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2017

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## REGULATORY OBSTACLES TO HARM REDUCTION: THE CASE OF SMOKING

Jonathan H. Adler\*

### INTRODUCTION

Cigarette use remains the leading cause of avoidable death in the United States.<sup>1</sup> Smoking rates have declined over the past several

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<sup>1</sup> See generally DEP'T OF HEALTH & HUMAN SERVS., THE HEALTH CONSEQUENCES OF SMOKING—50 YEARS OF PROGRESS: A REPORT OF THE SURGEON GENERAL (2014), [https://www.cdc.gov/tobacco/data\\_statistics/sgr/50th-anniversary/index.htm](https://www.cdc.gov/tobacco/data_statistics/sgr/50th-anniversary/index.htm); see also Goodarz Danaei et al., *The Preventable Causes of Death in the United States: Comparative Risk Assessment of Dietary, Lifestyle, and Metabolic Risk Factors*, 6 PLOS MED. e100058 (2009) (identifying smoking as leading cause of preventable death). Smoking

decades, but millions of Americans continue to smoke.<sup>2</sup> Many find it difficult to quit, whether due to nicotine addiction or a dependence upon smoking as a behavioral habit.<sup>3</sup>

The inability of many smokers to quit is a significant public health problem. The demand for a product that can help smokers kick the habit is an entrepreneurial opportunity. In surveys, a majority of smokers express concern for their health and a desire to kick the habit.<sup>4</sup> Product innovations that help smokers quit, whether by satisfying nicotine addiction in a less harmful manner or by helping wean smokers from current habits, could reduce the death toll of tobacco and prove profitable for innovative firms. In the case of tobacco harm reduction, entrepreneurs have the opportunity to do well by doing good. Yet, as in many areas, government regulation threatens to hamper welfare-enhancing innovation and discourage the use of life-saving technologies.

Electronic cigarettes (“e-cigarettes” or “e-cigs”) appear to be the most promising smoking alternative to enter the market to date. E-

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may be responsible for up to one-quarter of mortalities for those between 35 and 69 years old in the 1980s. See Prabhat Jha et al., *21st-Century Hazards of Smoking and Benefits of Cessation in the United States*, 368 *NEW ENG. J. MED.* 341, 342 (2013).

<sup>2</sup> See Ahmed Jamal et al., *Cigarette Smoking Among Adults – United States, 2005–2015*, 65 *MORBIDITY & MORTALITY WKLY. REP.* 1205, 1205 (2016) (estimating 36.5 million Americans smoked in 2015); see also Michael C. Fiore, Steven A. Schroeder & Timothy B. Baker, *Smoke, the Chief Killer – Strategies for Targeting Combustible Tobacco Use*, 370 *NEW ENG. J. MED.* 297, 297 (2014) (noting precipitous drop in smoking rates between 1965 and 2012).

<sup>3</sup> See Scott Gottlieb, Comm’r, Food & Drug Admin., Prepared Remarks, Protecting American Families: Comprehensive Approach to Nicotine and Tobacco, (July 28, 2017), at <https://www.fda.gov/NewsEvents/Speeches/ucm569024.htm>. (“[T]oo many people who are addicted to cigarettes today and want to quit are unable to do so”).

<sup>4</sup> See Frank Newport, *Most U.S. Smokers Want to Quit, Have Tried Multiple Times*, GALLUP (July 31, 2013), <http://www.gallup.com/poll/163763/smokers-quit-tried-multiple-times.aspx>.

cigarettes have the potential to satisfy smokers' craving for nicotine in a less dangerous way.<sup>5</sup> The available evidence suggests e-cigarettes expose smokers (and others) to a fraction of the health risks posed by combustible tobacco.<sup>6</sup> For this reason, the use and promotion of e-cigarettes is a potential harm reduction strategy for smoking.<sup>7</sup> Yet the harm reduction potential of e-cigarettes is hampered by federal regulation and the not-so-subtle suggestion from government officials that e-cigarettes are as dangerous as tobacco cigarettes.<sup>8</sup> However well-intentioned, regulatory measures adopted by the Food & Drug Administration (FDA) may come at the expense of public health.

This Article discusses how FDA regulation of e-cigarettes and other alternatives to traditional tobacco products inhibits their life-saving potential. Part I provides a brief overview of federal tobacco

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<sup>5</sup> See *infra* notes 66-69 and accompanying text.

<sup>6</sup> See A. MCNEILL ET AL., PUB. HEALTH ENG., PHE PUB. GATEWAY NO. 2015260 E-CIGARETTES: AN EVIDENCE UPDATE 76 (2015), [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/457102/Ecigarettes\\_an\\_evidence\\_update\\_A\\_report\\_commissioned\\_by\\_Public\\_Health\\_England\\_FINAL.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/457102/Ecigarettes_an_evidence_update_A_report_commissioned_by_Public_Health_England_FINAL.pdf) ("An expert review of the latest evidence concludes that e-cigarettes are around 95% safer than smoked tobacco and they can help smokers to quit."). See also Fiore et al., *supra* note 2, at 297-98 ("[U]p to 98% of tobacco-related deaths are attributable to combustible products . . .").

<sup>7</sup> See Zachary Cahn & Michael Siegel, *Electronic Cigarettes as a Harm Reduction Strategy for Tobacco Control: A Step Forward or a Repeat of Past Mistakes?*, 32 J. PUB. HEALTH POL'Y 16 (2011) ("Harm reduction is a framework for public health policy that focuses on reducing the harmful consequences of recreational drug use without necessarily reducing or eliminating the use itself."). For an early example of tobacco harm reduction advocacy, see Brad Rodu, *Editorial: An Alternative Approach to Smoking Control*, 308 AMER. J. MED. SCI. 32 (1994).

<sup>8</sup> As one tobacco-control advocate commented, "[T]he unintended consequence is more lives are going to be lost." See Sabrina Tavernise, *Safer to Puff, E-Cigarettes Can't Shake Their Reputation as a Menace*, N.Y. TIMES (Nov. 1, 2016), <https://www.nytimes.com/2016/11/02/health/e-cigarette-vape-njoy-bankruptcy.html> (quoting David Abrams of the Truth Initiative).

regulation. Part II discusses electronic cigarettes, their use, and potential health effects. Part III details the FDA's so-called "deeming rule," through which the FDA has asserted regulatory authority over electronic cigarettes and other "vaping" products. Part IV details how FDA restrictions on truthful health information and comparative risk claims further inhibits potentially life-saving innovation by threatening to keep smokers and other consumers in the dark about the harm-reducing potential of e-cigarettes. The article then concludes with broader comments on the risk tradeoffs inherent in technological innovation.

### I. FEDERAL REGULATION OF TOBACCO PRODUCTS

For most of the Twentieth Century, the tobacco industry was largely unregulated.<sup>9</sup> After publication of the Surgeon General's 1964 report on the harms of cigarette smoking,<sup>10</sup> the Federal Trade Commission (FTC) sought to require dramatic warning labels on cigarette packages.<sup>11</sup> Congress responded by mandating milder warnings, preempting state-level efforts to require more explicit

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<sup>9</sup> See generally Peter D. Jacobson et al., *Historical Overview of Tobacco Legislation and Regulation*, 53 J. SOC. ISSUES 75 (1997). For a useful history of tobacco regulation and litigation, see also Bruce Yandle et al., *Bootleggers, Baptists & Televangelists: Regulating Tobacco By Litigation*, 2008 U. ILL. L. REV. 1225 (2008); RICHARD KLUGER, *ASHES TO ASHES: AMERICA'S HUNDRED YEAR CIGARETTE WAR, THE PUBLIC HEALTH, AND THE UNABASHED TRIUMPH OF PHILIP MORRIS* (1997). Until the 1990s, it was generally recognized that the FDA lacked authority over tobacco products under the Food, Drug & Cosmetic Act. See *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 143-55 (2000).

<sup>10</sup> See DEP'T OF HEALTH, EDUC. AND WELFARE, PUB. NO. 1103, *SMOKING AND HEALTH: REPORT OF THE ADVISORY COMMITTEE TO THE SURGEON GENERAL OF THE PUBLIC HEALTH SERVICE* (1964).

<sup>11</sup> *Unfair or Deceptive Advertising and Labeling of Cigarettes in Relation to the Health Hazards of Smoking*, 29 Fed. Reg. 8325 (July 29, 1965) (to be codified at 16 C.F.R. pt. 408).

warnings.<sup>12</sup> A few years later—also in response to more aggressive agency initiatives—Congress prohibited cigarette and cigar advertising on television.<sup>13</sup>

Meaningful federal regulation of tobacco products would not emerge until after plaintiffs' lawyers and state attorneys general were able to impose substantial losses on the major cigarette manufacturers through tort litigation and the imposition of the Master Settlement Agreement (MSA).<sup>14</sup> The MSA required cigarette manufacturers to pay substantial sums to participating states and abide by various restrictions on advertising and promotion. As structured, the agreement also helped protect incumbent producers from potential competition.<sup>15</sup>

In 1996, the Food & Drug Administration sought to regulate cigarettes and other tobacco products under the Food, Drug & Cosmetic Act (FDCA).<sup>16</sup> According to the FDA, nicotine constituted

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<sup>12</sup> See Federal Cigarette Labeling and Advertising Act, Pub. L. No. 89-92, § 5(a), 79 Stat. 283 (1965). The preemption is codified at 15 U.S.C. § 1334(a) (2017). For a discussion of these developments, see Yandle et al., *supra* note 9, at 1249-51; see also *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 513-15 (1992).

<sup>13</sup> See Public Health Cigarette Smoking Act of 1969, Pub. L. No. 91-222, 84 Stat. 87 (1970) (codified as amended at 15 U.S.C. §§ 1331-38); see also 15 U.S.C. § 1335 (2017). As Jack Calfee discusses, major cigarette companies often stood to benefit from the anti-competitive effects of advertising restrictions. See John E. Calfee, *The Ghost of Cigarette Advertising Past*, 10 REG. 35 (1986); see also John E. Calfee, *Cigarette Advertising, Health Information and Regulation Before 1970* (Fed. Trade Comm'n, Working Paper No. 134, 1985).

<sup>14</sup> See Yandle et al., *supra* note 9, at 1270-71.

<sup>15</sup> *Id.* See also Michael Greve, *Compacts, Cartels, and Congressional Consent*, 68 MO. L. REV. 285, 353 (2003) ("In order to protect the original participating manufacturers against new market entrants, the MSA provides non-participating manufacturers with an incentive to join the MSA without incurring proportionate payment obligations—provided, however, that those small manufacturers agree to stabilize their sales at pre-MSA levels.").

<sup>16</sup> See Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. 44,418 (1996).

a “drug” and cigarettes and smokeless tobacco products should be considered “drug delivery devices” under the Act.<sup>17</sup> On this basis, the FDA asserted regulatory jurisdiction over tobacco products and sought to regulate tobacco advertising and promotion. Although the FDA’s rules focused on advertising and promotion directed at children, treating cigarettes and smokeless tobacco as drug-delivery devices created the opportunity for broader regulation of tobacco products, if not their eventual prohibition.

