests of public health.<sup>176</sup> None of these statutes granted FDA authority over tobacco products or banned their sale.<sup>177</sup> To the Court majority, this legislative history “effectively ratified” FDA’s longstanding position that tobacco products were not subject to the FDCA and proved Congress did not delegate its tobacco authority to the agency.<sup>178</sup>

In a blistering dissent, Justice Breyer (joined by Justices Stevens, Souter, and Ginsburg), argued that under a plain language reading of the FDCA, nicotine is a “drug” and tobacco products are a “device.”<sup>179</sup> Moreover, the FDCA’s primary objective is to protect the public’s health; a goal that is best served by including tobacco products within the scope of the Act.<sup>180</sup> Justice Breyer also took issue with the Court’s reading of the FDCA as requiring FDA to ban tobacco products.<sup>181</sup> Instead arguing that the statute permitted the agency to choose alternative remedies more consistent with previous Congressional action.<sup>182</sup> Finally, the dissent constructs a statutory and policy argument that scientific

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170. *Id.* at 142.

171. *Id.* at 141.

172. *See id.* (explaining that this would require an implausible inquiry into whether tobacco products purported benefits outweigh the risks to from their use).

173. *Id.* at 134.

174. *Brown*, 529 U.S. 161.

175. *Id.* at 156.

176. *Id.* at 143.

177. *Id.* at 144.

178. *Id.* at 156.

179. *Id.* at 164, 168–169 (Breyer, J., dissenting).

180. *Brown*, 529 U.S. 162 (Breyer, J., dissenting).

181. *Id.* at 174 (Breyer, J., dissenting) (describing the “perverse” consequence of a statute that does not allow FDA to weigh the consequences of a cigarette ban with the consequences of regulating cigarettes).

182. *Id.* at 163 (Breyer, J., dissenting).

advancements, such as discovering the addictive qualities of nicotine, should permit FDA to change agency policy related to previously unregulated products such as cigarettes and smokeless tobacco.<sup>183</sup>

### *E. Decade-Long Legislative Battle Ensues*

The Supreme Court's decision invalidated FDA's final rule regulating cigarettes and smokeless tobacco, which had been promulgated in August 1996.<sup>184</sup> It also ensured that any future regulatory efforts would necessarily have to be the product of Congress.<sup>185</sup> The issue of FDA authority over tobacco products lay dormant in the courts until 2008 when the agency moved to regulate electronic cigarettes as drug delivery devices and block their importation into the United States.<sup>186</sup>

In the aftermath of the *Brown & Williamson* decision several bills were introduced authorizing FDA to regulate tobacco products. During the 107<sup>th</sup> Congress (2001-2003) alone seven different bills were filed granting FDA new regulatory authority over tobacco products. Four bills (S. 190<sup>187</sup>, S. 2626<sup>188</sup>, S. 2764<sup>189</sup>, and H.R. 2180<sup>190</sup>) would have created a new chapter within the FDCA solely regulating tobacco products, and three bills (S. 247<sup>191</sup>, H.R. 1044<sup>192</sup>, and H.R. 1097<sup>193</sup>) would have expanded the drug-delivery device authority to include tobacco products. None of the introduced bills received a vote, as legislators continued to work with industry representatives and public health advocates to craft a bill acceptable to both sides.<sup>194</sup>

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183. *Id.* at 188–189 (Breyer, J., dissenting).

184. *Id.* at 127, 161.

185. *Id.* at 160–61.

186. *Smoking Everywhere, Inc. v. FDA*, 680 F. Supp. 2d 62, 64 (D.D.C.), *aff'd sub nom. Sottera, Inc. v. Food & Drug Admin.*, 627 F.3d 891 (D.C. Cir. 2010).

187. National Youth Smoking Reduction Act, S. 190, 107th Cong. (2001) (expanding the definition of tobacco product in the FDCA).

188. Youth Smoking Prevention and Public Health Protection Act, S. 2626, 107th Cong. (2002) (amending the FDCA to include an expanded definition of “tobacco product”).

189. Tobacco Livelihood and Economic Assistance for Our Farmers Act of 2002, S. 2764, 107th Cong. (2002) (strengthening provisions respecting adulterated and misbranded tobacco products).

190. National Youth Smoking Reduction Act, H.R. 2180, 107th Cong. (2001) (revises the definition of “tobacco product” to include any product made or derived from tobacco that is intended for human consumption).

191. Kids Deserve Freedom from Tobacco Act of 2001, S. 247, 107th Cong. (2001) (amending language to expand the definition of a “restricted device”).

192. Child Tobacco Use Prevention Act of 2001, H.R. 1044, 107th Cong. (2001) (expanding the Federal Food, Drug, and Cosmetic Act jurisdiction over tobacco products as drugs or devices).

193. FDA Tobacco Authority Amendments Act, H.R. 1097, 107th Cong. (2001) (including “a tobacco product” in the definition of the term “device”).

194. National Youth Smoking Reduction Act, S. 190, 107th Cong. (2001), *available at* <https://www.congress.gov/bill/107th-congress/senate-bill/190?q=%7B%22search%22%3A%5B%22Tobacco%22%5D%7D&resultIndex=1> (explaining that S.

In early 2004, Senators Ted Kennedy (D-MA) and Bill DeWine (R-OH) and Representatives Tom Davis (R-VA) and Henry Waxman (D-CA) introduced the “Family Smoking Prevention and Tobacco Control Act” (S. 2461<sup>195</sup>, H.R. 4433<sup>196</sup>), a bipartisan bill authorizing FDA to regulate tobacco products and codifying the 1996 agency regulations.<sup>197</sup> The bill was widely endorsed by both the tobacco industry and public health community.<sup>198</sup> Philip Morris and the Campaign for Tobacco-Free Kids even proclaimed “enthusiastic” support, but after receiving unanimous consent in the Senate the House failed to take legislative action.<sup>199</sup> Senator Kennedy and Representatives Davis and Waxman re-introduced the bill in 2005 and 2007, with the 2007 version even passing the House by a vote of 326-102.<sup>200</sup> Strong opposition from the Bush Administration, the Secretary of Health and Human Services, and the FDA Commissioner, however, kept the upper house from voting on the bill.<sup>201</sup>

The 111<sup>th</sup> Congress (2009-2011) convened on January 3, 2009, and with the support of administration of the newly elected President, Barack Obama, the Family Smoking Prevention and Tobacco Control Act (“Tobacco Control Act”) was reintroduced.<sup>202</sup> The bill passed the House on April 2, 2009, the Senate

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190 was read twice and referred to Committee but went no further); Youth Smoking Prevention and Public Health Protection Act, S. 2626, 107th Cong. (2001), *available at* <https://www.congress.gov/bill/107th-congress/senate-bill/2626> (stating that S. 2626 was read twice and referred to Committee but went no further); Tobacco Livelihood and Economic Assistance for Our Farmers Act of 2002, S. 2764, 107th Cong. (2001), *available at* <https://www.congress.gov/bill/107th-congress/senate-bill/2764> (explaining that S. 2764 was read twice and referred to Committee but went no further); National Youth Smoking Reduction Act, H.R. 2180, 107th Cong. (2001), *available at* <https://www.congress.gov/bill/107th-congress/house-bill/2180> (stating that H.R. 2180 was referred to Committee and a Subcommittee but went no further); KIDS Act, S. 247, 107th Cong. (2001), *available at* <https://www.congress.gov/bill/107th-congress/senate-bill/247> (explaining that S. 247 was read twice and referred to Committee but went no further); Child Tobacco Use Prevention Act of 2001, H.R. 1044, 107th Cong. (2001), *available at* <https://www.congress.gov/bill/107th-congress/house-bill/1044> (stating that H.R. 1044 was referred to Committee but went no further); FDA Tobacco Authority Amendments Act, H.R. 1097, 107th Cong. (2001), *available at* <https://www.congress.gov/bill/107th-congress/house-bill/1097> (stating that H.R. 1097 was referred to Committee and a Subcommittee but went no further); *see also* C. STEPHEN REDHEAD & VANESSA K. KURROWS, FDA TOBACCO REGULATION: HISTORY OF THE 1996 RULE AND RELATED LEGISLATIVE ACTIVITY, 1998-2008 2, FN2 (Cong. Res. Serv. ed., 2009) (explaining while no bills received a vote in the 107th Congress, lawmakers worked for months in negotiations balancing “the competing interests of public health groups and the tobacco industry”).

195. Family Smoking Prevention and Tobacco Control Act, S. 2461, 108th Cong. (2004).

196. Family Smoking Prevention and Tobacco Control Act, H. R. 4433, 108th Cong. (2004).

197. REDHEAD & KURROWS, *supra* note 194, at 1–2.

198. *Id.* at 13.

199. *Id.*

200. *Id.* at 1–2.

201. REDHEAD & BURROWS, *supra* note 194, at 14 (stating that the Bush Administration, along with the FDA Commissioner and Secretary of HHS, were concerned that the bill would give the impression that the regulated tobacco products were safe, which would ultimately encourage individuals to smoke).

202. Family Smoking Prevention and Tobacco Control Act, H.R. 1256, 111th Cong. (2009); *Statement of Administration Policy: H.R. 1256 – Family Smoking Prevention and Tobacco Control Act*, THE AMERICAN PRESIDENCY PROJECT (Apr. 1, 2009), <http://www.presidency.ucsb.edu/ws/?pid=85939> (expressing the support of the Obama administration for H.R. 1256); Judy Schneider et al., *The First Day*

on June 11, 2009, and was signed by the President on June 22, 2009.<sup>203</sup> After nearly 15 years, FDA was granted the authority over the tobacco products that the agency had asserted in its proposed 1995 rule.

#### *F. The Family Smoking Prevention and Tobacco Control Act*

The Tobacco Control Act gives FDA authority to regulate the manufacture, distribution, and marketing of tobacco products, including specific restrictions on the marketing of tobacco products to youth.<sup>204</sup> The Act also requires FDA to reissue the 1996 regulations that were struck down in *Brown & Williamson*, including: minimum packaging requirements for cigarettes, minimum purchase age and ID requirements, and bans on free product samples, self-service displays, and tobacco-brand sponsorship of sporting and entertainment events.<sup>205</sup> In addition, the Act prohibits the sale of flavored cigarettes and the use of modified risk terms such as “light,” “mild,” and “low tar.”<sup>206</sup>

The Act defines “tobacco product” as “any product made or derived from tobacco that is intended for human consumption.”<sup>207</sup> While this broad definition encompasses all tobacco products, the Act provides specific requirements and restrictions applicable only to cigarettes, smokeless tobacco, and roll-your-own tobacco.<sup>208</sup> Congress gave FDA the power to regulate all tobacco products (e.g., cigars, hookah, and ENDS), but requires the agency to first promulgate a regulation specifically asserting that power over any tobacco products other than cigarettes, smokeless tobacco, and roll-your-own tobacco.<sup>209</sup>

Most importantly, with few exceptions, the Tobacco Control Act expressly permits state and local governments to enact more stringent measures.<sup>210</sup> Previous federal tobacco legislation largely preempted state and local regulatory efforts.<sup>211</sup> In *Lorillard Tobacco Co. v. Reilly* (2001), the Supreme Court held

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*of the New Congress: A Guide to Proceedings on the House Floor*, CONG. RES. SERV., 1 (2010) (explaining that the 111<sup>th</sup> congress convened on January 6, 2009).

203. Family Smoking Prevention and Tobacco Control Act, H.R. 1256, 111th Cong. (2009), available at <https://www.congress.gov/bill/111th-congress/house-bill/1256>.

204. Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776, 1830 (2009) (codified at 21 U.S.C. § 301–387).

205. *See id.* at 1830.

206. *See id.* at 1799, 1812.

207. *Id.* at 1783.

208. *See, e.g., id.* at 1830–32 (prohibiting the distribution of free samples of cigarettes, smokeless tobacco, and other tobacco products).

209. *See id.* at 1786.

210. *See id.* at 1823 (stating that local and state governments may enact more stringent requirements than established by this chapter).

211. *See* Federal Cigarette Labeling and Advertising Act, Pub. L. No. 89-92, 79 Stat. 282, 283 (1965) (preempting state laws that would require cigarette manufacturers to print a notice on their packaging that indicates the health consequences of smoking); *see also* Public Health Cigarette Smoking Act of 1969, Pub. L. No. 91-222, 84 Stat. 84, 88 (1970) (preempting requirement or prohibition based on smoking and health imposed by the state with respect to advertising or promotion of any cigarettes packages); *see also* Comprehensive Smoking Education Act, Pub. L. No. 98-474, 98 Stat. 2200 (1984) (prohibiting state

that the Federal Cigarette Labeling and Advertising Act (“FCLAA”) preempted the Attorney General of Massachusetts from promulgating regulations banning cigarette advertising and sales within 1,000 feet of playgrounds and schools and limiting point-of-sale advertising.<sup>212</sup> Likewise, the U.S. Court of Appeals for the Second Circuit held FCLAA preempted a New York City Board of Health regulation requiring tobacco retailers to post graphic warning signs about the adverse health effects of smoking.<sup>213</sup> In contrast, the Tobacco Control Act preserves the authority of state and local governments to regulate the advertising, distribution, and sale of tobacco products:

Nothing in this chapter, or rules promulgated under this chapter, shall be construed to limit the authority of . . . a State or political subdivision of a State. . . to enact, adopt, promulgate, and enforce any law, rule, regulation, or other measure with respect to tobacco products that is in addition to, or more stringent than, requirements established under this chapter, including a law, rule, regulation, or other measure relating to or prohibiting the sale, distribution, possession, exposure to, access to, advertising and promotion of, or use of tobacco products by individuals of any age, information reporting to the State, or measures relating to fire safety standards for tobacco products. No provision of this chapter shall limit or otherwise affect any State, tribal, or local taxation of tobacco products.<sup>214</sup>

The Act permits state and local governments to enact more stringent requirements in areas as disparate as sales and distribution, youth possession, use (e.g. smoke-free laws), fire safety standards, and excise taxes.<sup>215</sup> State and local governments may even regulate the time, place, and manner of tobacco advertising and marketing within the boundaries of First Amendment commercial speech protections.<sup>216</sup> Federal law still preempts, however, any requirement or prohibition related to product manufacturing, including premarket review, adulteration, misbranding, labeling, and product registration, as well as the content of tobacco advertisements with respect to health

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regulations that concern cigarette and smokeless tobacco advertisements and packaging); *see also* Comprehensive Smokeless Tobacco Health Education Act, Pub. L. No. 99-252, 100 Stat. 30, 34 (1986) (prohibiting federal agencies, state or local statutes or regulations requiring statements relating to the use of smokeless tobacco products and health).

212. *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 565–66, 569–71 (2001). The Court also found that the advertising restrictions as applied to smokeless tobacco and cigars, which were not included in FCLAA, violated the First Amendment. The Court did allow the ban on self-service displays to remain in effect, finding this to be a sales practice and not the promotion or advertising of cigarettes. *Id.* at 569–70 (finding that the advertising restriction applied to smokeless tobacco and cigars and upholding ban on self-service displays because it was a sales practice and not advertising or promotion).

213. 23-34 94th St. Grocery Corp. v. N.Y.C. Bd. of Health, 685 F.3d 174, 185–186 (2nd Cir. 2012).

214. Family Smoking Prevention and Tobacco Control Act, Pub. L. 111-31, 123 Stat. 1776, 1823 (2009) (codified as 21 U.S.C. § 387p(a)(1)).

215. Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, § 101(b)(3), 123 Stat. 1823 (2009) (codified at 21 U.S.C. § 387p(a)(1) (2012)).

216. Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, § 203, 123 Stat. 1846 (2009) (codified at 15 U.S.C. § 1334(e) (2012)).

warnings.<sup>217</sup> This preemption reflects that tobacco products manufactured in one state are generally available for sale across the country such that state-by-state product standards could cripple the industry in seeming violation of the spirit of the Commerce Clause.<sup>218</sup>

### G. New Kids on the Block

In 2007, ENDS manufacturers Smoking Everywhere and NJOY began importing inventory into the United States and marketing their products for “smoking pleasure.”<sup>219</sup> Although designed to resemble traditional cigarettes, these cig-alike products do not burn or contain tobacco.<sup>220</sup> In fact, NJOY’s promotional materials emphasized “it’s NOT a real cigarette, there is NO real smoke, flame, tar, or tobacco,” and promised to “deliver the nicotine hit that smokers crave.”<sup>221</sup> In October 2008, FDA denied entry to a shipment of Smoking Everywhere products from China because they appeared to be an “unapproved drug-device combination product.”<sup>222</sup> Shortly thereafter, FDA denied entry to a shipment of NJOY products on the same grounds.<sup>223</sup> In response, Smoking Everywhere filed suit in the U.S. District Court for the District of Columbia, and NJOY joined as an intervenor-plaintiff.<sup>224</sup> The ENDS manufacturers sought a preliminary injunction barring FDA from regulating their products under the drug/device provisions of the FDCA.<sup>225</sup> They argued that *Brown & Williamson* applies equally to electronic cigarettes as to conventional cigarettes because the nicotine in electronic cigarettes is derived from tobacco, and that FDA lacks authority under the FDCA to regulate their products as customarily marketed.<sup>226</sup> FDA countered that the Supreme Court decision did not extend to electronic cigarettes, which do not contain tobacco and are not subject to the federal statutes

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217. See Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, § 101(b)(3), 123 Stat. 1823 (2009) (codified as amended in 21 U.S.C. § 378p(a)(2)(A) (2012)) (stating that federal law preempts state regulation relating to product manufacturing, including premarket review, adulteration, misbranding, labeling and product registration); see also 15 U.S.C. § 1334(b) (stating that federal law preempts state regulations pertaining to health-related warning labels); see generally *Fact Sheet 3: Preemption of State and Local Authority*, TOBACCO CONTROL LEGAL CONSORTIUM 1–2 (July 2009), <http://publichealthlawcenter.org/sites/default/files/fda-3.pdf> (providing an overview of recent changes to preemption of tobacco regulations).