The FDA’s initial effort to regulate cigarettes would not last long. The major tobacco companies challenged the FDA’s authority to regulate tobacco products under the FDCA and ultimately prevailed in the Supreme Court.<sup>18</sup> Despite the seemingly plain language of the Act, the Supreme Court concluded that Congress had not delegated the FDA authority to regulate tobacco.<sup>19</sup> The history of federal legislation concerning tobacco made clear that Congress had no intention to subject cigarettes and other tobacco products to FDA regulation, let alone to create the potential for the FDA to prohibit tobacco products because cigarettes could not be deemed “safe and effective” when used as intended.<sup>20</sup>

The major cigarette producers opposed the FDA’s effort to regulate tobacco products under the FDCA. After the MSA, however, they concluded federal tobacco regulation might be acceptable after all—and potentially even beneficial. The nation’s largest cigarette producer, Altria (aka Philip Morris), encouraged the adoption of

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<sup>17</sup> *Id.* at 44,397, 44,402.

<sup>18</sup> *See* FDA v. Brown & Williamson Tobacco Co., 529 U.S. 120 (2000).

<sup>19</sup> *Id.* at 126 (“Congress has clearly precluded the FDA from asserting jurisdiction to regulate tobacco products.”).

<sup>20</sup> *Id.* (“Such authority is inconsistent with the intent that Congress has expressed in the FDCA’s overall regulatory scheme and in the tobacco-specific legislation that it has enacted subsequent to the FDCA.”).

federal legislation that would give the FDA carefully-tailored authority over cigarettes and other tobacco products.<sup>21</sup> Altria concluded that a new federal law could insulate the industry from future waves of tort litigation while simultaneously limiting competition within the industry.<sup>22</sup> Accordingly, Altria worked with anti-smoking organizations to craft federal legislation it could “live with” as the dominant player in the tobacco industry.<sup>23</sup>

The result of these efforts was the Family Smoking Prevention and Tobacco Control Act of 2009 (“Tobacco Act”),<sup>24</sup> which gave the FDA formal authority to regulate cigarettes and other tobacco products, including those “made or derived from” tobacco.<sup>25</sup> By its terms, the Tobacco Act imposes regulatory restrictions on cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco.<sup>26</sup> It also provided the FDA with the authority to reach other tobacco products, including pipes and cigars and at least some smoking

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<sup>21</sup> See P.A. McDaniel & R.E. Malone, *Understanding Philip Morris’s Pursuit of US Government Regulation of Tobacco*, 14 TOBACCO CONTROL 193 (2005), <http://tobaccocontrol.bmj.com/content/14/3/193.full>.

<sup>22</sup> See Samuel Lowenberg, *Smoke Screen: Why Is Philip Morris Supporting FDA Regulation of Cigarettes?*, SLATE (July 25, 2002), [http://www.slate.com/articles/business/money\\_box/2002/07/smoke\\_screen.html](http://www.slate.com/articles/business/money_box/2002/07/smoke_screen.html).

<sup>23</sup> See Duff Wilson, *Philip Morris’s Support Casts Shadow Over a Bill to Limit Tobacco*, N.Y. TIMES (Mar. 1, 2009), <http://www.nytimes.com/2009/04/01/business/01tobacco.html> (calling the resulting law “the tobacco regulation that Philip Morris can live with.”).

<sup>24</sup> See Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009) (codified in scattered sections of 5, 15, and 21 U.S.C.).

<sup>25</sup> For an overview of the Tobacco Act, see C. STEPHEN REDHEAD & VANESSA K. BURROWS, CONG. RESEARCH SERV., R40475, FDA TOBACCO REGULATION: THE FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT OF 2009 (2009).

<sup>26</sup> See 21 U.S.C. § 387a(b) (2012).



alternatives that compete with tobacco but that could not be regulated under other existing authorities.<sup>27</sup>

The Tobacco Act created a new division within the FDA, the Center for Tobacco Products, which is authorized to develop and impose tobacco regulations and is financed by fees imposed on tobacco companies.<sup>28</sup> The Tobacco Act requires tobacco companies to disclose their product contents<sup>29</sup> and authorizes the FDA to set tobacco product standards.<sup>30</sup> The Act further provides for more explicit warning labels on tobacco products,<sup>31</sup> imposes stringent limits on tobacco product advertising and promotion,<sup>32</sup> and limits the use of flavoring in cigarettes.<sup>33</sup> It also adopts additional controls to prevent tobacco sales to minors.<sup>34</sup>

Significantly for product development and innovation, the Act requires manufacturers to obtain premarket approval for new tobacco products.<sup>35</sup> This requirement does not apply to all products, however. Those products that have been on the market for more than a decade are exempt from the premarket approval requirement. Specifically, the Act grandfathers those products marketed prior to February 15, 2007.<sup>36</sup> The Act also imposes additional restrictions on

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<sup>27</sup> See, e.g., *Sottera, Inc. v. FDA*, 627 F.3d 891, 898 (D.C. Cir. 2010) (holding that the FDA may not regulate e-cigarettes under the FDCA absent therapeutic claims by manufacturers).

<sup>28</sup> See 21 U.S.C. § 387a(e).

<sup>29</sup> See 21 U.S.C. §§ 387d, 387i.

<sup>30</sup> See 21 U.S.C. § 387g.

<sup>31</sup> See 15 U.S.C. § 1333.

<sup>32</sup> See 21 U.S.C. §§ 387f, 387k(g).

<sup>33</sup> See 21 U.S.C. § 387g (a)(1).

<sup>34</sup> See 21 U.S.C. §§ 387f(d)(3).

<sup>35</sup> See 21 U.S.C. § 387j.

<sup>36</sup> *Id.* The FDA has indicated that even relatively modest changes in product design or packaging will be sufficient to identify a product as a new tobacco product, and not substantially equivalent to a product already on the market. See FOOD & DRUG ADMIN.,

“modified risk tobacco products”<sup>37</sup> and authorizes the FDA to “deem” other “tobacco products” to be subject to the Act’s regulatory requirements.<sup>38</sup> In May 2016, the FDA used this authority to “deem” electronic cigarettes to be tobacco products subject to federal regulation.<sup>39</sup>

## II. ELECTRONIC CIGARETTES

### A. THE INDUSTRY

E-cigarettes are a relatively new competitor to cigarettes and conventional tobacco products. First developed in China, e-cigarettes have been marketed in the United States since 2006.<sup>40</sup> Also known as

GUIDANCE FOR INDUSTRY: DEMONSTRATING THE SUBSTANTIAL EQUIVALENCE OF A NEW TOBACCO PRODUCT: RESPONSES TO FREQUENTLY ASKED QUESTIONS (3d ed. Dec. 2016), available at <http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM436468.pdf>.

<sup>37</sup> See 21 U.S.C. § 387k.

<sup>38</sup> Specifically, 21 U.S.C. §387a(b) provides,

This subchapter shall apply to all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and to any other tobacco products that the Secretary by regulation deems to be subject to this subchapter.

The Act defines a “tobacco product” as

any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product). 21 U.S.C. § 321(rr)(1).

<sup>39</sup> Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products; Final Rule, 81 Fed. Reg. 28,974 (May 10, 2016) [hereinafter “Final Deeming Rule”].

<sup>40</sup> See Peter Hajek et al., *Electronic Cigarettes: Review of Use, Content, Safety, Effects on Smokers and Potential for Harm and Benefit*, 109 ADDICTION 1801 (2014), <http://onlinelibrary.wiley.com/doi/10.1111/add.12659/full>; Barbara Demick, *A High Tech Approach to Getting a Nicotine Fix*, L.A. TIMES (Apr. 25, 2009), <http://articles>.

“electronic nicotine delivery systems” (ENDS), e-cigarettes typically consist of a battery-powered atomizer, electronic components, and a cartridge that holds a liquid solution.<sup>41</sup> E-cigarettes come in a variety of forms, including “cigalikes” – which have the shape and appearance of traditional cigarettes and are available in both disposable and rechargeable models – and various forms of modular vaping devices, known as vapors, tanks, and mods (VTMs) that come in a range of shapes and sizes and are refillable.<sup>42</sup>

Despite the label, e-cigarettes are not really cigarettes at all: they do not contain tobacco and their use does not involve combustion or the inhalation of smoke.<sup>43</sup> Instead, e-cigarettes heat and vaporize a propylene-glycol or glycerol solution that typically contains nicotine and some sort of flavoring.<sup>44</sup> Users inhale the vapor as a cigarette

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latimes.com/2009/apr/25/world/fg-china-cigarettes25. Although not developed for retail sale until the 21<sup>st</sup> century, early patents for smokeless delivery of nicotine were filed as early as 1965. See Jordan Paradise, *No Sisyphean Task: How the FDA Can Regulate Electronic Cigarettes*, 13 YALE J. HEALTH POL'Y L. & ETHICS 326, 352-53 (2013).

<sup>41</sup> See Riccardo Polosa et al., *A Fresh Look at Tobacco Harm Reduction: The Case for the Electronic Cigarette*, 10 HARM REDUCTION J. 19, 22 (2013); Chitra Dinakar & George T. O'Connor, *The Health Effects of Electronic Cigarettes*, 375 NEW ENGL. J. MED. 1372, 1372-73 (2016).

<sup>42</sup> The two types of e-cigarette devices are also characterized as “closed system” and “open system,” respectively. See *Nicopure Labs, LLC v. FDA*, No. CV 16-0878 (ABJ), 2017 WL 3130312, at \*11 (D.D.C. July 21, 2017).

<sup>43</sup> See Zachary Cahn & Michael Siegel, *Electronic Cigarettes as a Harm Reduction Strategy for Tobacco Control: A Step Forward or a Repeat of Past Mistakes?*, 32 J. PUB. HEALTH POL'Y 16, 17 (2011); Dinakar & O'Connor, *supra* note 41, at 1372 (noting use of e-cigarettes “is fundamentally different from the combustion of tobacco, and consequently the composition of the aerosol from e-cigarettes and the smoke from tobacco is quite different.”).

<sup>44</sup> See Polosa, et al., *supra* note 41, at 22; Dinakar & O'Connor, *supra* note 41, at 1374; Caroline Franck et al., *Ethical Considerations of E-cigarette Use for Tobacco Harm Reduction*, 17 RESPIRATORY RES. 53, 54-55 (2016). While most e-cigarette fluids contain nicotine, nicotine-free fluids are also available.

user might inhale smoke. For this reason, e-cigarette use is referred to as “vaping.”

E-cigarettes have proven to be a disruptive technology, threatening the market for traditional tobacco products.<sup>45</sup> Initially manufactured and distributed by small firms, e-cigarettes are now made and sold by a range of firms, including the major tobacco companies.<sup>46</sup> By 2015, the market for e-cigarettes and related accessories topped \$3 billion in the U.S., \$8 billion worldwide.<sup>47</sup> Most e-cigarette users appear to be current or former smokers.<sup>48</sup> E-cigarettes are an alternative way for smokers (and others) to consume nicotine at lower risk and (in many jurisdictions) lower cost.<sup>49</sup> Unlike other smoking cessation devices, such as most FDA-approved Nicotine Replacement Therapies (NRTs), e-cigarettes mimic the act

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<sup>45</sup> See generally David B. Abrams, *Promise and Peril of E-Cigarettes: Can Disruptive Technology Make Cigarettes Obsolete*, 311 J. AM. MED. ASS'N 135 (2014).

<sup>46</sup> A 2014 study reported there were over 450 brands of e-cigarettes. See Shu-Hong Zhu, et al., *Four Hundred and Sixty Brands of E-cigarettes and Counting: Implications for Product Regulation*, 23 TOBACCO CONTROL iii3 (2014); see also Dinakar & O'Connor, *supra* note 41, at 1372 (citing estimate of 466 e-cigarette brands and 7764 “unique flavors of e-cigarette products”).