218. Family Smoking Prevention and Tobacco Control Act § 2(9)–(12).

219. *Smoking Everywhere, Inc. v. U.S. Food & Drug Admin.*, 680 F.Supp.2d 62, 64 (D.D.C. 2010), *aff’d sub nom. Sottera, Inc. v. Food & Drug Admin.*, 627 F.3d 891 (D.C. Cir. 2010).

220. *Id.* at 63–64.

221. Brief for Appellants at 3, *Sottera, Inc. v. Food & Drug Admin.*, 627 F.3d 891 (D.C. Cir. 2010) (No. 10-5032).

222. See *Smoking Everywhere, Inc.*, 680 F.Supp.2d at 64–65; see also Brief for Appellants at 4, *Sottera, Inc. v. Food & Drug Admin.*, 627 F.3d 891 (D.C. Cir. 2010) (No. 10-5032).

223. See *Smoking Everywhere, Inc.*, 680 F.Supp.2d at 65–66.

224. *Id.* at 64–65.

225. *Id.* at 63.

226. *Id.* at 66–67.

the *Brown & Williamson* Court relied upon in finding that Congress has not intended to give regulatory power over tobacco products to FDA.<sup>227</sup> The injunction was granted by the District Court and FDA appealed.<sup>228</sup>

Similar to FDA’s attempt to regulate tobacco products in 1996, the agency invoked its FDCA authority to regulate drugs and drug-delivery devices when preventing the importation of ENDS.<sup>229</sup> However, the issue of whether the agency has authority to regulate ENDS under the drug/device provisions of the FDCA soon became entangled with the issue of whether the Tobacco Control Act, signed into law on June 22, 2009, provided the agency with authority to regulate ENDS.<sup>230</sup> Therefore, as the case moved to the U.S. Court of Appeals for the District of Columbia Circuit, the question was not only whether FDA *could* regulate electronic cigarettes, but whether Congress had authorized the agency to regulate electronic cigarettes under the drug-device provisions of the FDCA or under the Tobacco Control Act.<sup>231</sup>

FDA moved forward in *Sottera v. Food and Drug Admin.* with three main arguments: (1) electronic cigarettes are combination drug devices under the provisions of the FDCA, (2) the reasoning of *Brown & Williamson* does not apply to electronic cigarettes, and (3) the Tobacco Control Act does not restrict FDA’s preexisting authority under the FDCA to regulate electronic cigarettes as drug-delivery devices.<sup>232</sup> First, FDA argued that unlike traditional cigarettes, the agency had regulated nicotine products under the FDCA, without challenge, for at least two decades.<sup>233</sup> For instance, the agency regulated “Favor Smokeless Cigarettes,” a product virtually identical to ENDS, under its FDCA authority beginning in the mid-1980s.<sup>234</sup> FDA advised Favor that the product was “a nicotine delivery system intended to satisfy a nicotine dependence and to affect the structure and one or more functions of the body” and therefore an unapproved new drug.<sup>235</sup> FDA likewise had long used its drug-device authority to regulate nicotine hand gels, lollipops, lip balms, and water.<sup>236</sup> All of these similar products were regulated as drug-devices under the FDCA, and FDA argued that the electronic cigarettes sold by NJOY and Smoking Everywhere were likewise subject to the Act’s provisions.<sup>237</sup>

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227. *Id.* at 67–68.

228. *Id.* at 66; *Sottera, Inc. v. Food & Drug Admin.*, 627 F.3d 891 (D.C. Cir. 2010).

229. *Sottera*, 627 F.3d at 894-95.

230. *See id.* at 892, 894.

231. *See id.* at 892.

232. *See id.* at 895.

233. *Id.* at 902 (Garland, J., concurring).

234. *Id.*

235. Brief for Appellant at 14–15, *Sottera, Inc. v. Food & Drug Admin.*, 627 F.3d 891 (D.C. Cir. 2010). (No. 10-5032).

236. *Smoking Everywhere, Inc.*, 680 F. Supp. 2d at 79 n.13.

237. Brief for Appellant at 9, *Sottera, Inc. v. Food & Drug Admin.*, 627 F.3d 891 (D.C. Cir. 2010). (No. 10-5032).



Second, the *Brown & Williamson* Court gleaned from a handful of federal statutes that Congress had reserved tobacco authority for itself and did not intend for FDA to regulate cigarettes.<sup>238</sup> In *Sottera*, FDA argued that *Brown & Williamson* did not apply to electronic cigarettes because, unlike conventional cigarettes, electronic cigarettes were not subject to any of the federal statutes cited in the Supreme Court case as Congress's intent to preclude FDA oversight in the area of tobacco control.<sup>239</sup> Rather, electronic cigarettes were never mentioned in *Brown & Williamson*, nor were they ever the subject of specific federal legislation.<sup>240</sup>

Third, FDA argued that the newly enacted Tobacco Control Act did not limit its ability to regulate electronic cigarettes or other drug-device products under the FDCA.<sup>241</sup> While the Tobacco Control Act granted FDA new authority over any product derived from tobacco, the statute expressly excluded any drug, device or combination product regulated under the FDCA.<sup>242</sup> According to FDA, since electronic cigarettes "fit" the drug-device statutory definition FDA was authorized to regulate these products under its preexisting FDCA authority.<sup>243</sup>

NJOY opposed FDA's action on nearly identical grounds as the cigarette manufacturers in *Brown & Williamson*.<sup>244</sup> The company argued that (1) electronic cigarettes are tobacco products and (2) the FDCA does not grant FDA authority to regulate tobacco products absent therapeutic claims (i.e. as customarily marketed).<sup>245</sup> First, the Tobacco Control Act defines "tobacco product" as "any product made or derived from tobacco," which even FDA conceded encompasses electronic cigarettes like those sold by NJOY that contain nicotine derived from tobacco.<sup>246</sup> Second, NJOY asserted that in passing the Tobacco Control Act Congress ratified the *Brown & Williamson* decision that FDA lacked jurisdiction over tobacco products under the FDCA.<sup>247</sup> Given that Congress enacted specific legislation to regulate "any product made or derived

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238. Food & Drug Admin. v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 143, 156 (U.S. 2000).

239. *Sottera, Inc.*, 627 F.3d at 895.

240. Brief of Appellant at 14, *Sottera, Inc. v. Food & Drug Admin.*, 627 F.3d 891 (D.C. Cir. 2010) (No. 10-5032).

241. *Id.* at 19–20.

242. 21 U.S.C. § 321 (rr)(2) (2012).

243. Brief for Appellants at 19–20, *Sottera, Inc. v. Food & Drug Admin.*, 627 F.3d 891 (No. 10-5032).

244. *Sottera, Inc. v. Food & Drug Admin.*, 627 F.3d 891, 893 (D.C. Cir. 2010).

245. Brief for Appellee at 25, 38, *Sottera, Inc. v. Food & Drug Admin.*, 627 F.3d 891 (D.C. Cir. 2010) (No. 10-5032).

246. 21 U.S.C. § 321 (rr)(1) (2016) (providing a broad definition of "tobacco product" to extend the FDA's regulatory authority to any product made or derived from tobacco); Brief for Appellee at 2-3, *Sottera, Inc. v. Food & Drug Admin.*, 627 F.3d 891 (D.C. Cir. 2010) (No. 10-5032) (explaining that the FDA conceded that e-cigarettes qualify under the statutory definition of "tobacco products" because they deliver nicotine "made or derived from tobacco").

247. Brief for Appellee at 46, *Sottera, Inc. v. Food & Drug Admin.*, 627 F.3d 891 (D.C. Cir. 2010) (No. 10-5032).

from tobacco,” the company argued that their products, which are derived from tobacco, could only be regulated under the Tobacco Control Act.<sup>248</sup>

In its decision the Court of Appeals admitted that *Brown & Williamson* was not “crystal clear,” but ultimately sided with NJOY holding that electronic cigarettes fit into the definition of “tobacco product” under the Tobacco Control Act and Congress did not intend for tobacco products to be regulated as drug/devices absent a therapeutic claim.<sup>249</sup> Rather than appeal the decision, FDA elected to regulate NJOY and other ENDS products under its tobacco control authority through the “deeming rule” process outlined in the Tobacco Control Act.<sup>250</sup>

## VII. THE “DEEMING RULE”

The Tobacco Control Act grants FDA immediate authority to regulate cigarettes, cigarette tobacco, smokeless tobacco, and roll-your-own tobacco, and contains specific prohibitions on the advertising and sale of these products.<sup>251</sup> The Act does not expressly regulate other tobacco products such as cigars, pipe tobacco, hookah, or ENDS, but FDA may promulgate regulations governing any product derived from tobacco.<sup>252</sup> In order to extend agency oversight to include other tobacco products such as ENDS, FDA must first issue regulations “deeming” the product as subject to its tobacco regulatory authority.<sup>253</sup> Once deemed, the agency may regulate the manufacturing, distribution, marketing, and sale of any tobacco product.<sup>254</sup>

On April 25, 2014, nearly five years after the Tobacco Control Act was enacted, FDA published the proposed Deeming Rule in the *Federal Register*.<sup>255</sup>

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248. *Id.* at 2, 24–5.

249. *Sottera, Inc.*, 627 F.3d at 891, 893 (finding *Brown & Williamson* not “crystal clear” because the case focused on the FDA’s authority under the drug/device provisions of the FDCA, rather than on the particular products that the statute covers).

250. 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, 79 Fed. Reg. 23,142 (Apr. 25, 2014), available at <https://www.gpo.gov/fdsys/pkg/FR-2014-04-25/pdf/2014-09491.pdf> (explaining the decision not to appeal *Sottera* and instead extend its control to other types of tobacco products that meet the statutory definition of “tobacco product”); Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, § 901(b), 123 Stat. 1776 (2009) (codified at 21 U.S.C. 387a(b)) (“This chapter shall apply to all... other tobacco products that the Secretary by regulation deems to be subject to this chapter.”).

251. *Id.* (indicating that all the prohibitions outlined in the act apply immediately to “cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco”).

252. *Id.*

253. *Id.*

254. Family Smoking Prevention and Tobacco Control Act, § 901(b), 906(d) Pub. L. No. 111-31, 123 Stat. 1776 (2009) (codified at 21 U.S.C. 387a(b)) (2012) (applying all the regulations in the act regarding manufacturing, distribution, marketing and sale to tobacco products deemed within their jurisdiction by regulation).

255. Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for

The proposed rule extended agency jurisdiction to all other present and future products derived from tobacco, specifically including ENDS, cigars, pipe tobacco, nicotine gels, waterpipe/hookah tobacco, and dissolvable tobacco products.<sup>256</sup> More than 135,000 comments were filed in response to the draft rule.<sup>257</sup> FDA reviewed each submission, as required by statute, prior to submitting the final rule to the White House Office of Management and Budget (OMB) for approval.<sup>258</sup> OMB approval resulted in the removal of several proposed regulations including the banning of flavors and premarket approval for ENDS.<sup>259</sup> The final rule was published more than two years later, on May 10, 2016, with an effective date of August 8, 2016,<sup>260</sup> although many provisions governing ENDS manufacturers have later effective dates.<sup>261</sup>

The Deeming Rule is a foundational rule that authorizes FDA to regulate all products derived from tobacco.<sup>262</sup> The rule also triggers specific requirements and restrictions for tobacco manufacturers and retailers.<sup>263</sup> All newly deemed tobacco product manufacturers must register with the FDA and report product and ingredient listings; only market new products after FDA review; not make reduced risk claims without scientific data and FDA approval; not distribute free samples; and pay user fees.<sup>264</sup> In addition, retailers may not sell tobacco products to individuals under 18 years of age and must check ID for anyone appearing to

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Tobacco Products, 79 Fed. Reg. 23,142, 23,148 (Apr. 25, 2014) (codified at 21 C.F.R. pts. 1100, 1140, 1143).

256. *Id.* at 23,143.

257. Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 81 Fed. Reg. 28,974, 28,982 (May 10, 2016) (codified at 21 C.F.R. pts. 1100, 1140, 1143), available at <https://www.gpo.gov/fdsys/pkg/FR-2016-05-10/pdf/2016-10685.pdf>.

258. See 5 U.S.C. § 553 (2012) (requiring administrative agencies to consider relevant comments); see also *FDA Rules and Regulations*, U.S. FDA, <https://www.fda.gov/RegulatoryInformation/RulesRegulations/> (last visited Mar. 10, 2017) (explaining after issuing a proposed rule, it reviews the comments and if the proposed or final rule is “significant” the OMB must review it).

259. Desmond Jenson & Joelle Lester, *FDA Overruled By White House On Removing Flavored Cigars and E-Cigarette Liquids From The Market*, PUB. HEALTH L. CTR. (June 2, 2016), <http://publichealthlawcenter.org/blogs/2016-06-02/fda-overruled-white-house-removing-flavored-cigars-and-e-cigarette-liquids-market>.

260. Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic 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) (codified at 21 C.F.R. pts. 1100, 1140, 1143).

261. *Id.* at 29,003.

262. *Id.* at 28,982, 29,003.

263. *Id.* at 29,057.

264. Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 79 Fed. Reg. 23,142, 23,148 (Apr. 25, 2014) (codified at 21 C.F.R. pts. 1100, 1140, 1143).

be under 27 years of age; vending machine sales are prohibited except in adult-only facilities.<sup>265</sup>

In the Deeming Rule, FDA also clarified that all ENDS products are subject to the Tobacco Control Act and that most provisions regulating cigarettes, smokeless tobacco, and roll-your-own tobacco will extend to these products, including premarket approval.<sup>266</sup> Under the Act, manufacturers of new tobacco products must secure FDA authorization prior to marketing their product.<sup>267</sup> The agency will consider several factors in determining whether a product is new and therefore subject to the premarket approval process, but the most important is whether a “substantially equivalent” tobacco product was commercially available on or before February 15, 2007.<sup>268</sup> This issue is critical for ENDS manufacturers because there is uncertainty as to whether any electronic devices containing liquid nicotine were on the U.S. market by this date.<sup>269</sup> Without a substantially equivalent product, ENDS manufacturers must undergo the lengthy, costly, and uncertain premarket tobacco application process.<sup>270</sup>

As discussed earlier, Favor Smokeless Cigarettes – electronic smoking devices that aerosolized liquid nicotine – were briefly marketed in the mid-1980s, but these devices were non-flavored.<sup>271</sup> Moreover, while Favor Smokeless Cigarettes resembled closed-system cig-alikes in size and design, they are likely not similar enough to the large tank open systems that dominate the ENDS market today for substantial equivalence. The Deeming Rule permits

265. Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 79 Fed. Reg. 23,142, 23,160, 23,162 (Apr. 25, 2014) (codified at 21 C.F.R. pts. 1100, 1140, 1143).

266. Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 81 Fed. Reg. 28,974, 28,993, 29,035 (May 10, 2016) (codified at 21 C.F.R. pts. 1100, 1140, 1143).

267. *Id.* at 28,990, 29,035.

268. *Id.* at 28,991.

269. *See, e.g.,* Daniela Saitta et al., *Achieving Appropriate Regulations for Electronic Cigarettes*, 5 THERAPEUTIC ADVANCES CHRONIC DISEASE 50, 61 (2014) (stating that “[p]roducts introduced after that date would need to prove that they are ‘substantially equivalent’ to products that were on the market on or before 15 February 2007... [t]he unintended consequence of applying this provision to e-cigarettes would be to remove from the market products that have undergone significant improvements, freezing the technology at a stage of development when battery life was too short, vapour production was inconsistent and cartridges leaked...”).

270. 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, 29,079 (May 10, 2016) (codified at 21 C.F.R. pts. 1100, 1140, 1143) (providing three marketing pathways for new tobacco products – substantial equivalence to a valid predicate product, exemption, and premarket tobacco product application).

271. *Reducing the Health Consequences of Smoking: 25 Years of Progress*, U.S. DEP’T HEALTH & HUM. SERVS. (1989), available at <https://profiles.nlm.nih.gov/ps/access/NNBBXS.pdf> (describing how FDA determined that the Favor Smokeless Cigarette was a “new drug” under the FDCA).

ENDS manufacturers to continue marketing their products for up to 3 years if they submit substantial equivalence or premarket tobacco applications, but industry experts claim premarket approval would be catastrophic for the ENDS market.<sup>272</sup> Several lawsuits have been filed challenging FDA's decision to subject ENDS to the premarket approval process.<sup>273</sup> In addition, Congress could step-in and alter the substantial equivalence date to accommodate ENDS manufacturers or otherwise exempt the devices from premarket approval.<sup>274</sup> The regulatory landscape post-deeming remains uncertain for ENDS, but the devices are expected to stay on the market until FDA and the industry determine the appropriate pathway to regulation.

FDA can and will adopt additional rules in the future regulating the newly deemed tobacco products, including ENDS.<sup>275</sup> These rules could restrict ingredients or limit concentrations, restrict online sales, ban flavored products or self-service displays (both of which currently apply to cigarettes), or limit advertising and promotion.<sup>276</sup> The Deeming Rule represents the beginning, not the end, of ENDS regulation. FDA may enact, and is expected to pursue, a wide variety of provisions not specified in the Deeming Rule in order to protect public health.

#### A. Child Nicotine Poisoning Prevention Act

While the long-term health effects of ENDS use remain uncertain, acute exposure to liquid nicotine can result in immediate adverse health effects, particularly in young children. As little as 1 tablespoon of liquid nicotine is

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272. Burke, *supra* note 60 (stating that “if the FDA’s current approach is implemented, producers would be required to remove every single product from the market and submit expensive and burdensome applications for the chance to allow their products to stay on the market”).

273. Lydia Wheeler, *Lawsuits Mount Against FDA Regs on E-cigarettes*, THE HILL (Jul. 10, 2016), <http://thehill.com/regulation/court-battles/287056-lawsuits-mount-against-fda-regs-on-e-cigarettes> (“five lawsuits have been filed against the agency over the rules finalized... which require any product that hit store shelves after February 2007 to go through a costly approval process”).

274. *Vaporizers, E-Cigarettes, and other Electronic Nicotine Delivery Systems (ENDS)*, FDA, <http://www.fda.gov/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm456610.htm> (last visited Mar. 10, 2017).