<sup>47</sup> See Jilian Mincer, *The U.S. Vaporizer Market is Booming*, BUS. INSIDER (July 29, 2015), <http://www.businessinsider.com/r-in-rise-of-us-vape-shops-owners-eye-new-marijuana-market-2015-7> (estimating \$35 billion electronic cigarette market in U.S.); Diane Caruana, *E-cigarette Market estimated at USD 44.56 Billion by 2024*, VAPING POST (Aug. 9, 2017), <https://www.vapingpost.com/2017/08/09/e-cigarette-market-estimated-at-usd-44-56-billion-by-2024/> (noting estimate of \$8 billion global market in 2015).

<sup>48</sup> See Final Deeming Rule, *supra* note 39, at 29,036 (“[M]ost ENDS are consumed by smokers and former smokers . . . .”); see also K.E. Farsalinos et al., *Characteristics, Perceived Side-Effects and Benefits of Electronic Cigarette Use: A Worldwide Survey of More than 19,000 Consumers*, 11 INTL J. ENVTL RES. & PUB. HEALTH 4356, 4356 (2014).

<sup>49</sup> See Jonathan H. Adler et al., *Baptists, Bootleggers, & Electronic Cigarettes*, 33 YALE J. ON REG. 313, 335, 357 (2016).

of smoking, potentially satisfying “both pharmacologic and behavioral components of cigarette addiction.”<sup>50</sup>

Over the past decade, the e-cigarette industry developed and evolved rapidly. Low barriers to entry ensured a highly competitive market. The lack of regulation has meant e-cigarette and vaping fluid producers have not needed to seek government approval before marketing or selling new product designs or flavorings. Producers have been free to experiment and innovate in an effort to discover what product designs, features, or characteristics will most satisfy consumer demand. As a consequence, the e-cigarettes on the market today are quite different than those sold five or ten years ago.

The industry itself is marked by a range of participants, from small retailers that sell imported products from China to larger firms, including some tobacco companies. To date, no single firm has been able to maintain a dominant market position.<sup>51</sup> Each year from 2012 through 2015 saw a different brand emerge as the market leader among “cigalike” e-cigarettes.<sup>52</sup> Over this same period, the demand for customizable VTM or “open-system” products also increased.<sup>53</sup> Traditional cigarette companies have invested heavily in this market, acquiring competing firms and taking advantage of their distribution

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<sup>50</sup> See Cahn & Siegel, *supra* note 43, at 17.

<sup>51</sup> See Adler et. al, *supra* note 49, at 337.

<sup>52</sup> See *Id.* at 337. In 2016, NJoy, “once one of the country’s biggest e-cigarette manufacturers” declared bankruptcy. Sabrina Tavernise, *Safer to Puff, E-Cigarettes Can’t Shake Their Reputation as a Menace*, N.Y. TIMES (Nov. 1, 2016), <https://www.nytimes.com/2016/11/02/health/e-cigarette-vape-njoy-bankruptcy.html>.

<sup>53</sup> See K.E. Farsalinos et al., *Nicotine Absorption from Electronic Cigarette Use: Comparison between First and New-Generation Devices*, 4 SCI. REP. 4133 (2014) (reporting increased popularity of open-system devices). There is also some evidence that use of open-system devices is associated with greater success in quitting smoking. See S.C. Hitchman et al., *Associations Between E-cigarette Type, Frequency of Use, and Quitting Smoking: Findings from a Longitudinal Online Panel Survey in Great Britain*, 17 NICOTINE & TOBACCO RES. 1187, 1191 (2015).

networks and market power in retail outlets to push their product lines.<sup>54</sup> Increased regulation could help major cigarette manufacturers establish a dominant position in a less dynamic and less innovative market—which could explain why tobacco companies have been supportive of e-cigarette regulation.<sup>55</sup>

#### B. POTENTIAL HEALTH EFFECTS

Much is still unknown about the potential health effects of e-cigarettes, particularly their prolonged use.<sup>56</sup> Nonetheless, there is a fairly widespread consensus that e-cigarettes pose a tiny fraction of the risks posed by cigarettes.<sup>57</sup> The primary reason for this is that e-cigarettes do not involve combustion and therefore do not expose the user (or others) to the thousands of contaminants that are found in

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<sup>54</sup> See Jilian Mincer & Martinne Geller, *A BAT Deal with Reynolds Adds to Big Tobacco's E-Cig Advantage*, REUTERS (Oct. 25, 2016), <http://www.reuters.com/article/us-reynolds-amricn-m-a-vape-analysis-idUSKCN12P2YW>; Rich Duprey, *Altria Group Inc. Tries to Save the E-Cig Industry*, THE MOTLEY FOOL (Aug. 6, 2016), <https://www.fool.com/investing/2016/08/06/altria-group-inc-tries-to-save-the-e-cig-industry.aspx>.

<sup>55</sup> See Adler et al., *supra* note 49, at 348-49.

<sup>56</sup> See generally Dinakar & O'Connor, *supra* note 41, at 1372 (noting “long-term effects” of e-cigarette use are “unknown”).

<sup>57</sup> See Cahn & Siegel, *supra* note 43, at 18 (“Although the existing research does not warrant a conclusion that electronic cigarettes are safe in absolute terms and further clinical studies are needed to comprehensively assess the safety of electronic cigarettes, a preponderance of the available evidence shows them to be much safer than tobacco cigarettes and comparable in toxicity to conventional nicotine replacement products.”). See generally Hajek et al., *supra* note 40, at 1806 (concluding that e-cigarettes are likely to be much less harmful to users and bystanders than cigarettes); Fiore et al., *supra* note 2, at 298 (“Evidence shows that all the noncombustible delivery vehicles are substantially less dangerous than combustible tobacco products, though that’s not to say they are totally safe.”).

smoke.<sup>58</sup> As the FDA has itself acknowledged, “the inhalation of nicotine (i.e., nicotine without the products of combustion) is of less risk to the user than the inhalation of nicotine delivered by smoke from combusted tobacco products.”<sup>59</sup> As one recent review of the available scientific literature concluded, e-cigarettes “contain some toxicants in concentrations much lower than in tobacco smoke and negligible concentrations of carcinogens.”<sup>60</sup> The FDA likewise noted such findings when proposing to deem e-cigarettes as tobacco products subject to FDA regulation, reporting that “several studies support the notion that the quantity of toxicants [in e-cigarette vapor] is significantly less than those in tobacco cigarettes and tobacco smoke and similar to those contained in recognized nicotine-replacement therapies.”<sup>61</sup>

E-cigarettes also do not appear to pose the same threat to bystanders or non-consumers as do tobacco cigarettes.<sup>62</sup> This is

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<sup>58</sup> Cahn & Siegel, *supra* note 43, at 17 (“Theoretically, we would expect *vaping* to be less harmful than smoking as it delivers nicotine without the thousands of known and unknown toxicants in tobacco smoke.”).

<sup>59</sup> Final Deeming Rule, *supra* note 39, at 28981.

<sup>60</sup> See Hajek et al., *supra* note 40, at 1801; see also Maciej L. Goniewicz, et al., *Exposure to Nicotine and Selected Toxicants in Cigarette Smokers Who Switched to Electronic Cigarettes: A Longitudinal Within-Subjects Observational Study*, 19 NICOTINE & TOBACCO RES. 160 (2017) (finding that after smokers switched to e-cigarettes, exposure to selected carcinogens and toxicants declined substantially, while nicotine exposure was unchanged).

<sup>61</sup> Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products; Proposed Rule, 79 Fed. Reg. 23,157 (April 25, 2014) [hereinafter “Proposed Deeming Rule”].

<sup>62</sup> See Pub. Health Eng., *E-Cigarettes in Public Places and Workplaces* (July 6, 2016), <https://www.gov.uk/government/publications/use-of-e-cigarettes-in-public-places-and-workplaces/e-cigarettes-in-public-places-and-workplaces-a-5-point-guide-to-policy-making> (“[I]nternational peer-reviewed evidence indicates that the risk to the

because e-cigarettes do not produce “side-stream” smoke and do not remain burning while being used (indeed, as already noted, e-cigarettes do not burn at all).<sup>63</sup> Preliminary studies have also failed to identify significant exposures to vapor components in areas where e-cigarettes have been used.<sup>64</sup> Much more research on the health effects of e-cigarettes needs to be done, but the research to date is largely supportive of the claims that vaping is vastly less dangerous than smoking.

Despite the weight of existing research, public health officials in the United States have been ambivalent to hostile about the life-saving and harm-reducing potential of e-cigarettes.<sup>65</sup> Their reticence

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health of bystanders from secondhand e-cigarette vapour is extremely low and insufficient to justify prohibiting e-cigarettes.”)

<sup>63</sup> See MCNEILL ET AL., *supra* note 6, at 76 (noting that “the health risks of passive exposure to electronic cigarette vapour are likely to be extremely low”). Side-stream smoke is one component of secondhand smoke. Different from mainstream smoke, which is secondhand smoke that is exhaled by a smoker, side-stream smoke is produced by the combusting tip of a cigarette or other tobacco product. See *Health Risks of Secondhand Smoke*, AM. CANCER SOC’Y, <http://www.cancer.org/cancer/cancer-causes/tobaccocancer/secondhand-smoke> (last updated Nov. 13, 2015).

<sup>64</sup> See, e.g., LEONARD M. ZWACK, ET AL., U.S. DEP’T OF HEALTH & HUMAN SERVS., HEALTH HAZARD EVALUATION REPORT 2015-0107-3279, EVALUATION OF CHEMICAL EXPOSURES AT A VAPE SHOP 13 (July 2017), <http://www.cdc.gov/niosh/hhe/reports/pdfs/2015-0107-3279.pdf> (employee exposure to diacetyl and 2,3-pentanedione in the air was below applicable occupational exposure limits); Jan Czogala, et al., *Secondhand Exposure to Vapors from Electronic Cigarettes*, 16 NICOTINE & TOBACCO RES. 655 (2014) (reporting e-cigarettes are a source of secondhand exposure to nicotine but not to combustion toxicants). *But see* Wolfgang Schober, et al., *Use of Electronic Cigarettes (E-cigarettes) Impairs Indoor Air Quality and Increases FeNO Levels of E-cigarette Consumers*, 217 INTL. J. HYGIENE & ENVTL HEALTH 628 (2014).

<sup>65</sup> The U.S. Surgeon General produced an alarmist report about youth consumption of e-cigarettes and urging greater government regulation to reduce youth access to vaping products. U.S. DEP’T OF HEALTH & HUMAN SERVS., *E-CIGARETTE USE AMONG YOUTH AND YOUNG ADULTS: A REPORT OF THE SURGEON GENERAL* (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).