275. 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, 28,975 (May 10, 2016) (codified at 21 C.F.R. pts. 1100, 1140, 1143) (explaining that the deeming rule allows them to regulate newly deemed tobacco products appropriately for the protection of public health and they plan to do so).

276. See *Vaporizers, E-Cigarettes, and other Electronic Nicotine Delivery Systems (ENDS)*, *supra* note 274 (explaining that FDA now regulates the “manufacture, import, packaging, labeling, advertising, promotion, sale, and distribution of ENDS”); see also *Commonly Asked Questions: About the Center for Tobacco Products*, FDA, <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/AbouttheCenterforTobaccoProducts/ucm378205.htm> (last visited Mar. 10, 2017) (explaining that the existing framework for traditional cigarettes is being extended to newly deemed tobacco products).

“capable of killing four small children.”<sup>277</sup> Even smaller levels of exposure to liquid nicotine, whether absorbed through the skin or eyes, or ingested, can lead to nausea, cardiac arrest, seizure, or coma.<sup>278</sup> In 2014, poison control centers received more than 4,000 liquid nicotine exposure calls, and over half were for young children.<sup>279</sup>

To address the rising number of accidental liquid nicotine poisonings, Congress enacted the Nicotine Poisoning Prevention Act in January 2015.<sup>280</sup> The Act requires any liquid nicotine container sold in the United States to meet the “special packaging” requirements for hazardous household products.<sup>281</sup> Beginning July 26, 2016, all liquid nicotine containers must be significantly difficult for children under 5 years of age to open, which is the standard for all hazardous household substances.<sup>282</sup> This means 80 % of the children tested are unable to open the packaging within 10 minutes. The Act also grants the Consumer Products Safety Commission (CPSC) the power to enforce the new provisions.<sup>283</sup> Finally, the Act does not limit FDA’s authority over ENDS or liquid nicotine.<sup>284</sup> Rather, FDA is permitted to otherwise regulate liquid nicotine, including adopting more stringent packaging standards.<sup>285</sup>

#### VIII. STATE AND LOCAL POLICY RECOMMENDATIONS

Prior to the Tobacco Control Act, tobacco products were primarily regulated at the state and local level.<sup>286</sup> With its passage, FDA stepped to the fore of tobacco regulation, establishing and administering a comprehensive federal tobacco control program.<sup>287</sup> The agency now regulates the manufacture, marketing, labeling, distribution, and sale of tobacco products; develops mass media campaigns to educate the public about the dangers of tobacco products;

277. S. REP. NO. 114-12, at 1–2 (2015).

278. Neal L. Benowitz et al., *Prolonged Absorption with Development of Tolerance to Toxic Effects After Cutaneous Exposure to Nicotine*, 42 CLINICAL PHARMACOLOGY & THERAPEUTICS 119, 119–20 (1987).

279. *E-Cigarettes and Liquid Nicotine*, AM. ASS’N POISON CONTROL CTRS., <http://www.aapcc.org/alerts/e-cigarettes/> (last visited Mar. 10, 2017).

280. Child Nicotine Poison Prevention Act of 2015, Pub. L. No. 114-116, 130 Stat. 3 (codified at 15 U.S.C. § 1471 (2016)).

281. *Id.*

282. *Liquid Nicotine Packaging Surveillance Revised Guidance*, U.S. CONSUMER SAFETY COMM. (July 22, 2016), <https://www.icphso.org/files/cpsc/cpsc-guidance-liquid-nicotine.pdf> (informing the industry that all liquid nicotine must be sold in “special packaging” as of July 26, 2016); 16 C.F.R. § 1700.1(a) (2016) (defining “special packaging” as packaging that is “significantly difficult for children under 5... to open”).

283. Child Nicotine Poisoning Prevention Act of 2015, Pub. L. No. 114-116, 130 Stat. 3 (2016) (codified at 15 U.S.C. §1471).

284. *Id.*

285. *Id.*

286. Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009).

287. *Id.* (adding additional regulations and legislation to tobacco and other drugs in order to assist in preventing adolescent drug use due to recent failures to prevent wide-spread drug use).

and funds and directs scientific research to better understand the harms associated with tobacco use and how to reduce them.<sup>288</sup> Through the Deeming Rule FDA also expanded its jurisdiction to include any product derived from tobacco, including ENDS.<sup>289</sup> But, the Tobacco Control Act and the Deeming Rule leave significant gaps in regulation.<sup>290</sup> Gaps that state and local governments are expressly authorized by the Tobacco Control Act to fill.<sup>291</sup>

In 2014, the Surgeon General released *The Health Consequences of Smoking – 50 Years of Progress*, a 900-page report highlighting the progress made to reduce tobacco use in the United States and looking ahead to the immense burdens still presented by smoking.<sup>292</sup> Chapter 14 of the report identifies the most effective tobacco control measures for decreasing youth tobacco use: (1) taxation/price increases, (2) restricting indoor use, (3) restricting youth access, and (4) bans and restrictions on advertising and promotion.<sup>293</sup> These measures have been largely credited with reducing youth cigarette smoking rates from 28 % in 1991 to 9.3 % in 2015.<sup>294</sup> Yet, federal laws mostly do not extend these effective measures to ENDS.<sup>295</sup>

Cigarettes are subject to a \$1.01 per pack federal excise tax, while ENDS and e-liquid are not subject to any federal taxation.<sup>296</sup> The Deeming Rule extends youth sales and ID check provisions to ENDS, but not the bans on self-service displays and flavored products.<sup>297</sup> Cigarette advertising is heavily regulated, with bans on television and radio ads, event sponsorship, promotional items, and

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288. Mitchell Zeller, *Progress and Challenges: The State of Tobacco Use and Regulation in the U.S.*, FOOD & DRUG ADMIN. (May 15, 2014), <https://www.fda.gov/NewsEvents/Testimony/ucm397399.htm>.

289. 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) (to be codified at 21 C.F.R. pts. 1100, 1140, 1143).

290. *State and Local Tobacco Regulation in a Post-Deeming World*, TOBACCO CONTROL LEGAL CONSORTIUM, <http://publichealthlawcenter.org/sites/default/files/resources/tclc-fda-deemingreg-state-and-local-regulation-2016.pdf> (last updated May, 2016) (noting there are gaps for smokeless tobacco, cigars, e-cigarettes and others in areas like prohibition on self-service displays, minimum package size requirements, prohibition on characterizing flavors and required notice of advertising in a non-traditional medium).

291. Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776, 1823 (2009).

292. OFFICE OF THE SURGEON GENERAL, U.S. DEP'T OF HEALTH AND HUMAN SERVICES, *THE HEALTH CONSEQUENCES OF SMOKING – 50 YEARS OF PROGRESS* (2014).

293. *Id.* at 788.

294. *Cigarette Smoking Among U.S. High School Students at an All-Time low, but E-Cigarette Use a Concern*, CDC (2016), <https://www.cdc.gov/media/releases/2016/p0609-yrbs.html>.

295. Michael Freiburg, *Options for State and Local Governments to Regulate Non-Cigarette Tobacco Products*, 21 ANNALS HEALTH L. 407 (Dec. 2012).

296. *Federal Excise Tax Increase and Related Provisions*, ALCOHOL & TOBACCO TAX & TRADE BUREAU, [https://www.ttb.gov/main\\_pages/schip-summary.shtml](https://www.ttb.gov/main_pages/schip-summary.shtml) (last updated Sept. 4, 2012) (listing tobacco products subject to federal taxes, a list that does not include ENDS or e-liquid products).

297. *State and Local Tobacco Regulation in a Post-Deeming World*, *supra* note 290.

magazines with youth readership.<sup>298</sup> In contrast, ENDS may be marketed on any medium, including TV, radio, magazines, billboards, and the internet.<sup>299</sup>

As discussed, the Tobacco Control Act preserves the authority of state and local governments to further regulate ENDS.<sup>300</sup> The following are evidence-based policy interventions that communities across the country have implemented to reduce youth tobacco use. These policies can and should be extended to ENDS to tackle rising youth use, and a growing number of jurisdictions have applied many of these provisions to ENDS. In some instances, these are laws passed to apply specifically to ENDS; in others, jurisdictions are choosing to incorporate ENDS into laws that already regulate tobacco products and new provisions regulating tobacco products. The dynamic of including ENDS in laws regulating tobacco products should expand now that FDA has deemed ENDS to be tobacco products.<sup>301</sup>

#### A. Retail Licensing

Retail tobacco licensing laws require businesses to secure a license prior to selling tobacco products.<sup>302</sup> The license enables the state or local government to identify tobacco retailers and conduct enforcement checks to ensure compliance with tobacco regulations.<sup>303</sup> Jurisdictions may also use retail licensing to restrict the density and location of tobacco retailers or suspend or revoke the ability to sell tobacco products for failure to adhere to tobacco regulations.<sup>304</sup>

At least 40 states and the District of Columbia require tobacco retailers to secure a retail tobacco license.<sup>305</sup> In contrast, only 14 states and the District of

298. Public Health Cigarette Smoking Act of 1969, Pub. L. No. 91-222 § 6, 84 Stat. 87, 89 (1970) (making it illegal to advertise cigarettes on any medium of electronic communication subject to the jurisdiction of the FCC); 21 C.F.R. §§ 1140.32, 1140.34 (2016) (prohibiting cigarette advertisements in youth magazines, promotional material, and sponsorship of events).

299. *Electronic Nicotine Delivery System: Key Facts*, CDC OFF. ON SMOKING & HEALTH, <https://www.cdc.gov/tobacco/stateandcommunity/pdfs/ends-key-facts-oct-2016.pdf>.

300. Family Smoking Prevention and Tobacco Control Act, Pub. L. 111-31, 123 Stat. 1776, 1823 (2009) (codified as 21 U.S.C. §387p(a)(1)).

301. Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, 81 Fed. Reg. 28974, 29028 (May 10, 2016) (to be codified at 21 C.F.R. pts. 1100, 1140, and 1143). Although FDA now considers ENDS to be tobacco products by definition, most state and local laws define tobacco product differently such that the law needs to be amended to include ENDS in any tobacco product regulation. See Lauren K. Lempert et al., *The importance of product definitions in US e-cigarette laws and regulations*, TOBACCO CONTROL, (2014), [https://tobacco.ucsf.edu/sites/tobacco.ucsf.edu/files/u795/glantz\\_tobcontrol\\_ecig\\_laws%20and%20regs.2014.pdf](https://tobacco.ucsf.edu/sites/tobacco.ucsf.edu/files/u795/glantz_tobcontrol_ecig_laws%20and%20regs.2014.pdf) (explaining that most state laws define “tobacco product” differently than FDA).

302. Ian McLaughlin, *License to Kill?: Tobacco Retailer Licensing as an Effective Enforcement Tool*, TOBACCO CONTROL L. CONSORTIUM, 1,1 (Apr. 2010), <http://publichealthlawcenter.org/sites/default/files/resources/tclc-syn-retailer-2010.pdf>.

303. *Id.* at 2.

304. *Id.* at 8.

305. See *Nationwide Tobacco Retailer License Fees*, LEGAL RES. CTR. FOR PUB. HEALTH POL’Y, [https://www.law.umaryland.edu/programs/publichealth/documents/Nationwide\\_Tobacco\\_Retailer\\_License\\_Fees\\_One\\_Pager.pdf](https://www.law.umaryland.edu/programs/publichealth/documents/Nationwide_Tobacco_Retailer_License_Fees_One_Pager.pdf) (last updated May, 2016) (ranking annual tobacco retailer license fees by state).



Columbia have incorporated ENDS into existing retail tobacco licensing schemes or enacted ENDS-specific licensing provisions.<sup>306</sup> This means that in 36 states, the location, prevalence, and density of ENDS retailers is unknown.<sup>307</sup> The rise of vape shops, which generally do not sell traditional tobacco products and therefore are not required to secure a special trader's license, further complicates this issue. Active tobacco compliance check programs are the most effective measure at reducing youth tobacco access and licensing fees can be used to support enforcement efforts.<sup>308</sup> Without being able to identify the stores selling ENDS, enforcement entities are incapable of preventing youth access to tobacco products.

### *B. Advertising and Promotion Bans*

In 2014, more than 18 million middle and high school students (7 in 10) were exposed to ENDS advertising in retail stores, the internet, magazines and newspapers, and television and movies.<sup>309</sup> ENDS industry advertising expenditures increased from \$6 million to \$115 million between 2011 and 2014, and over this same time youth use more than quadrupled.<sup>310</sup> The Tobacco Control Act authorizes state and local governments to regulate the time, place and manner of ENDS advertising.<sup>311</sup> This means that communities may limit the location, number, and size of ENDS ads at retail outlets, including prohibiting ads near cash registers or at youth eye level. Interested communities should be aware that attempts to regulate ENDS advertising must comply with the First Amendment, state constitutional law, and the Federal Cigarette Labeling and

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306. See *U.S. E-Cigarette Regulation: A 50-State Review*, TOBACCO CONTROL L. CONSORTIUM, 4, 8, 18, 26–27, 30–32, 34–35, 43, 45, 56, 67, 74–77, 81 (June 15, 2016), <http://publichealthlawcenter.org/sites/default/files/tclc-50state-The-Legal-Landscape-for-Electronic-Cigarettes-2016.pdf> (listing those states as: Arkansas, California, Indiana, Iowa, Kansas, Louisiana, Maine, Missouri, Montana, North Carolina, Rhode Island, Utah, Washington and Vermont).

307. *Id.*

308. See Lindsay F. Stead & Tim Lancaster, *A Systematic Review of Interventions for Preventing Tobacco Sales to Minors* 9 TOBACCO CONTROL 169, 175 (2000), <http://tobaccocontrol.bmj.com/content/tobaccocontrol/9/2/169.full.pdf> (explaining that the successful interventions used a variety of active compliance check strategies including personal visits and mobilizing community support); see also McLaughlin, *supra* note 302, at 2 (noting the benefits of self-funding licensing fee programs).

309. *E-Cigarette Ads and Youth*, CDC (Jan. 5, 2016), <http://www.cdc.gov/vitalsigns/ecigarette-ads/>.

310. *Id.*

311. Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776, 1823 (2009) (codified at 21 U.S.C. § 387p (2012)).

Advertising Act.<sup>312</sup> Recent attempts to restrict retail advertising have been met with legal challenges from the tobacco industry, with mixed results.<sup>313</sup>

### C. Sales Restrictions

Sales restrictions are among the most effective strategies to reduce youth tobacco use. These restrictions include raising the minimum sales age, restricting the sale of flavored products, and restricting self-service displays.<sup>314</sup> Following the Deeming Rule federal law sets the minimum age to purchase any tobacco product at 18 years, but state or local governments may raise the age of access.<sup>315</sup> Four states (Alabama, Arkansas, New Jersey, and Utah) set the minimum sales age at 19, while two others (California and Hawaii) have recently raised it to 21.<sup>316</sup> More than 100 localities have joined California and Hawaii in raising the minimum sales age to 21 including Boston, Chicago, Cleveland, and New York.<sup>317</sup> While primarily targeted at cigarettes, minimum age sales restrictions generally incorporate ENDS into the law.<sup>318</sup> Preliminary studies indicate that raising the minimum sales age significantly reduces tobacco use by youth age 12-17 years old.<sup>319</sup>

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312. *Restricting Tobacco Advertising*, TOBACCO CONTROL L. CONSORTIUM, 3–4, <http://publichealthlawcenter.org/sites/default/files/resources/tclc-guide-restricttobadvert-2011.pdf> (last updated May 2011).

313. See Arlen W. Langvardt, *Tobacco Advertising and the First Amendment: Striking the Right Balance*, 5 WM. & MARY BUS. L. REV. 331, 335 (2014), <http://scholarship.law.wm.edu/wmblr/vol5/iss2/2> (discussing circuit split resulting from tobacco company challenges to tobacco advertising and promotion regulations).

314. INSTITUTE OF MEDICINE, PUBLIC HEALTH IMPLICATIONS OF RAISING THE MINIMUM AGE OF LEGAL ACCESS TO TOBACCO PRODUCTS (Richard J. Bonnie et al. eds., 2015); Bridget Ambrose et al., *Flavored Tobacco Product Use Among US Youth Aged 12–17 Years, 2013-2014*, 314 J. AM. MED. ASS'N 1871, 1872 (2015) (finding that flavors make tobacco products attractive to youth users and about 80% of youth users of tobacco consumed flavored products); Marianne Wildey et al., *Self-Service Sale of Tobacco: How it Contributes to Youth Access*, 4 TOBACCO CONTROL 355 (1995).

315. 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. 90 (proposed May 10, 2016) (to be codified at 21 C.F.R. pts. 1100, 1140, 1143); 21 U.S.C. §387(p) (allowing states to regulate tobacco access more stringently than federal law permits).

316. ALA. CODE §§ 28-11-2, 28-11-3; ALASKA STAT. § 11.76.100 (2016); N.J. STAT. ANN. § 2A:170-51.4 (West 2010); UTAH CODE ANN. § 76-10-104 (2010); Adam Nagourney, *California Raising Smoking Age to 21*, N.Y. TIMES, May 4, 2016, at A14, available at <http://www.nytimes.com/2016/05/05/us/california-raising-smoking-age-to-21.html>.

317. See *Tobacco 21 Cities*, TOBACCO 21, <http://tobacco21.org/wp-content/uploads/2014/02/Tobacco-21-Cities-new-5.pdf> (last visited Feb. 19, 2017) (listing all municipalities that have increased the purchase age for tobacco products to 21).

318. Kristy Marynak et al., *State Laws Prohibiting Sales to Minors and Indoor Use of Electronic Nicotine Delivery Systems – United States, November 2014*, 63 MORBIDITY & MORTALITY WKLY. REP. 1145 (2014), <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6349a1.htm> (explaining that as of November 2014, 40 states have prohibited the sale of ENDS to minors).

319. Shari Kessel Schneider et al., *Community Reductions in Youth Smoking After Raising the Minimum Tobacco Sales Age to 21*, 25 TOBACCO CONTROL 355, 355–58 (2016).