Curiously, the Surgeon General’s report did not address the evidence that increases in youth consumption may have come at the expense of youth smoking, and did not even



has not been matched overseas. In 2014, Public Health England (the research arm of the United Kingdom's Department of Health) produced a comprehensive report surveying the available medical literature on e-cigarettes and concluded that e-cigarettes are significantly less harmful than other tobacco products, cigarettes in particular.<sup>66</sup> A follow-up report published in 2015 was even more emphatic about this conclusion.<sup>67</sup> Among other things, the 2015 report cited favorably the conclusion of an international expert panel estimating that e-cigarettes pose no more than five percent of the risk posed by tobacco cigarettes to users and others combined.<sup>68</sup> Recent research seems to indicate a potential for relatively significant and rapid health gains for smokers who switch to e-cigarettes.<sup>69</sup>

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cite (let alone discuss) multiple peer-reviewed studies suggesting that regulatory measures to reduce youth consumption of e-cigarettes could increase traditional cigarette consumption. See Abigail S. Friedman, *How Do Electronic Cigarettes Affect Adolescent Smoking?*, 44 J. OF HEALTH ECON. 300 (2015), <http://www.sciencedirect.com/science/article/pii/S0167629615001150>; Michael F. Pesko et al., *The Influence of Electronic Cigarette Age Purchasing Restrictions on Adolescent Tobacco and Marijuana Use*, 87 PREVENTATIVE MED. 207 (2016), <http://www.sciencedirect.com/science/article/pii/S0091743516000396?via%3Dihub>; Michael F. Pesko & Janet M. Currie, *The Effect of E-Cigarette Minimum Legal Sale Age Laws on Traditional Cigarette Use and Birth Outcomes among Pregnant Teenagers* (Nat'l Bureau of Econ. Research, Working Paper No. 22792, 2016), <http://www.nber.org/papers/w22792>. For a critique of the Surgeon General's report, see Riccardo Polosa et al., *A Critique of the US Surgeon General's Conclusions Regarding E-Cigarette Use among Youth and Young Adults in the United States of America*, 14 HARM REDUCTION J. 61 (2017).

<sup>66</sup> JOHN BRITTON & ILZE BOGDANOVICA, PUB. HEALTH ENG., ELECTRONIC CIGARETTES (2014), [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/311887/E-cigarettes\\_report.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/311887/E-cigarettes_report.pdf).

<sup>67</sup> See MCNEILL ET AL., *supra* note 6.

<sup>68</sup> See David J. Nutt et al., *Estimating the Harms of Nicotine-Containing Products Using the MCDA Approach*, 20 EUR. ADDICTION RES. 218 (2014). The 2015 Public Health UK report concluded this was a "reasonable estimate." MCNEILL ET AL., *supra* note 6, at 80.

<sup>69</sup> See, e.g., Stephen S. Hecht et al., *Evaluation of Toxicant and Carcinogen Metabolites in the Urine of E-Cigarettes Users Versus Cigarette Smokers*, 17 NICOTINE & TOBACCO RES. 704 (2015); Riccardo Polosa, *Electronic Cigarette Use and Harm Reversal: Emerging Evidence*

Because e-cigarettes appear to present far fewer risks than tobacco cigarettes, some public health advocates encourage the use and promotion of e-cigarettes by current smokers.<sup>70</sup> The Royal College of Physicians, for example, has encouraged the promotion of e-cigarettes as an aid in smoking cessation.<sup>71</sup> This view is more widely advanced by public health entities in the United Kingdom than the United States.<sup>72</sup> The FDA, however, has acknowledged that e-cigarettes “may have the potential to reduce the death and disease toll from overall tobacco product use depending on who uses the products and how they are used.”<sup>73</sup>

One reason some public health advocates are open to encouraging e-cigarette use as a potential aid in smoking cessation is because many smokers find it very difficult to quit.<sup>74</sup> Pharmaceutical companies have developed a range of nicotine-containing products to aid in smoking cessation; however, such so-called NRTs, including gums, patches, lozenges, and inhalers, have had limited results.<sup>75</sup> The quit rates for smokers using such products remains disturbingly

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*in the Lung*, 13 BMC MED. 54, 54 (2015) (“[S]mokers completely switching to regular EC use are likely to gain significant health benefits.”).

<sup>70</sup> See, e.g., Franck, et al., *supra* note 44; Cahn & Siegel, *supra* note 7.

<sup>71</sup> See, e.g., ROYAL COLL. OF PHYSICIANS, NICOTINE WITHOUT SMOKE: TOBACCO HARM REDUCTION (Apr., 2016), <https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction-0> (encouraging the use of e-cigarettes and other tobacco alternatives as a means of curbing smoking).

<sup>72</sup> See Sharon H. Green, Ronald Bayer, & Amy L. Fairchild, *Evidence, Policy, and E-Cigarettes – Will England Reframe the Debate?*, 374 N. ENG. J. MED. 1301 (2016), <http://www.nejm.org/doi/10.1056/NEJMp1601154>. See also Sabrina Tavernise, *Safer to Puff, E-Cigarettes Can’t Shake Their Reputation as a Menace*, N.Y. TIMES, Nov. 1, 2016.

<sup>73</sup> Proposed Deeming Rule, *supra* note 61, at 23,147.

<sup>74</sup> See Fiore, et al., *supra* note 2, at 298 (“[M]any smokers build an extensive history of failed quit attempts.”)

<sup>75</sup> See Fiore, et al., *supra* note 2, at 298 (“current smoking-cessation treatments fail for the majority of smokers who use them . . .”).

low.<sup>76</sup> Are e-cigarettes the answer? Not for everyone, but e-cigarettes and similar products can help at least some smokers who are trying to reduce their cigarette consumption or quit altogether.<sup>77</sup> As e-cigarette use has increased, smoking rates have declined. Perhaps more significantly, the increase in e-cigarette use appears associated with an increase in smoking cessation.<sup>78</sup>

Preliminary research suggests that, at least for some smokers, e-cigarettes may be a more effective smoking cessation aid than existing NRTs.<sup>79</sup> One reason for this is that e-cigarettes do a better job of mimicking the smoking experience and smoking-related behaviors than available NRTs.<sup>80</sup> Nicotine addiction is not the only

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<sup>76</sup> See, e.g., David Moore et al., *Effectiveness and Safety of Nicotine Replacement Therapy Assisted Reduction to Stop Smoking: Systematic Review and Meta-Analysis*, 338 BRIT. MED. J. 867 (2009); Shu-Hong Zhu et al., *Interventions to Increase Smoking Cessation at the Population Level: How Much Progress Has Been Made in the Last Two Decades?*, 21 TOBACCO CONTROL 110 (2012). An older survey article indicates the low success rate of NRTs. See J.R. Hughes et al., *A Meta-Analysis of the Efficacy of Over-the-Counter Nicotine Replacement*, 12 TOBACCO CONTROL 21 (2003).

<sup>77</sup> See Jamie Brown, et al., *Real-world Effectiveness of E-cigarettes When Used to Aid Smoking Cessation: A Cross-sectional Population Study*, 109 ADDICTION 1531 (2014).

<sup>78</sup> See Shu-Hong Zhu, et al., *E-cigarette Use and Associated Changes in Population Smoking Cessation: Evidence from US Current Population Surveys*, 358 BMJ 3262 (2017).

<sup>79</sup> See Brown et al., *supra* note 77; Michael D. Stein et al., *An Open Trial of Electronic Cigarettes for Smoking Cessation Among Methadone-Maintained Smokers*, 18 NICOTINE & TOBACCO RES. 1157 (2016); Victoria A. Nelson et al., *Comparison of the Characteristics of Long-Term Users of Electronic Cigarettes Versus Nicotine Replacement Therapy*, 153 DRUG & ALCOHOL DEPENDENCE 300 (Aug. 1, 2015). See also Cristina Russo et al., *Evaluation of Post Cessation Weight Gain in a 1-Year Randomized Smoking Cessation Trial of Electronic Cigarettes*, SCI. REPS. (2016), <http://www.nature.com/articles/srep18763> (finding evidence use of e-cigarettes may help limit post-smoking cessation weight gain). While e-cigarettes may be more effective than existing NRTs for some smokers, most existing research suggests that any smoking cessation aid is more effective when used in combination with behavioral therapy.

<sup>80</sup> See Brown et al., *supra* note 77; see also Dinakar & O'Connor, *supra* note 41, at 1372 (noting e-cigarettes provide "an experience for the user that is closer to cigarette smoking than the forms of nicotine-replacement therapy that have been approved by the Food & Drug Administration").

reason smokers continue to smoke. For at least some smokers, aspects of the addiction are behavioral.<sup>81</sup>

E-cigarette manufacturers have made numerous product design changes over the past decade to make the vaping experience more satisfying to current and former smokers. With continued innovation, the ability of e-cigarettes to help wean smokers from tobacco could further improve. On the other hand, insofar as regulation hampers continued innovation in this market and reduces the availability of e-cigarette products, the harm reduction potential of e-cigarettes is constrained.

None of this is to say that e-cigarettes are risk-free. Some chemicals contained in vaping fluids are potentially toxic, even if they appear to be present at significantly lower levels than cigarette smoke.<sup>82</sup> More concerning to some, many flavoring chemicals have not been subjected to meaningful testing.<sup>83</sup> News reports have highlighted the possibility of e-cigarette battery explosions<sup>84</sup> and the lack of quality control, particularly among smaller manufacturers.<sup>85</sup>

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<sup>81</sup> See Dinakar & O'Connor, *supra* note 41, at 1372.

<sup>82</sup> See MCNEILL ET AL., *supra* note 6, at 80 ("While vaping may not be 100% safe, most of the chemicals causing smoking-related disease are absent and the chemicals that are present pose limited danger."); Dinakar & O'Connor, *supra* note 41, at 1376 (noting potentially toxic substances in e-cigarette aerosol under normal use conditions "are found in substantially lower concentrations . . . that in the smoke from tobacco cigarettes").

<sup>83</sup> See Andrey Khlystov et al, *Flavoring Compounds Dominate Toxic Aldehyde Production During E-Cigarette Vaping*, ENVTL SCI. & TECH. (2016) <http://pubs.acs.org/doi/abs/10.1021/acs.est.6b05145>.

<sup>84</sup> See Elisha G. Brownson, M.D., et al., Letter to the Editor, *Explosion Injuries from E-Cigarettes*, 375 NEW ENGLAND JOURNAL OF MEDICINE 1400 (Oct. 6, 2016).

<sup>85</sup> See 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>; David Barboza, *China's e-Cigarette Boom Lacks Oversight for Safety*, N.Y. TIMES (Dec. 13, 2014), <https://www.nytimes.com/2014/12/14/business/international/chinas-e-cigarette-boom-lacks->

Labeling of e-cigarettes and vaping fluids can be inconsistent, particularly by smaller firms, and nicotine dosages are not always consistent.<sup>86</sup>

The nicotine levels contained in most e-cigarettes do not appear to pose a meaningful health risk,<sup>87</sup> but the concentration of nicotine in vaping fluid can pose significant risks if consumed directly, particularly if consumed by children.<sup>88</sup> The FDA has proposed separate regulations to address this risk directly.<sup>89</sup> Nonetheless, nicotine remains a highly addictive substance, and insofar as e-cigarettes introduce consumers to nicotine, they could provide for a pathway to nicotine addiction and consequent negative health effects. Of course, existing nicotine replacement therapies (NRTs)

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oversight-for-safety-.html (discussing concerns about lack of oversight of imported e-cigarette products, including vaping fluid).

<sup>86</sup> See Britton & Bogdanovica, *supra* note 66, at 7.

<sup>87</sup> See Britton & Bogdanovica, *supra* note 66, at 7; see also U.S. DEP'T OF HEALTH & HUMAN SERVS, *supra* note 65. Cf. Jeremy Samuel Faust, *E-Cigarettes Might Be the Best Addiction to Have*, SLATE (Dec. 13, 2016), [http://www.slate.com/articles/health\\_and\\_science/medical\\_examiner/2016/12/the\\_surgeon\\_general\\_s\\_report\\_on\\_e\\_cigarettes\\_is\\_surprisingly\\_mild.html](http://www.slate.com/articles/health_and_science/medical_examiner/2016/12/the_surgeon_general_s_report_on_e_cigarettes_is_surprisingly_mild.html).