The Tobacco Control Act bans the sale of flavored cigarettes and the use of self-service displays for cigarettes and smokeless tobacco (e.g., customer may directly handle the product).<sup>320</sup> Despite their effectiveness in reducing youth smoking rates, the Deeming Rule did not extend these provisions to ENDS.<sup>321</sup> As mentioned earlier, FDA originally included a flavor ban in its draft final rule, but the White House Office of Management and Budget removed this provision.<sup>322</sup> Flavored ENDS products are extremely popular among youth and likely play a role in ENDS initiation.<sup>323</sup> More than 85 % of youth ENDS users prefer flavored products and more than 80 % use ENDS because “they come in flavors I like.”<sup>324</sup> A handful of municipalities, including Chicago, Illinois, Minneapolis, Minnesota, New York, New York, and Providence, Rhode Island have enacted sales restrictions on flavored tobacco products.<sup>325</sup> The tobacco industry challenged the Chicago, New York, and Providence ordinances, arguing that the flavor restrictions were preempted by the Tobacco Control Act and unconstitutional.<sup>326</sup> Each was held to be a legal and valid use of local authority.<sup>327</sup>

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320. Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (codified as amended in scattered sections of 15 U.S.C. and 21 U.S.C.); 21 C.F.R. §§ 1140.14(c), 1140.16(c) (2014) (banning the sale of tobacco products which do not require a face-to-face interaction, such as in a vending machine).

321. 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. 28974, 29041 (May 10, 2016) (to be codified at 21 C.F.R. pts. 1100, 1140, 1143) (the FDA noting in response to Comment 166 that restrictions on self-service displays will not apply to newly-deemed ENDS products).

322. *Deeming Final Rule as Cleared by OMB*, REGULATIONS.GOV, FDA-2014-N-0189-83195 (posted May 27, 2016), available at <https://www.regulations.gov/docket?D=FDA-2014-N-0189> (deleting all language enforcing a flavor ban).

323. Ambrose et al., *supra* note 314, at 1871–72 (finding that the majority of youth who have tried tobacco report that their first product was flavored and that flavoring is a reason for use across product types).

324. Ambrose et al., *supra* note 314 at 1872.

325. CHI., ILL., MUN. CODE ch. 4-64-098, 4-64-180 (2013) (banning the sale of flavored tobacco products within 500 feet from a school); MINN., MINN., CODE §13-281.45 (2016) (prohibiting the sale of flavored tobacco products); N.Y.C., NEW YORK, Rules of N.Y.C. §17-715 (2016) (prohibiting the sale of flavored tobacco products); PROVIDENCE, R.I. CODE ch. 14-308, 14-309 (2012) (prohibiting the sale of flavored tobacco except menthol, mint, or wintergreen products).

326. *See 76 Enterprises, Inc. v. City of Chicago*, No. 14-CV-08306 (N.D. Ill. Nov. 4, 2014) (order denying tobacco company’s request for a temporary restraining order against Chicago flavored-tobacco ordinance); *U.S. Smokeless Tobacco Mfg. Co. v. City of N.Y.*, 703 F. Supp. 2d 239 (S.D.N.Y. Mar. 23, 2010) (denying injunction sought by tobacco company against ordinance banning sale of flavored tobacco products); *Nat’l Ass’n of Tobacco Outlets, Inc. v. City of Providence*, 731 F.3d 71 (1st Cir. Sept. 30, 2013) (affirming district court’s judgment in favor of the city against tobacco manufacturer’s challenge to flavored-tobacco ban).

327. *See e.g., Chicago - 76 Enterprises Inc.*, 1:14-cv-08306 at 4 (noting that many jurisdiction’s tobacco control ordinances were considered constitutional and within the valid use of local authority); *see also U.S. Smokeless Tobacco Mfg. Co., LLC*, 703 F.Supp.2d. at 1 (noting that many jurisdiction’s tobacco control ordinances were considered constitutional and within the valid use of local authority); *see also National Ass’n of Tobacco Outlets, Inc.*, 731 F.3d at 89 (noting that many jurisdiction’s tobacco control ordinances were considered constitutional and within the valid use of local authority).

Although the tobacco industry may always push the preemption argument, the statutory language and case law should give confidence to communities considering flavor restrictions. Other hurdles may exist, such as the process of enforcing flavored restrictions, so policymakers should be clear and comprehensive when having such legislation drafted.<sup>328</sup>

#### *D. Indoor Air Restrictions*

Laws restricting indoor smoking are effective at reducing exposure to secondhand smoke and cigarette smoking rates, particularly among youth.<sup>329</sup> As of October 1, 2016, 25 states and the District of Columbia have enacted comprehensive laws restricting smoking in indoor workplaces, including bars and restaurants.<sup>330</sup> In addition, tens of thousands of counties and municipalities have implemented clean indoor air laws.<sup>331</sup> These policies vary by location, but can also include schools, hospitals, college campuses, and other public places.<sup>332</sup>

Most clean indoor air laws restrict the use of a lighted tobacco product in the indoor space; since ENDS do not burn tobacco most clean indoor air laws and policies do not restrict their use.<sup>333</sup> While the long-term effects of secondhand exposure remain uncertain, several public policy arguments support expanding clean indoor air laws to include ENDS. First, permitting ENDS use may make it more difficult to enforce existing clean indoor air laws.<sup>334</sup> Many ENDS brands resemble cigarettes and the devices were specifically designed to mimic the act of smoking.<sup>335</sup> Second, the precautionary principle dictates that in

328. See, e.g., *Regulation Flavored Tobacco Product*, PUB. HEALTH L. CTR. 1, 4 (Sept. 2017) <http://www.publichealthlawcenter.org/sites/default/files/resources/Regulating-Flavored-Tobacco-Products-2017.pdf>, (describing the elements of well-crafted laws that communities can easily enforce them).

329. See, e.g., U.S. DEP’T OF HEALTH AND HUMAN SERVICES, *supra* note 292, at 795 (noting how statutes that restricted indoor smoking led to a reeducation in smoking rates, secondhand smoking exposure, and smoking use in youth populations).

330. See e.g., *U.S. 100% Smokefree Laws in Non-Hospitality Workplaces AND Restaurants AND Bars*, AMERICANS FOR NON-SMOKERS’ RIGHTS, <http://www.no-smoke.org/pdf/WRBLawsMap.pdf> (map and list downloadable as pdf).

331. *Id.*

332. *Id.* (noting that each municipality has unique laws prohibiting indoor use of ENDS with some banning all indoor use while other municipalities ban them in select locations like schools, college campuses, and hospitals).

333. See, e.g., Dustin Heap, *No Smoking Laws For All Fifty States*, SIGNS.COM (May 20, 2014), <https://www.signs.com/blog/no-smoking-laws-for-all-fifty-states/> (noting how most state statutes only cover traditional tobacco products).

334. See, e.g., Kristy Marynak et al., *State Laws Prohibiting Sales to Minors and Indoor Use of Electronic Nicotine Delivery Systems – United States, November 2014*, 63 MORBIDITY & MORTALITY WKLY. REP. 1145 (Dec. 12, 2014), <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6349a1.htm> (explaining how ENDS use could raise hardships in enforcement of smoke-free policies).

335. Chen et al., *supra* note 4 at 356 (describing closed system e-cigarettes as designed to look like regular cigarettes); see also *E-cigarettes: What are Electronic Cigarettes?*, QUIT.ORG, <http://www.quit.org.au/resource-centre/policy-advocacy/policy/e-cigarettes1> (last visited Mar. 10, 2017) (stating that ENDS are designed to simulate the act of smoking).

cases of serious threats to health (or the environment) scientific uncertainty should not be used to delay preventative measures.<sup>336</sup> The devastating toll tobacco has taken on the United States and the globe is undisputed – more than 100 million people were killed by tobacco during the 20<sup>th</sup> century.<sup>337</sup> Until researchers can determine whether and to what extent ENDS aerosol is harmful, the use of these devices should be restricted in indoor areas open to the public. Third, youth are particularly susceptible to tobacco marketing and studies indicate they perceive ENDS as less harmful (or in some cases safe) compared to cigarettes.<sup>338</sup> Permitting indoor ENDS use could reinforce these beliefs and promote youth ENDS use.

State and localities have begun to incorporate ENDS into existing clean indoor air laws.<sup>339</sup> At least 10 states have prohibited ENDS use in indoor workplaces, including bars and restaurants, and more than a dozen others have restricted ENDS use in schools, government facilities, public transportation and similar public venues.<sup>340</sup> In addition, more than 500 hundred counties and municipalities across the country have laws regulating the indoor use of ENDS.<sup>341</sup> None of these acts has been the subject of reported legal challenge; policymakers should be mindful when drafting such a provision to be clear about the basis for the inclusion of ENDS, relying on the current state of the research and noting the precautionary principle.<sup>342</sup>

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336. WHO, THE PRECAUTIONARY PRINCIPLE: PROTECTING PUBLIC HEALTH, THE ENVIRONMENT AND THE FUTURE OF OUR CHILDREN 7 (Marco Martuzzi & Joel A. Tickner eds., 2004), available at [http://www.euro.who.int/\\_data/assets/pdf\\_file/0003/91173/E83079.pdf](http://www.euro.who.int/_data/assets/pdf_file/0003/91173/E83079.pdf).

337. See, e.g., *Global Cancer Prevention and Early Detection*, AM. CANCER SOC'Y, <http://www.cancer.org/aboutus/globalhealth/tobacco-control> (last visiting Mar. 10, 2017) (explaining how 100 million people were killed by tobacco in the 20th century and as many as 1 billion are expected to die in the 21st century).

338. See U.S. DEP'T HEALTH & HUMAN SERVICES, PREVENTING TOBACCO USE AMONG YOUTH AND YOUNG ADULTS: REPORT OF THE SURGEON GENERAL 512 (2012) (noting studies that have found that advertisements often increase adolescents' desire to smoke); see B.K. Ambrose et al., *Perceptions of the Relative Harm of Cigarettes and E-Cigarettes Among U.S. Youth*, 47 AM. J. PREVENTIVE MED., S53-S60, 1, 7 (2014) (indicating that adolescents who perceive a continuum of cigarette related harm consistently perceived e-cigarettes as less harmful than conventional cigarettes).

339. *States and Municipalities with Laws Regulating Use of Electronic Cigarettes*, AM. NONSMOKERS' RIGHTS FOUND. (Jan. 2, 2017), <http://www.no-smoke.org/pdf/ecigslaws.pdf>.

340. *Id.* at 1–2.

341. *Id.* at 4–19.

342. The Federal Aviation Administration has banned the use of ENDS on airplanes. Use of Electronic, 81 Fed. Reg. 11,415 (Mar. 4, 2016) (codified at 14 C.F.R. pt. 252), available at <https://www.gpo.gov/fdsys/pkg/FR-2016-03-04/pdf/2016-04799.pdf>. That ban has been challenged by ENDS manufacturers. Brief for Petitioners, *Competitive Enterprise Institute v. U.S. Dep't of Transp.*, No. 16-1135 (Nov. 22, 2016), available at <http://casaa.org/wp-content/uploads/2016-11-22-cei-final-reply-brief.pdf>. The outcome of that case will likely inform policymakers moving forward with adding ENDS to clean indoor air laws. *Id.*

*E. Taxation and Minimum Price Strategies*

Increases in the purchase price of tobacco products can significantly reduce the prevalence of youth use. Studies estimate that a 10 % increase in price will result in a 5-15 % reduction in overall youth consumption.<sup>343</sup> The two primary methods of increasing tobacco prices are taxation and minimum price laws.<sup>344</sup> The Federal government, all 50 states and the District of Columbia, and hundreds of municipalities impose excise taxes on the sale of cigarettes and other tobacco products.<sup>345</sup> Since 2002, 47 states and the District of Columbia have raised their cigarette excise tax rates a total of 126 times.<sup>346</sup> Over this same time period reported smoking rates among U.S. high school students decreased from 22.2 to 9.3 %.<sup>347</sup> Minimum price laws typically establish a minimum wholesale or retail price under which products may not be sold.<sup>348</sup> Originally intended to prevent predatory price cutting, states and localities have begun to recognize the public health benefit of minimum price laws. In 2013, New York City passed the highest minimum price law in the country, setting the minimum legal price for a pack of cigarettes at \$10.50.<sup>349</sup>

Communities have begun applying similar pricing policies to ENDS in an effort to reduce youth use.<sup>350</sup> Jurisdictions may include ENDS in their definition

343. Chuck Marr & Chye-Ching Huang, *Higher Tobacco Taxes Can Improve Health and Raise Revenue*, CTR. ON BUDGET & POL’Y PRIORITIES 2 (Mar. 19, 2014), <http://www.cbpp.org/sites/default/files/atoms/files/6-19-13tax.pdf>.

344. See *Tobacco Price Promotion: Policy Responses to Industry Price Manipulation*, PUB. HEALTH & TOBACCO POL’Y CTR., 4, 7 (Oct. 2011), <http://www.tobaccopolicycenter.org/documents/Price%20Promotion%20Overview%20FINAL.pdf>.

345. Ann Boonn, *State Cigarette Excise Tax Rates & Rankings*, CAMPAIGN FOR TOBACCO-FREE KIDS (Jan. 3, 2017), available at <http://www.tobaccofreekids.org/research/factsheets/pdf/0097.pdf>.

346. *Id.*

347. See LaTisha Marshall et al., *Youth Tobacco Surveillance — United States, 2001—2002, 55 MORBIDITY & MORTALITY WKL’Y REP.* 1 (May 19, 2006), <https://www.cdc.gov/mmwr/preview/mmwrhtml/ss5503a1.htm> (stating that 22.5 % of high school students in 2002 reported in the National Youth Tobacco Survey that they currently smoked cigarettes); see also *Youth and Tobacco Use*, CTRS. FOR DISEASE CONTROL & PREVENTION, [http://www.cdc.gov/tobacco/data\\_statistics/fact\\_sheets/youth\\_data/tobacco\\_use/](http://www.cdc.gov/tobacco/data_statistics/fact_sheets/youth_data/tobacco_use/) (last updated Apr. 14, 2016) (stating that 9.3 % of high school students reported in 2015 that they smoked cigarettes in the past thirty days).

348. See Tobacco Control Legal Consortium, *Pricing Policy: A Tobacco Control Guide*, CTR. FOR PUB. HEALTH SYSS. SCI. 12 (2014), [https://cphss.wustl.edu/Products/Documents/CPHSS\\_TCLC\\_2014\\_PricingPolicy1.pdf](https://cphss.wustl.edu/Products/Documents/CPHSS_TCLC_2014_PricingPolicy1.pdf) (explaining that minimum price laws typically require a minimum %age markup to be added to the wholesale and/or retail price of cigarettes, which results in a minimum retail price being established for the consumer).

349. See *id.* at 3; see also *Tobacco Price Promotion: Policy Responses to Industry Price Manipulation*, *supra* note 344 at 1.

350. See LEGAL RESOURCE CTR. FOR PUB. HEALTH POL’Y, [https://www.law.umaryland.edu/programs/publichealth/documents/ENDS\\_50-State\\_Survey.pdf](https://www.law.umaryland.edu/programs/publichealth/documents/ENDS_50-State_Survey.pdf) (last visited Mar. 10, 2017) (stating that states such as Louisiana and Kansas have excise taxes); see also Tobacco Control Legal Consortium, *U.S. E-Cigarette Regulation: A 50-State Review*, PUB. HEALTH & TOBACCO POL’Y CTR. 41, <http://publichealthlawcenter.org/sites/default/files/E-Cigarette-Legal->

of cigarettes or other tobacco products, which then subjects these products to the existing product tax, or separately define ENDS in the tax code.<sup>351</sup> Alternatively, ENDS may be taxed based on the volume of e-liquid or the amount of nicotine.<sup>352</sup> Under this method accurately calculating the tax may prove difficult since e-liquid is sold in a wide-range of sizes and nicotine concentrations. For this reason, an ad valorem tax (e.g., based on the price of the product) is preferred, regardless of whether ENDS are incorporated into the existing definition of tobacco products or separately defined in the tax code.

#### IX. CONCLUSION

Because the road to federal regulation of tobacco products was long and arduous—and remains so—federal regulation of ENDS, just about a decade after the product entered the market, seems swift.<sup>353</sup> Yet the FDA deeming rule is a tiny step in the scheme of regulating this ever-changing product that clearly poses some harm to individual and population health yet may hold some promise for smoking cessation. More comprehensive, sound research is needed for policymakers and public health officials to make the best policy decisions regarding the marketing, sale and use of ENDS. As that research progresses and FDA begins to implement the basic provisions applicable to ENDS via the deeming rule, state and local governments are considering policy options to prevent ENDS use from increasing, particularly among youth and those who have never smoked cigarettes. Using the framework of effective tobacco regulation and the preliminary research supporting a need for action, policymakers should consider what restrictions make sense for their communities.

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Landscape-50-State-Review-September-2016.pdf (last visited Mar. 10, 2017) (stating that Minnesota imposes a ninety-five % tax on the wholesale price of e-cigarettes).

351. See LEGAL RESOURCE CTR. FOR PUB. HEALTH POL'Y, *supra* note 350 (stating that e-cigarettes and e-juice are considered tobacco products in Minnesota and are subject to the Tobacco Tax, which is currently ninety-five % of the wholesale cost of any product containing or derived from tobacco).

352. See, e.g., KAN. STAT. ANN. § 79-3399(a) (2015) (“On and after January 1, 2017, a tax is hereby imposed upon the privilege of selling or dealing in electronic cigarettes in this state by any person engaged in business as a distributor thereof, at the rate of \$.20 per milliliter of consumable material for electronic cigarettes and a proportionate tax at the like rate on all fractional parts thereof.”); LA. REV. STAT. ANN. § 47:841F (2017) (“Upon vapor products and electronic cigarettes, a tax of five cents per milliliter of consumable nicotine liquid solution or other material containing nicotine that is depleted as a vapor product is used.”); N.C. GEN. STAT. ANN. § 105-113.35(a1) (2016) (“An excise tax is levied on vapor products at the rate of five cents (5¢) per fluid milliliter of consumable product.”).

353. See *supra* Section VI (describing the decade-long legislative battle that ensued before the President signed into law the Family Smoking Prevention and Tobacco Control Act).