<sup>88</sup> The American Academy of Pediatrics warns that even small amounts of liquid nicotine used to fill e-cigarette or ENDS cartridges can be deadly when consumed by children or spilled on a child's skin. See Trisha Koriath, *Liquid Nicotine Used in E-Cigarettes Can Kill Children*, HEALTHYCHILDREN.ORG (last updated Oct. 20, 2015), <https://www.healthychildren.org/English/safety-prevention/at-home/Pages/Liquid-Nicotine-Used-in-E-Cigarettes-Can-Kill-Children.aspx>.

<sup>89</sup> See Nicotine Exposure Warnings and Child-Resistant Packaging for Liquid Nicotine, Nicotine-Containing E-Liquid(s), and Other Tobacco Products; Request for Comments, 80 Fed. Reg. 37,555 (July 1, 2015). In August 2015, the FDA extended the comment period for a proposed rule intended to reduce the danger liquid nicotine poses to children. See Nicotine Exposure Warnings and Child-Resistant Packaging for Liquid Nicotine, Nicotine-Containing E-Liquid(s), and Other Tobacco Products; Request for Comments; Extension of Comment Period, 80 Fed. Reg. 51,146 (Aug. 24, 2015).

contain nicotine as well and often expose users to some of the same compounds found in e-cigarette vapor.<sup>90</sup>

At present, it appears that most e-cigarette users are current or former smokers.<sup>91</sup> So long as this holds true, e-cigarettes would seem to have substantial harm reduction potential. There are some concerns about increases in e-cigarette consumption among youth.<sup>92</sup> In recent years, youth e-cigarette use increased as cigarette smoking declined.<sup>93</sup> This data suggested a possible substitution effect: Those youth who would otherwise have tried smoking may have been trying vaping instead.<sup>94</sup> While survey data on youth smoking are not particularly reliable, the most recent data suggest that youth e-cigarette use may have started to decline.<sup>95</sup> Youth e-cigarette

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<sup>90</sup> See Lion Shabab, et al., *Nicotine, Carcinogen, and Toxin Exposure in Long-Term E-Cigarette and Nicotine Replacement Therapy Users: A Cross-sectional Study*, 166 ANNALS OF INTERNAL MED. 390 (2017).

<sup>91</sup> As the FDA noted:

Data reported by the CDC's National Center for Health Statistics (NCHS), which provides the first estimates of e-cigarette use among U.S. adults from a nationally representative household interview study, indicate that current cigarette smokers and recent former smokers (i.e., those individuals who quit smoking within the past year) were more likely to use e-cigarettes than long-term former smokers (i.e., those individuals who quit smoking more than one year ago) and adults who had never smoked.

Final Deeming Rule, *supra* note 39, at 29028.

<sup>92</sup> See Matt Richtel, *Use of E-Cigarettes by Young People Is Major Concern, Surgeon General Declares*, N.Y. TIMES (Dec. 8, 2016), <https://www.nytimes.com/2016/12/08/health/e-cigarettes-united-states.html>.

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

<sup>94</sup> See, e.g. Friedman, *supra* note 65; Pesko, et al., *supra* note 65. See also Jacob Sullum, *New Study Provides Strong Evidence That E-Cigarettes Boost Smoking Cessation*, REASON (July 27, 2017), <http://reason.com/blog/2017/07/27/news-study-provides-strong-evidence-that>.

<sup>95</sup> See Rob Stein, *Teens' Use Of E-Cigarettes Drops For The First Time, CDC Says*, NPR (June 15, 2017), <http://www.npr.org/sections/health-shots/2017/06/15/533062545/teens-use-of-e-cigarettes-drops-for-the-first-time-cdc-says>; see also Polosa, et al., *supra* note 41.

consumption is a serious concern nonetheless, and it is understandable why anti-smoking activists are wary of an industry that stands to profit by addicting younger consumers. Nonetheless, the empirical evidence to date suggests e-cigarette use may be substituting for tobacco use—a gain for public health—and there is little evidence that e-cigarettes are serving as a “gateway” to tobacco use.<sup>96</sup>

### III. THE FDA’S DEEMING RULE

In May 2016, the United States Food & Drug Administration (FDA) finalized regulations “deeming” e-cigarettes and other vaping products as “tobacco products” subject to regulation under the Tobacco Act.<sup>97</sup> In reaching this decision, the FDA determined that e-cigarettes “should be regulated due to their potential for public harm.”<sup>98</sup> According to the agency, regulating e-cigarettes and similar products “is necessary to learn more about that potential.”<sup>99</sup> This rule applies to all e-cigarettes and vaping products, including their

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<sup>96</sup> “E-cigarettes are not a gateway to smoking,” according to the Royal College of Physicians. “[I]n the UK, use of e-cigarettes is limited almost entirely to those who are already using, or have used, tobacco.” *Promote E-cigarettes Widely as Substitute for Smoking Says New RCP Report*, ROYAL COLLEGE OF PHYSICIANS (Apr. 28, 2016), <https://www.rcplondon.ac.uk/news/promote-e-cigarettes-widely-substitute-smoking-says-new-rcp-report>.

<sup>97</sup> Final Deeming Rule, *supra* note 39.

<sup>98</sup> *Id.* at 28,983.

<sup>99</sup> *Id.* at 28,984.

components and parts,<sup>100</sup> as well as to new products that may be used to deliver nicotine or tobacco in the future.<sup>101</sup>

In deeming e-cigarettes to be subject to federal regulation, the FDA declared that e-cigarettes “meet the statutory definition of ‘tobacco products’” because the nicotine in e-cigarettes is “made or derived from tobacco.”<sup>102</sup> It further extended regulatory authority to e-cigarette “parts and components,” including the various parts of open-system devices whether sold in combination or separately, but not e-cigarette accessories or nicotine-free liquids provided such liquids were not intended to be combined with nicotine-containing liquids.<sup>103</sup> In July 2017, a federal district court rejected a legal challenge to the broad scope of the FDA’s rule.<sup>104</sup>

With the deeming rule, the FDA effectively extended the Act’s regulatory framework to e-cigarettes. This includes requiring manufacturers to register and disclose product contents, prohibiting the sale of adulterated or misbranded products, and limiting

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<sup>100</sup> According to the FDA, regulated components and parts include: “E-liquids; atomizers; batteries (with or without variable voltage); cartomizers (atomizer plus replaceable fluid-filled cartridge); digital display/lights to adjust settings; clearomisers, tank systems, flavors, vials that contain e-liquids, [and] programmable software.” *Id.* at 29,074.

<sup>101</sup> According to the FDA, “FDA envisions that there could be tobacco products developed in the future that provide nicotine delivery through means (e.g., via dermal absorption or intranasal spray) similar to currently marketed medicinal nicotine products, but which are not drugs or devices. These products would be “tobacco products” and subject to FDA’s chapter IX authorities in accordance with this final deeming rule.” *Id.* at 28,976.

<sup>102</sup> *Id.* at 28,976; see also 21 U.S.C. § 387a (defining tobacco products).

<sup>103</sup> Final Deeming Rule, *supra* note 39, at 28,995, 28,974, 29,032.

<sup>104</sup> See *Nicopure Laps LLC v. FDA*, No. CV 16-0878 (ABJ), 2017 WL 3130312, at \*6 (D.D.C. July 21, 2017). In separate litigation, the U.S. Court of Appeals for the D.C. Circuit rejected a challenge to Department of Transportation decision to prohibit e-cigarette use on commercial airlines under the pre-existing authority to prohibit smoking. See *Competitive Enter. Inst. v. Dept. of Trans.*, 863 F.3d 911 (D.C. Cir. 2017).



advertising and promotional activities. Under the deeming rule, the FDA also prohibited sales to minors, mandated health warnings on product packaging, and severely limited vending machine sales. Perhaps most significantly, the FDA's deeming rule imposed a pre-market approval requirement on all e-cigarette products developed in the past ten years.<sup>105</sup> This rule is likely to produce significant consolidation within the e-cigarette industry, largely to the benefit of major tobacco companies, while simultaneously reducing innovation and the harm reduction potential of e-cigarettes.

While acknowledging the evidence that e-cigarettes are in all likelihood less harmful than tobacco cigarettes, the FDA claimed that the rule would benefit public health "by affording FDA critical information regarding the health risks of such products," preventing the marketing and sale of "new" products without prior FDA approval, and "preventing the use of unsubstantiated modified risk claims, which may mislead consumers and lead them to initiate tobacco product use or to continue using tobacco when they would otherwise quit."<sup>106</sup> The FDA also acknowledged that one consequence of the rule is likely to be "considerable product consolidation and exit."<sup>107</sup>

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<sup>105</sup> See Final Deeming Rule, *supra* note 39, at 28,974. See also Tripp Mickle, *FDA Cloud Hangs Over Vape Shops*, WALL ST. J. (July 7, 2015), <https://www.wsj.com/articles/SB10130211234592774869404581088451777513530>.

<sup>106</sup> Final Deeming Rule, *supra* note 39, at 28,976.

<sup>107</sup> U.S. Dep't of Health & Human Servs, Docket No. FDA-2014-N-0189 Deeming Tobacco Products to be Subject to the Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations Restricting the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Product Packages and Advertisements: Final Regulatory Impact Analysis, Final Regulatory Flexibility Analysis, Unfunded Mandates Reform Act Analysis 78, <https://www.fda.gov/downloads/aboutfda/reportsmanualsforms/reports/economicanalyses/ucm500254.pdf> [hereinafter Final Regulatory Impact Analysis].

The FDA says it “expects” that regulation of e-cigarettes will improve public “understanding and appreciation of the health effects and risks” of such products.<sup>108</sup> This is because, according to the FDA, regulating e-cigarettes will require producers to disclose product contents to the FDA and enable the agency to prevent misleading claims about e-cigarettes.<sup>109</sup> In the FDA’s view, the primary consumer misperception that needs to be addressed is that “tobacco products not regulated by FDA are safe alternatives to currently regulated tobacco products.”<sup>110</sup> Yet the survey data cited by the FDA in finalizing the deeming rule shows that far more adults believe that e-cigarettes are equally or more harmful than tobacco cigarettes than believe that e-cigarettes are not harmful.<sup>111</sup>

Recent surveys find that a substantial percentage of adults believe that e-cigarettes are as harmful or more harmful than conventional tobacco cigarettes.<sup>112</sup> In one recent state survey, a

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<sup>108</sup> Final Deeming Rule, *supra* note 39, at 29,036.

<sup>109</sup> Proposed Deeming Rule, *supra* note 61, at 23,148.

<sup>110</sup> Proposed Deeming Rule, *supra* note 61, at 23,148.

<sup>111</sup> The final rule cites Reference 176 throughout its discussion of misinformation and confusion about e-cigarettes. See Final Deeming Rule, *supra* note 39, at 29,036 (citing HARVARD T.H. CHAN SCH. OF PUBL. HEALTH & STAT, AMERICANS’ PERSPECTIVES ON E-CIGARETTES (2015), <https://cdn1.sph.harvard.edu/wp-content/uploads/sites/94/2015/11/Stat-Harvard-Poll-Oct-2015-Americans-Perspectives-on-E-Cigarettes.pdf>); cf. HARVARD T.H. CHAN SCH. OF PUBL. HEALTH & STAT, AMERICANS’ PERSPECTIVES ON E-CIGARETTES 8 (2015), <https://cdn1.sph.harvard.edu/wp-content/uploads/sites/94/2015/11/Stat-Harvard-Poll-Oct-2015-Americans-Perspectives-on-E-Cigarettes.pdf> (reporting 23 percent of respondents believe e-cigarettes are not harmful and 38 percent believe e-cigarettes are as harmful or more harmful than tobacco cigarettes)).

<sup>112</sup> *Id.* (reporting 32 percent and 6 percent of surveyed adults believe e-cigarettes are as harmful or more harmful than tobacco cigarettes, respectively). In this survey, fewer than half of those surveyed (44 percent) responded that e-cigarettes are less harmful than tobacco cigarettes. See also Marc T. Kiviniemi & Lynn T. Kozlowski, *Deficiencies in Public Understanding about Tobacco Harm Reduction: Results from a United States National Survey*, 12 HARM REDUCTION J. 21 (2015).

majority of respondents either did not know or believe that e-cigarettes are likely less harmful than tobacco cigarettes.<sup>113</sup> Other survey data suggest that perceptions of e-cigarettes as equally or more dangerous than tobacco cigarettes increased in tandem with efforts to subject e-cigarettes to greater regulation.<sup>114</sup>

As with prior limitations on advertising and promotion, the deeming rule is likely to advantage larger incumbent firms at the expense of smaller e-cigarette producers. In practical terms, these requirements are most likely to advantage the major tobacco companies, which have also entered the e-cigarette market.<sup>115</sup> Both Altria and Reynolds have e-cigarette brands that they may promote and market through their established marketing and distribution networks. The same market dynamics that enable these firms to dominate the cigarette market will give them a substantial competitive advantage in the e-cigarette market, particularly as smaller retailers, such as vape shops, are squeezed by the new

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<sup>113</sup> See INTERACT FOR HEALTH, *Most Ohio Adults Support Regulating, Taxing E-Cigarettes*, in OHIP 2015: OHIO HEALTH ISSUES POLL (Jan. 2016) [https://www.interactforhealth.org/upl/Most\\_Ohio\\_adults\\_support\\_regulating\\_taxing\\_e\\_cigarettes.pdf](https://www.interactforhealth.org/upl/Most_Ohio_adults_support_regulating_taxing_e_cigarettes.pdf); see also Michael Siegel, *New Ohio Poll Shows that Anti-Vaping Groups Have Completely Undermined the Public's Appreciation of the Hazards of Smoking*, THE REST OF THE STORY: TOBACCO NEWS ANALYSIS AND COMMENTARY (Jan. 26, 2016), <http://tobaccoanalysis.blogspot.com/2016/01/new-ohio-poll-shows-that-anti-vaping.html>.

<sup>114</sup> See Ban A. Majeed et al., *Changing Perceptions of Harm of E-Cigarettes Among U.S. Adults, 2012-2015*, 52 AMER. J. PREVENTATIVE MED. 331 (2017) (reporting increase in percentage of respondents who believe e-cigarettes are equally or more harmful than tobacco cigarettes from 12.8 percent in 2012 to 39.8 percent in 2015). According to some commentators, misleading statements by public health officials may be contributing to public misperception about the relative risk posed by e-cigarettes. See, e.g., Jacob Sullum, *Why is the CDC Lying About E-Cigarettes?* FORBES, Apr. 23, 2015, <https://www.forbes.com/sites/jacobsullum/2015/04/23/why-is-the-cdc-lying-about-e-cigarettes/#60b97075a23d>.

<sup>115</sup> As Jack Calfee has documented, prior regulation of cigarette advertising has often worked to the advantage of larger firms. See, e.g. John E. Calfee, *The Ghost of Cigarette Advertising Past*, REG. (Jun. 1, 1997).

rules.<sup>116</sup> Many of the marketing methods that new entrants might use to gain market share are effectively precluded by the marketing regulations.

More significantly, the deeming rule requires all e-cigarette manufacturers to obtain pre-market approval for all new products.<sup>117</sup> As interpreted by the FDA, this requirement is imposed quite broadly. Any change in product design, flavoring, or packaging can constitute a new product.<sup>118</sup> Each vape shop that mixes or bottles fluids is likewise considered a manufacturer, as they are creating “new” products each time they create a new flavor or otherwise modify a fluid or e-cigarette component.<sup>119</sup> This has stoked fears that the regulation will force many vape shops and independent firms to close.<sup>120</sup> It is also likely to hamper innovation and the development

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<sup>116</sup> At one point, Reynolds encouraged the FDA to ban all “open-system” vaping products. See Richard Craver, *Reynolds American Wants FDA to Ban Vapor e-Cigarettes*, WINSTON-SALEM J. (Sept. 7, 2014), <http://www.journalnow.com/business/business-news/local/reynolds-american-wants-fda-to-ban-vapor-e-cigarettes/article-77b131f5-540d-5f02-927c-733bac751529.html>.

<sup>117</sup> Final Deeming Rule, *supra* note 39, at 28,976.

<sup>118</sup> See 21 U.S.C. § 387j. The FDA has indicated that even relatively modest changes in product design or packaging will be sufficient to identify a product as a new tobacco product, and not substantially equivalent to a product already on the market. See FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: DEMONSTRATING THE SUBSTANTIAL EQUIVALENCE OF A NEW TOBACCO PRODUCT: RESPONSES TO FREQUENTLY ASKED QUESTIONS (3d ed. Dec. 2016), available at <http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM436468.pdf>.

<sup>119</sup> According to the FDA:

[E]stablishments that mix or prepare e-liquids or create or modify aerosolizing apparatus for direct sale to consumers are tobacco product manufacturers under the definition set forth in the FD&C Act and, accordingly, are subject to the same legal requirements that apply to other tobacco product manufacturers.

Final Deeming Rule, *supra* note 39, at 28979.

<sup>120</sup> See Sabrina Tavernise, *F.D.A. Imposes Rules for E-Cigarettes in a Landmark Move*, N.Y. TIMES (May 5, 2016), <http://nyti.ms/23rXQXX>; Shari Rudavsky, *Indiana Vape Shop Owners Say New FDA Rule Will Crush Industry*, INDY STAR (May 9, 2016)

of new products in what had been a very dynamic and competitive market.

The pre-market approval requirement also applies retroactively to all products introduced since February 2007. As a practical matter, this means most traditional tobacco products are grandfathered. Tobacco companies do not need to apply to the FDA to keep their cigarettes on the market. Nearly all currently marketed e-cigarette brands, on the other hand, entered the market after February 2007. This is an additional reason why the deeming rule works to the advantage of the major tobacco companies.<sup>121</sup>

The grandfathering date was not determined by the FDA, it is required under the Tobacco Act.<sup>122</sup> Under this requirement, manufacturers of any e-cigarette or vaping product, including parts and components, must submit an application for approval for any product that was not on the market in February 2007 or not the substantial equivalent of a product that was then on the market. For those products that are “substantial equivalents,” a separate application must be filed. Based upon how the FDA has applied this

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<http://www.indystar.com/story/news/2016/05/08/indiana-vape-shop-owners-say-new-fda-rule-crush-industry/84036264/>.

<sup>121</sup> Perhaps tellingly, when the FDA announced it would delay the deadline for submitting new tobacco product applications for e-cigarettes and other newly deemed products, share prices for the major cigarette companies “tumbled.” See Sheila Kaplan, *F.D.A. Delays Rules That Would Have Limited E-Cigarettes on Market*, N.Y. TIMES, July 28, 2017.

<sup>122</sup> During the rulemaking, the FDA received comments urging the adoption of a later date, but concluded that under the terms of the Tobacco Act, the agency lacked the flexibility to change it.

FDA has determined that it lacks authority to change the grandfather date, which is set by statute (79 FR 23142 at 23174). FDA specifically asked for comments on our legal interpretation. We received a large number of comments in response to this statement, but none provided a legal theory that would support changing the date.

Final Deeming Rule, *supra* note 39, at 28993.

standard to tobacco products, e-cigarette manufacturers can expect “substantial equivalence” to be applied quite stringently.<sup>123</sup> Even changes to packaging, labeling, and product size are enough for the FDA to consider something to be a new product.<sup>124</sup>

Although manufacturers are given some time to submit their applications,<sup>125</sup> this requirement means that virtually all e-cigarette and vaping products on the market must go through a lengthy and costly FDA approval process.<sup>126</sup> The time and money involved with submitting a new product are likely to be quite substantial.<sup>127</sup> According to the FDA, each premarket review application could cost between \$200,000 and \$2,000,000.<sup>128</sup> These requirements are likely to

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<sup>123</sup> See Micah Berman, “Substantial Equivalence”: Massive Backlog at the FDA Center for Tobacco Products, JREG NOTICE & COMMENT (Sept. 16, 2015), <http://yalejreg.com/nc/substantial-equivalence-massive-backlog-at-the-fda-center-for-tobacco-products-by-micah-berman/>.

<sup>124</sup> See FOOD & DRUG ADMIN., *supra* note 118.

<sup>125</sup> Under the rule, manufacturers of products that are not the substantial equivalent of products marketed prior to February 2007 will have between 12 and 24 months to submit their applications, and an additional 12-month compliance period while applications are being reviewed. In July 2017, the FDA announced it would delay these requirements by several more years as the agency develops a more comprehensive regulatory strategy to address nicotine addiction. See Press Release, Food & Drug Admin., FDA Announces Comprehensive Regulatory Plan to Shift Trajectory of Tobacco-Related Disease, Death (July 28, 2017), <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm568923.htm>.

<sup>126</sup> As the FDA acknowledged when proposing the deeming rule, “most proposed deemed tobacco products would be considered new tobacco products and would be required to obtain an order from FDA prior to marketing.” Proposed Deeming Rule, *supra* note 61, at 23,174.

<sup>127</sup> According to some estimates, the cost for each approval could exceed one million dollars. See Tavernise, *supra* note 120 (citing estimate that “submitting an application to get a product approved would take more than 1,700 hours and cost more than \$1 million.”).

<sup>128</sup> See DEP’T OF HEALTH & HUMAN SERVS., DEEMING TOBACCO PRODUCTS TO BE SUBJECT TO THE FDCA: FINAL REGULATORY IMPACT ANALYSIS 87 (Table 11(a)) (2014), <https://www.fda.gov/downloads/aboutfda/reportsmanualsforms/reports/economicanaly>

impose substantial burdens on smaller manufacturers and distributors and further enhance the competitive advantage of traditional cigarette manufacturers that seek to make inroads within the e-cigarette market.<sup>129</sup> As of this writing, the only premarket applications FDA has approved were those submitted by Swedish Match for eight smokeless tobacco (“snus”) products.<sup>130</sup>

The FDA claims that the deeming regulation will help safeguard public health.<sup>131</sup> Perhaps tellingly, though, the agency was not able to identify any specific health (or other) benefits of the rule that would come from the extension of regulatory oversight. As the FDA confessed, “The direct benefits of making each of the newly deemed tobacco products subject to the requirements of chapter IX of the FD&C Act are difficult to quantify, and we cannot predict the size of these benefits at this time.”<sup>132</sup> While acknowledging that e-cigarettes are likely to be less harmful than tobacco cigarettes,<sup>133</sup> the FDA maintains that regulation of e-cigarettes “will still benefit public health,” even if it is not entirely sure how.<sup>134</sup>

Authorizing the agency to police misbranding claims and take action against unsafe products could produce benefits, particularly if the threat of liability is not sufficient to induce more responsible

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ses/ucm500254.pdf. For delivery devices, the agency estimated a total cost of \$285,656 to \$2,622,224 per application. *Id.* at 90-91 (Table 12(a)).

<sup>129</sup> See Tavernise, *supra* note 120. See also Adler et al., *infra* note 175.

<sup>130</sup> See FDA Issues First Product Marketing Orders Through Premarket Tobacco Application Pathway (Nov. 10, 2015), <https://www.fda.gov/newsevents/newsroom/press-announcements/ucm472026.htm>. Actions on premarket applications are detailed by the FDA at *Marketing Orders for Tobacco Products*, <https://www.fda.gov/Tobacco-Products/Labeling/TobaccoProductReviewEvaluation/ucm339928.htm>.

<sup>131</sup> See FOOD & DRUG ADMIN., THE FACTS ON THE FDA’S NEW TOBACCO RULE (June 16, 2016), <https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm506676.htm>.

<sup>132</sup> Final Deeming Rule, *supra* note 39, at 28,981.

<sup>133</sup> *Id.* at 28,984.

<sup>134</sup> See *id.*

conduct by product manufacturers. The FDA's ability to collect content and other information from manufacturers could also facilitate the development of more targeted and cost-beneficial regulations in the future. It is also possible that regulation-induced concentration within the industry could facilitate greater regulatory oversight, as it will be easier for a federal agency to monitor and police the activities of a small handful of large firms than to try and monitor a dynamic, competitive marketplace with lots of smaller firms and new entrants.

In issuing the deeming rule, the FDA hypothesized that greater regulation will make some firms more willing to invest in new products as they will not have to fear competition from "dangerous" products.<sup>135</sup> A more concentrated market with fewer, more established players may also be more likely to produce standardized and reliable products than a myriad of smaller firms with varying production standards and capabilities. Such benefits, however, are difficult to quantify and should be weighed against the potential costs of reducing the availability and attractiveness of e-cigarettes as a substitute for tobacco cigarettes.

In July 2017, newly confirmed FDA Commissioner Scott Gottlieb announced the agency would adopt a new "comprehensive approach" to nicotine and tobacco in an effort to reduce the death toll

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<sup>135</sup> The FDA writes,

Greater regulatory certainty created by premarket authorizations should help companies to invest in creating novel products, with greater confidence that improved products will enter the market without having to compete against equally novel, but more dangerous products. For example, a company wishing to invest the additional resources needed to ensure that its e-cigarette is designed and manufactured with appropriate methods and controls will be more likely to do so if the product is not competing against products that are more cheaply and crudely made, yet appear to be identical to the consumer.

Final Deeming Rule, *supra* note 39, at 28,983.



from cigarettes.<sup>136</sup> While highlighting the threat posed by nicotine addiction, Commissioner Gottlieb stressed that the “bigger problem is the delivery mechanism,” i.e. smoking.<sup>137</sup> Further, Commissioner Gottlieb said that the FDA must be attentive to “the potential for innovation to lead to less harmful products . . . .”<sup>138</sup> Accordingly, the FDA would “reconsider aspects of the implementation of the final deeming rule with an eye towards fostering innovation where innovation could truly make a public health difference . . . .”<sup>139</sup> The FDA also announced that it would use its enforcement discretion to extend the deadline for e-cigarette manufacturers to submit product review applications, noting it “expects that manufacturers would continue to market products while the agency reviews product applications.”<sup>140</sup>

Commissioner Gottlieb’s July 2017 remarks suggest that he is aware of the significant harm reduction potential of e-cigarettes and other smoking alternatives.<sup>141</sup> While not questioning the need for FDA regulation of alternative tobacco products, Commissioner Gottlieb highlighted the need for innovation if smoking alternatives are to help smokers wean themselves of their current habits, and that

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<sup>136</sup> See Scott Gottlieb, Comm’r Food & Drug Admin, Prepared Remarks, *Protecting American Families: Comprehensive Approach to Nicotine and Tobacco*, FOOD & DRUG ADMIN. (July 28, 2017), <https://www.fda.gov/NewsEvents/Speeches/ucm569024.htm>.

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

<sup>138</sup> *Id.*

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

<sup>140</sup> See Press Release, Food & Drug Admin., FDA Announces Comprehensive Regulatory Plan to Shift Trajectory of Tobacco-Related Disease, Death (July 28, 2017), <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm568923.htm>.

<sup>141</sup> In an interview with reporters, Commissioner Gottlieb said the FDA thinks “there’s a potential opportunity for e-cigarettes to be a lower-risk alternative to smokers who want to quit combustible cigarettes.” Sheila Kaplan, *F.D.A. Delays Rules That Would Have Limited E-Cigarettes on Market*, N.Y. TIMES, July 28, 2017.

this should inform the FDA's regulatory approach. Time will tell how these priorities are operationalized.

#### IV. RESTRICTIONS ON TRUTHFUL SPEECH

In addition to deeming e-cigarettes as tobacco products subject to federal regulation, the FDA has also made clear its intention to police the claims made by e-cigarette manufacturers and retailers about the potential benefits of their products. According to the FDA, e-cigarette producers and retailers may neither claim that their products are less dangerous than tobacco cigarettes nor inform consumers about the potential health benefits of switching from smoking to vaping without first obtaining permission from the FDA. Nor may e-cigarette companies tout the potential use of their products to help smokers manage nicotine cravings or quit smoking without first submitting any proposed claims for government approval. As with the other regulations imposed on e-cigarettes, these limitations could come at the expense of harm reduction.

Under the Tobacco Act, it is illegal to sell a "modified risk tobacco product" (MRTP) without FDA approval.<sup>142</sup> The Act defines an MRTP as "any tobacco product that is sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products."<sup>143</sup> It further creates an application process, somewhat similar to the approval process for new drugs and devices, for MRTPs.<sup>144</sup> As the FDA noted in the deeming rule, the prohibition on selling "modified risk" tobacco products "applies automatically to deemed products."<sup>145</sup> As of this

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<sup>142</sup> See 21 U.S.C. § 387k(a).

<sup>143</sup> See 21 U.S.C. § 387k(b)(1).

<sup>144</sup> See 21 U.S.C. § 387k(g).

<sup>145</sup> Final Deeming Rule, *supra* note 39, at 29,039.

writing, the FDA has yet to approve an MRTP application.<sup>146</sup> More are pending, although none are for e-cigarettes.<sup>147</sup>

Unless and until the FDA approves an MRTP application, producers are broadly prohibited from making claims that express or imply that their product might be less risky than traditional tobacco cigarettes. In particular, this means that producers may not state “explicitly or implicitly” that

(I) the tobacco product presents a lower risk of tobacco-related disease or is less harmful than one or more other commercially marketed tobacco products;

(II) the tobacco product or its smoke contains a reduced level of a substance or presents a reduced exposure to a substance;  
or

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<sup>146</sup> See Jennifer Maloney, *Big Tobacco Finds Surprise Allies in Smokeless Push*, WALL ST. J., (July 21, 2017), <https://www.wsj.com/articles/big-tobacco-finds-surprise-allies-in-smokeless-push-1500629402> (noting FDA partially rejected MRTP application filed by Swedish Match and invited the firm to revise and resubmit the application). See also Press Release, Food & Drug Admin., FDA Takes Action on Applications Seeking to Market Modified Risk Tobacco Products (Dec. 14, 2016), <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm533219.htm>.

<sup>147</sup> Compare Richard Craver, *Reynolds Enters FDA Modified-Risk Regulatory Gauntlet for 6 Camel Snus Styles*, WINSTON-SALEM JOURNAL (Apr. 3, 2017), [http://www.journalnow.com/business/business\\_news/local/reynolds-enters-fda-modified-risk-regulatory-gauntlet-for-camel-snus/article\\_da629984-1880-11e7-8da3-6f26ad193658.html](http://www.journalnow.com/business/business_news/local/reynolds-enters-fda-modified-risk-regulatory-gauntlet-for-camel-snus/article_da629984-1880-11e7-8da3-6f26ad193658.html) (claiming the FDA approved Swedish Match snus as MRTPs, however the FDA does not list any MRTP applications as having been approved), with *Modified Risk Tobacco Products*, FOOD & DRUG ADMIN., <https://www.fda.gov/TobaccoProducts/Labeling/MarketingandAdvertising/ucm304465.htm> (last visited Oct. 19, 2017). More likely this was a reference to the FDA’s approval of several Swedish Match snus products as new tobacco products mentioned *supra*, note 130.

(III) the tobacco product or its smoke does not contain or is free of a substance.<sup>148</sup>

According to the FDA, this means that factually true claims, such as “contains less nicotine” or “healthier alternative to smoking” would likely cause a product to be deemed a MRTP, requiring FDA approval.<sup>149</sup> As the agency explained in a follow-up rulemaking designed to clarify the scope of FDA regulation of newly deemed tobacco products,

A manufacturer’s making a modified risk claim for a specific tobacco product renders the product an MRTP, which can be marketed only after the manufacturer substantiates any modified risk claims in an MRTP application and after FDA determines that the product meets the statutory standard.<sup>150</sup>

In other words, an e-cigarette manufacturer or retailer that wants to tell consumers basic facts about the product is prohibited from doing so without first obtaining the FDA’s approval.

The FDA has also concluded that e-cigarette manufacturers may not inform consumers about the potential of e-cigarettes to facilitate smoking reduction or cessation without obtaining FDA approval as a medical drug, device, or combination product. In January 2017, the FDA adopted a regulation expressly providing that any tobacco product “intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease, *including use in the cure or treatment of nicotine addiction (e.g., smoking cessation)*, relapse prevention, or relief of nicotine withdrawal

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<sup>148</sup> See 21 U.S.C. § 387k(b)(2)(A)(i).

<sup>149</sup> Clarification of When Products Made or Derived from Tobacco Are Regulated as Drugs, Devices, or Combination Products, 82 Fed. Reg. 2193, 2205 (Jan. 9, 2017).

<sup>150</sup> 82 Fed. Reg. 2193, 2212 (Jan. 9, 2017).

symptoms,” is “subject to regulation as a drug, device, or combination product”.<sup>151</sup> As the FDA explained, “if an ENDS product seeks to be marketed as a cessation product, the manufacturer must file an application with FDA’s Center for Drug Evaluation and Research (CDER) and no ENDS have been approved by FDA as effective cessation aids.”<sup>152</sup>

As with modified risk claims, the FDA has adopted a fairly broad conception of what sorts of claims could trigger regulation of an e-cigarette as a medical product. For instance, the FDA noted that “claims such as ‘treatment of tobacco dependence,’ ‘wean yourself off of nicotine,’ ‘for people who wish to quit smoking,’ ‘stop smoking aid,’ ‘prevent relapse,’ or ‘stay quit’ generally will bring a product within” the parameters for regulation as a medical product.<sup>153</sup> Further, “if the instructions provided by the manufacturer convey that the product is to be used as a cessation device, then the product will generally be regulated as a medical product.”<sup>154</sup> As with the regulation of medical devices, the FDA also made clear that in determining the “intended use” of a product, the FDA will look at “any . . . relevant source,’ including but not limited to the product’s labeling, promotional claims, and advertising.”<sup>155</sup>

Although cigarettes and e-cigarettes may be viewed as “recreational” products, marketing the latter as an alternative to the

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<sup>151</sup> 21 C.F.R. § 1100.5. *See also* Clarification of When Products Made or Derived from Tobacco Are Regulated as Drugs, Devices, or Combination Products, 82 Fed. Reg. 2193, 2194 (Jan. 9, 2017) (emphasis added).

<sup>152</sup> Final Deeming Rule, *supra* note 39, at 29,036.

<sup>153</sup> 82 Fed. Reg. 2193, 2205 (Jan. 9, 2017). The FDA expressly notes that these are just illustrative examples and not an exclusive list. *Id.* at 2205 n.14.

<sup>154</sup> 82 Fed. Reg. 2193, 2212 (Jan. 9, 2017).

<sup>155</sup> 82 Fed. Reg. 2193, 2195 (Jan. 9, 2017) (citing *Action on Smoking & Health v. Harris*, 655 F.2d 236, 239 (D.C. Cir. 1980) and *United States v. Storage Spaces*, 777 F.2d 1363, 1366 (9th Cir. 1985), *Hanson v. United States*, 417 F. Supp. 30, 35 (D.Minn.), *aff’d* 540 F.2d 947 (8th Cir. 1976)).

former may land a manufacturer in hot water. This is because “FDA considers claims about smoking cessation to be more than simply ‘consumer-oriented marketing statements.’”<sup>156</sup> As it explained, “smoking cessation claims on any product generally create a strong suggestion of intended therapeutic benefit to the user that generally will be difficult to overcome absent clear context indicating that the product is not intended for use to cure or treat nicotine addiction or its symptoms, or for another therapeutic purpose.”<sup>157</sup> The FDA has been quite explicit that, in its view, “The most important consideration is that ENDS are not an FDA-approved cessation product. If an ENDS manufacturer wishes to make a cessation claim of otherwise market its product for therapeutic purposes, the company must submit an application for their ENDS to be marketed as a medical product.”<sup>158</sup> Although the FDA recognizes “there is emerging data that some individual smokers may potentially use ENDS to transition away from combustible tobacco products,”<sup>159</sup> it does not believe e-cigarette manufacturers should be allowed to provide consumers with this evidence unless and until FDA agrees.<sup>160</sup> Any such efforts to encourage or facilitate smoking cessation are only allowed if first approved by the FDA.

Although relevant Supreme Court precedent suggests that government agencies should consider the use of mandatory disclaimers or qualifying statements before prohibiting truthful product claims,<sup>161</sup> the FDA has thus far rejected the use of disclaimers

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<sup>156</sup> 82 Fed. Reg. 2193, 2196 (Jan. 9, 2017).

<sup>157</sup> *Id.* at 2198.

<sup>158</sup> Final Deeming Rule, *supra* note 39, at 29,038.

<sup>159</sup> *Id.* at 29,037.

<sup>160</sup> The FDA has declared that “statements related to quitting smoking generally create a strong suggestion that a product is intended for a therapeutic purpose.” 82 Fed. Reg. 2193, 2214 (Jan. 9, 2017).

<sup>161</sup> *See Thompson v. Western States Medical Center*, 535 U.S. 357 (2002).

for either modified-risk or smoking cessation claims. In its January rulemaking, the FDA declared that it “does not believe that disclaimers will sufficiently mitigate consumer confusion due to the product’s claimed therapeutic benefit.”<sup>162</sup> This position is constitutionally suspect, but as of this writing has not been challenged in court.

In its application and anticipated enforcement of the relevant legal provisions, it is the FDA’s position that an e-cigarette manufacturer is legally prohibited from informing consumers of the FDA’s own conclusions about e-cigarettes without first obtaining the FDA’s permission. Indeed, an e-cigarette manufacturer could be sanctioned for merely quoting the FDA’s own statements in an advertisement or on a webpage, even if followed by a prominent disclaimer indicating that the FDA had not sanctioned or approved the manufacturer’s claim. The FDA acknowledges that such a prohibition may raise First Amendment concerns, but decided that any such concerns could be “considered in a separate proceeding” that would address First Amendment concerns about FDA regulation more generally.<sup>163</sup>

The FDA justifies this position, in part, because “the potential for consumer confusion is increasing” due to public claims made about the potential for e-cigarettes to aid in smoking reduction or

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<sup>162</sup> 82 Fed. Reg. 2199; *See also id.* at 2203 (“FDA does not believe that disclaimers will be sufficient in most cases to mitigate consumer confusion about whether a product made or derived from tobacco is intended for medical use.”).

<sup>163</sup> 82 Fed. Reg. at 2209. As of this writing, litigation challenging the MRTP provisions of the Tobacco Act have been unsuccessful. *See* *Discount Tobacco City & Lottery Inc. v. United States*, 674 F.3d 509 (6th Cir. 2012); *Nicopure Labs, LLC v. FDA*, No. CV 16-0878 (ABJ), 2017 WL 3130312, at \*11 (D.D.C. July 21, 2017). Nonetheless, there is reason to believe that these restrictions raise the same sorts of First Amendment problems as do prohibitions on off-label marketing of prescription pharmaceuticals or truthful health claims about nutritional supplements.

cessation.<sup>164</sup> Yet as noted above, insofar as there is consumer confusion about e-cigarettes, it appears to be that a large proportion of adults (wrongly) believe that e-cigarettes are likely to be as or more dangerous than tobacco cigarettes, and there is reason to believe that the FDA's regulatory approach to e-cigarettes has contributed to the confusion.

Research on product marketing has shown the consumer benefits of allowing product manufacturers to make truthful and non-misleading health-related claims. Where competing producers can position their products as healthier or less dangerous than their competitors, they have an incentive to both educate consumers about the relative health benefits of their products as well as to develop products about which truthful positive health claims can be made.<sup>165</sup> At the same time, consumers tend to draw negative inferences from the failure to make positive health claims about competing products.<sup>166</sup> Once cereal producers were allowed to inform consumers about the potential health benefits of a high-fiber diet, fiber consumption increased;<sup>167</sup> no less significantly, cereal producers began to modify their products to increase their fiber

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<sup>164</sup> 82 Fed. Reg. at 2196.

<sup>165</sup> See J. Howard Beales III, *Health Related Claims, the Market for Information and the First Amendment*, 21 HEALTH MATRIX: J. LAW-MED. 7, 8-9 (2011); see also Paul Milgrom, *What the Seller Won't Tell You: Persuasion and Disclosure in Markets*, 22 J. ECON. PERSP. 115, 116 (2008) ("In modern economies, sellers routinely supply helpful information about their products."); Pauline Ippolito & Janis Pappalardo, *Advertising Nutrition & Health: Evidence from Food Advertising 1977-1997* (2002); Elise Golan et al., *Economics of Food Labeling*, 24 J. CONSUMER POL'Y 117 (2001); John E. Calfee, *How Advertising Informs to Our Benefit*, CONSUMERS RESEARCH, (April 1, 1998); J. Howard Beales III et al., *The Efficient Regulation of Consumer Information*, 24 J.L. & ECON. 491 (1981).

<sup>166</sup> See Golan et al., *supra* note 165, at 128; see also Pauline M. Ippolito & Alan D. Mathios, *The Regulation of Science-Based Claims in Advertising*, 13 J. CONSUMER POL'Y 413, 427-28 (1990) (discussing dynamic of "unfolding" product claims in competitive markets).

<sup>167</sup> See Beales, *supra* note 165 at 18-19.



content.<sup>168</sup> Allowing truthful health claims induced positive changes in both consumer and producer behavior.<sup>169</sup>

The history of cigarette advertising is similarly instructive.<sup>170</sup> When such advertising was *less* regulated, there was greater competition among producers to position their products as less dangerous than their competitors. This further encouraged producers to investigate and develop potentially less dangerous product designs and, no less important, increased the salience of the health risks of smoking.<sup>171</sup> By emphasizing health concerns, individual firms may have been able to capture greater market share, but at the cost of a shrinking market. Yet once cigarette companies were no longer able to make such claims, they had less incentive to make investments in products that might be less dangerous.

Limiting reduced risk and smoking cessation claims by e-cigarette manufacturers and retailers advantages tobacco companies and limits market positioning of e-cigarettes as an alternative to tobacco. It also risks misleading consumers, and current smokers in particular, into believing there are no meaningful health differences between e-cigarette use and smoking. Limiting truthful product claims also discourages e-cigarette manufacturers from competing

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<sup>168</sup> *Id.* at 19; see also PAULINE IPPOLITO & ALAN D. MATHIOS, HEALTH CLAIMS IN ADVERTISING AND LABELING: A STUDY OF THE CEREAL MARKET ix-xx (Fed. Trade Comm'n Staff Report, 1989); Pauline M. Ippolito & Alan D. Mathios, *Information, Advertising and Health Choices: A Study of the Cereal Market*, 21 RAND J. ECON. 459 (1990).

<sup>169</sup> For similar research concerning the market effects of fat claims, see Pauline M. Ippolito & Alan D. Mathios, *Information and Advertising: The Case of Fat Consumption in the United States*, 85 AMER. ECON. REV. 91 (1995).

<sup>170</sup> See Calfee, *supra* note 165.

<sup>171</sup> As Calfee noted, during the "Great Tar Derby" between 1957 and 1959, cigarette companies made claims about tar then sales-weighted tar and nicotine levels dropped dramatically. *Id.* at 41-42. See also Carl A. Sheraga & John E. Calfee, *The Industry Effects of Information and Regulation in the Cigarette Market 1950-1965*, 15 J. PUB. POLY & MARKETING 216 (1996).

with each other on health and safety grounds. Consequently, “[t]he risk of tragedy from keeping people in the dark is much greater than the risk of tragedy from informing people,” observes Dr. Lynn Kozlowski.<sup>172</sup>

### CONCLUSION

The regulation of e-cigarettes as tobacco products, however well-intentioned, threatens to sacrifice harm reduction and significant opportunities to reduce the tragic health costs of smoking. Regulation is likely to advantage larger, more established firms, minimize innovation, and frustrate efforts to help long-term smokers quit. As Dr. David Abrams warned in the *Journal of the American Medical Association*,

Applying overly burdensome, expensive regulatory hurdles to e-cigarettes could stifle innovation and favor the market domination of tobacco companies, which potentially promote dual use of cigarettes and e-cigarettes to minimize losing market share for their primary cigarette products. Independent e-cigarette companies are more likely to have the goal of eliminating combusted cigarettes.<sup>173</sup>

The claim here is not that e-cigarettes are harmless or risk-free, merely that e-cigarettes are less dangerous substitutes for a far more dangerous product, and that continued innovation and development of e-cigarette and vaping products could produce substantial benefits for public health. It is no accident that the most promising technological alternative emerged from an unregulated

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<sup>172</sup> Quoted in Maloney, *supra* note 146.

<sup>173</sup> David B. Abrams, *Promise and Peril of E-Cigarettes: Can Disruptive Technology Make Cigarettes Obsolete?*, 311 J. AMER. MED. ASSN. 135 (2014).

environment. The ability of e-cigarette producers to modify and adjust their products in an effort to identify and satisfy consumer preferences has helped maximize their potential as a viable smoking alternative that may help more smokers quit than would have otherwise.

The world is made safer by dangerous technologies.<sup>174</sup> The question for public health is not whether e-cigarettes pose risks or whether those risks are fully understood. The question is whether regulation of e-cigarettes—regulation that produces market competition, advantages tobacco companies, reduces innovation, and silences truthful speech about relative risks—is a net benefit. Products have risks, but so does product regulation. As with other precautionary efforts, premature and excessive regulation can do more harm than good, and, in the case of e-cigarettes, over-cautious regulation can even kill.

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<sup>174</sup> See Fred L. Smith, Jr., *Assessing the Political Approach to Risk Management*, ECON. AFFAIRS (Winter 1995). See generally AARON WILDAVSKY, *SEARCHING FOR SAFETY* (1st ed. 2017). See also Jonathan H. Adler, *More Sorry than Safe: Assessing the Precautionary Principle and the Proposed International Biosafety Protocol*, 35 TX INTL. L.J. 173, 174 (2000) (discussing the pitfalls of precautionary regulation of new technologies).